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The Honorable Lisa Jackson
Administrator
U.S. Environmental Protection Agency
1200 Pennsylvania Avenue, N.W.
Washington, D.C. 20460

Re: EPA's Design for the Environment Alternatives Assessment Program

Dear Administrator Jackson:

One of my initiatives as a member of the Senate Committee on Environment and Public Works has been to ensure that science drives legislative and regulatory decisions. As part of this effort, my colleagues and I have been focused on addressing some of the deficiencies in the Environment Protection Agency's (EPA) flagship program for conducting chemical safety assessments, the Integrated Risk Information System (IRIS). With the National Academy of Sciences' involvement and with a Congressional mandate, progress is being made to identify and fix areas that need to be changed. While it is commendable that progress is being made on IRIS, it has come to my attention that a non-regulatory division in EPA, Design for Environment (DfE), appears to be using a much less rigorous system in selecting and assessing priority chemicals and their alternatives in the Alternatives Assessment process.

Under IRIS, EPA follows a published, scientific process of hazard identification and dose response assessment that involves public comment and peer review, often including EPA's Science Advisory Board (SAB). EPA program offices then combine the IRIS values with exposure considerations to assess potential risks to the public. In contrast, the DfE program conducts a less rigorous hazard assessment that evaluates the target chemical and a range of possible substitutes against a set of hazard endpoints. Chemicals are typically scored "high," "medium" or "low" on each endpoint, and then the scores are compared to judge whether the substitutes are safer for use. As a result, the DfE alternatives assessment process is essentially a rough, "hazard banding" approach to assessing potential risks that does not take into account the potential for exposure. In addition, the DfE assessment is not peer-reviewed. Compared to traditional risk assessment, it is less scientific and more subjective.

The DfE Alternatives Assessment Program purports to identify priority chemicals and to produce a list of safer alternatives if they exist. Unfortunately, while this objective is laudable, the program is significantly flawed in the way it selects chemicals as well as evaluates them. As a result of these flaws, the program may actually increase rather than reduce risks to consumers while imposing higher costs on manufacturing and the economy. The ultimate danger is that while many of the chemicals under review have already undergone careful scrutiny many of the alternatives are less tested and potentially less safe. EPA official Bridget Williams heightened this concern earlier this year when she publicly stated that some of the chemicals assessed as safer alternatives may have "data gaps." Despite its admission that data gaps exist, EPA has proceeded to implement the alternatives assessment program.

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Given the significant potential for increasing public exposure to inadequately tested and potentially unsafe chemicals, it is unclear why EPA is not following established risk assessment principles in making decisions under the DfE program. These risk principles have been refined over the course of more than 25 years of repeated scientific peer evaluation. Although EPA states that the DfE program is voluntary, the alternatives assessment is demonizing chemicals by sending a clear governmental signal to the marketplace to deselect chemicals under review even before the alternatives assessment has been conducted. EPA has also failed to follow a transparent set of criteria for selecting priority chemicals to review. This may suggest that an arbitrary if not political process may be in use to select priority chemicals for review. If these issues are not rectified, the DfE program could lead to counterproductive changes in the marketplace that could hurt the economy and diminish consumer health and safety.

It is my understanding that EPA developed the DfE program without a specific legislative mandate, and without obtaining public input regarding the need for such a program. Furthermore, it is also my understanding that the EPA does not send its DfE standards to OMB for review, and it does not publish notice of its proposals for such in the Federal Register. Given the lack of clear standards in selecting chemicals for review and in conducting risk assessments, the DfE program may allow some to end run the more rigorous risk assessment process and regulatory process and ultimately stigmatize chemicals in the market place because they believe without full proof that safer alternatives exist. This potential for manipulation is why we have a rigorous and transparent risk assessment processes that involves public participation and peer review.

As currently implemented, the DfE program will have significant economic consequences for small businesses and chemical manufacturers if the agency promotes new chemicals based on less than a full scientific evaluation. Manufacturers and chemical companies select chemicals based on (1) the properties they convey (i.e., flammability, durability); and (2) an assessment of their safety for their intended uses that includes hazard and exposure considerations. Encouraging manufacturers and consumers to use alternative chemicals in the products they manufacture could lead to impaired product performance and quality, and potentially greater health or safety risks.

Finally, the DfE program may also have adverse consequences for U.S. manufacturers competing in the global market, if it pushes US manufacturers to rely on more expensive and less functional alternatives. This could encourage some businesses in the chemical industry to take their products and jobs abroad, where their products are not stigmatized.

Given the importance of these questions, I respectfully request that you respond in writing by October 5, 2012. Please contact Bryan Zumwalt on my staff at 202-224-4623 or bryan_zumwalt@vitter.senate.gov if you have any questions concerning this letter.

Sincerely,

Senator David Vitter
United States Senate

CC:
Boris Bershteyn, OIRA Acting Administrator
Ambassador Ron Kirk, United States Trade Representative
John P. Holdren, Director Office of Science and Technology Policy

Questions on EPA's Design for the Environment Alternatives Assessment Program

- Was DfE authorized by Congress? If not, what statutory basis does the EPA derive the authority to select chemicals for replacement (even if they have a significant safety and performance record) and suggest alternative chemicals that may not have been as thoroughly tested for durability, cost-effectiveness, market availability, and – most important – safety?

- What is EPA's overall budget for this program in FY 2012? What has EPA proposed for FY 2013?

- How many part-time and full-time EPA employees and contractors are dedicated to implementing the DfE program? How many of the EPA employees working full time on this program are trained epidemiologists or trained toxicologists?

- The DfE program's chemical assessment methodology does not employ the public participation and peer review processes that EPA uses in its IRIS program. How does EPA justify operating DfE program without full public participation and peer review?

- Does the EPA consider the DfE programs to be non-regulatory in nature? Does the EPA consider the DfE program Alternatives Assessment as rulemaking? Does it plan to send its DfE standards to OMB for review? Does EPA plan to publish notice of its proposals for such in the Federal Register?

- Given that a DfE assessment can cause consumers and manufacturers to deselect chemicals, does EPA believe that the assessments conducted under the DfE program constitute "influential scientific information" under the Information Quality Act? If so, isn't EPA violating the IQA by failing to obtain peer review?

- What steps will EPA take to ensure that proposed alternative chemicals are adequately assessed? Will they be subject to the same degree and level of public and scientific peer review? Will their suitability for commercial usage be assessed?

- Why has EPA failed to make public the criteria the Agency uses to select priority chemicals? Will EPA pledge to make these criteria public and provide the public an opportunity to comment on the criteria?

- Why has EPA proceeded with its alternatives assessments despite the potential "data gaps" that Bridget Williams acknowledged? What steps has EPA taken to inform the public that

proposed alternative chemicals may be less well tested than chemicals currently in the marketplace? If none have been taken, why not?

- How does EPA assess potential data gaps in assessing the hazard posed by potential alternatives? How many proposed alternatives have data gaps? What types of missing information are sufficient for EPA to decide there is insufficient information to determine that an alternative is safe?

- Does EPA consider the cost of deselecting chemicals in the marketplace? If not, why not? Shouldn't the cost of retooling businesses and the loss in product qualities or performance be weighed against the potential benefits?

- The Regulatory Flexibility Act requires federal agencies to assess the economic impact of their regulatory actions on small businesses and, if the impact on a substantial number of them is significant, to consider a different path that is less burdensome. Has EPA considered conducting an economic impact analysis on small businesses or on the economy in general? Is there any constraint on EPA from conducting this analysis? Will EPA commit to do this with future assessments?