EPA Stakeholder Meeting on Implementing the New Chemicals Review Program under Amended TSCA: EDF Oral Comments

December 14, 2016

Part 1:

Thank you for the opportunity to comment. My name is Joanna Slaney. I am the Legislative Director for the Health Program at Environmental Defense Fund.

Strong implementation restores public and market confidence.

EDF believes that the reforms to the New Chemicals program in the Frank R. Lautenberg Chemical Safety for the 21st Century Act, and the robust implementation of these reforms by the EPA, are absolutely essential to the task of restoring public and market confidence in our national chemical safety system. It is this shared objective, restoring public and market confidence, that allowed disparate stakeholders and lawmakers to come together to support the Lautenberg Act in the first place. And without a strong New Chemicals program, there is no restored public confidence.

It's a public health issue.

With between 500 and 1,000 new chemicals entering the market every year, ensuring the safety of these chemicals is clearly a public health priority. It is critical that new chemicals clear a safety bar before they are allowed in products and in our homes. For decades, chemicals have been allowed on the market simply because there wasn't enough information to make a safety decision one way or another. In 2007 EPA reported that 85% of pre-manufacture notices contained no health data. That's not right, and it puts the public's health at risk, most especially the health of vulnerable populations like children, pregnant women, and workers. Any chemical entering the market should be reviewed and managed to provide a reasonable assurance of its safety. In fact, I expect that most Americans believe that their government already does so in order to protect their health and the health of their families.

It's congressional intent.

Many in Congress worked hard to drive significant improvements to the new chemicals provisions in the new law; indeed, for some it was a central reason for their involvement in reforming TSCA. And the record is clear that even where certain Members were less inclined to see the need for change, they acknowledged that significant changes were made to the New Chemicals program as part of the compromise legislation. The changes that were made were a compromise on both sides but they were not insignificant, and the new requirements are clearly laid out in the language of the Lautenberg Act.

It's a primary purpose of TSCA.

It has been argued that EPA's implementation of the new chemicals program under the Lautenberg Act risks impeding innovation and is at odds with the intent of the law. In fact, the intent of the law is quite clear:

> "It is the policy of the United States that— authority over chemical substances and mixtures should be exercised in such a manner as not to impede unduly or create unnecessary economic barriers to technological innovation **while fulfilling the primary purpose of this Act to assure that such innovation and commerce in such chemical substances and mixtures do not present an unreasonable risk of injury to health or the environment."**

While innovation is central, it cannot come at the expense of protection for public health and the environment. Innovation without safety is not true innovation.

The changes made to the New Chemicals program are fundamental to the reform of TSCA and the promise of the new system. Given that the development and application of new chemicals are a clear source of innovation, how else is that primary purpose of TSCA – providing an assurance that innovation and commerce in chemicals do not present unreasonable risk – to be realized other than through robust scrutiny of new chemicals prior to their commercialization.

The public has a right to expect that chemicals to which they may be exposed will not be allowed into use without adequate assurance of their safety. The lack of that basic assurance has undermined consumer confidence in our chemical safety system. The most efficient and effective stage at which to provide assurance of safety is before commercial production and use begins, rather than waiting and then having to try to mitigate risks that arise after a new chemical is embedded in commerce.

Environmental Defense Fund supports the actions taken by EPA to date in implementing the New Chemicals Program and believes they are clearly required under the new law. We look forward to EPA continuing to implement a robust New Chemicals program that can restore public and market confidence in our national chemical safety system, while both protecting human health and the environment and fostering safe innovation.

Part 2:

Good morning. My name is Lindsay McCormick, I'm a Project Manager with the Health Program at Environmental Defense Fund.

EDF fully supports the improvements EPA is making to the New Chemicals Program, and recognizes them as not only critical to protect public health and the environment, but as fully consistent with and mandated by the new law.

We have heard from various industry representatives, both in the press and here today, that the New Chemicals Program was a "success" under the old law. While it may have been an efficient system for them, it did not adequately protect human health and the environment. This was one of the key flaws with TSCA and a reason why many in Congress worked so hard to drive improvements to the New Chemicals Program. Congressional testimony, ranging from industry groups like the American Chemistry Council and the American Cleaning Institute to health, labor, and environmental groups, acknowledged that changes were needed.

Some have also claimed that TSCA reform was not intended to make significant changes to the New Chemicals Program. This is also inaccurate. In fact, major changes were intentionally made to the new chemicals provisions of TSCA, with bipartisan support and full awareness on the part of Congress.

Five major changes were made – that go well beyond increased transparency. Each addresses a critical flaw in the original law by mandating EPA actions:

- ONE: The Lautenberg Act mandates that EPA both review each new chemical and make an affirmative finding as to its safety. The old law had neither such mandate.

- TWO: If EPA lacks sufficient information to reasonably evaluate the safety of a new chemical, it now must issue an order prohibiting or limiting the chemical to mitigate any unreasonable risk. The old law lacked such a requirement, essentially forcing EPA to allow new chemicals with insufficient information onto the market at the end of the 90 day review period.

- THREE: The Lautenburg Act requires EPA to consider and mitigate unreasonable risks of a new chemical under its "conditions of use." In addition to intended uses identified in a PMN submission, the law explicitly defines "conditions of use" to include "reasonably foreseen" circumstances of production, processing, distribution, use or disposal. Under the old law EPA had to confine any risk finding to the specific uses identified by a PMN submitter – despite the fact that, once in the marketplace, chemicals could be and often were used for purposes beyond those described in the PMNs.

- FOUR: The new law requires EPA to protect against potential risks to "potentially exposed or susceptible subpopulations," explicitly including workers. Such a provision did not exist in the old law.

- FIVE: Where EPA imposes conditions on the manufacturer of a new chemical, it must consider whether to promulgate a Significant New Use Rule (SNUR) to apply those conditions to other companies making the same chemical. It must either initiate the SNUR rulemaking or publish a statement explaining why it is not doing so. Under the old law, taking such action was entirely discretionary and, until recently, was infrequent.

EDF recognizes that the changes being implemented in EPA's new chemicals review process, while fully consistent with and required by the new law, are resulting in the development of more orders and longer review times. It's not unexpected, therefore, that some in industry are expressing angst over EPA's implementation of the new requirements. At the risk of sounding cliché, change rarely comes easily.

The new requirements not only changed the status quo significantly, but they also became effective immediately upon passage of the law, without any time given to EPA to migrate to the new system.

We need to remember that the law passed only six months ago. Over time, we expect that EPA's processes will become more efficient and allow, in many cases, for more expeditious reviews. As EPA develops and implements new procedures and practices to meet the new mandates and as manufacturers begin to anticipate the kinds of data that EPA needs to make their decisions, the process will become smoother for all parties involved.

In the long run, we expect the new law to change the incentive structure for the better. It is abundantly clear from this morning's presentation that lack of data submitted with the PMN can lengthen the review process. Companies now have a greater incentive to provide information upfront for EPA to efficiently review and make determinations on the safety of their chemicals. And companies concerned that limitations placed on uses of a new chemical may impede innovation or competitive position can and should incorporate a broader range of conditions of use into their PMNs and provide EPA with information it needs to evaluate such reasonably foreseeable uses.

In summary, EDF firmly supports EPA's recent activities under the New Chemicals Program and believes that the agency is following the letter and intent of the law. We strongly urge EPA to stay on track. It is the right thing to do for public health and environmental protection, the best way to restore public confidence, and now – finally - required by law.

Part 3:

Good afternoon. My name is Jennifer McPartland and I am a senior scientist with the health program at Environmental Defense Fund.

The Lautenberg Act's mandate that EPA review and manage for safety every new chemical prior to market entry represents one of the most critical paradigm shifts created by the new law. The previous absence of such a mandated review and determination was a signature failure of the old law that, despite EPA's best efforts, not only put human health and the environment at risk, but also contributed significantly to the erosion of marketplace and public confidence in the chemicals sector. Provisions related to the new chemicals program under the Lautenberg Act, and every step the agency has taken pursuant to it, should be viewed from this reality.

My comments will address specific actions EPA has taken under the new chemicals program—actions that are consistent with the Lautenberg Act and that EDF strongly supports.

First, EPA reset the 90-day clock on new chemical reviews already in progress on the date of enactment. Because new requirements applied immediately to these new chemicals, that action was appropriate and necessary under the law. It should not be construed as a failure of the agency to meet deadlines.

Second, EPA has identified a number of new chemicals for which it either lacked sufficient information to "permit a reasoned evaluation" or had information that led it to make a finding that the chemical "may present an unreasonable risk." In such cases, EPA is proceeding, as required under the new law, to impose testing or other requirements through an order. As under the old law, the additional time required for testing or negotiating a consent order usually necessitates an extension of the initial 90-day review period or a suspension of the review. Again, this action is appropriate and necessary under the law. It should not be interpreted as a failure to meet deadlines.

Third, it appears EPA has identified a number of new chemicals for which it has identified "reasonably foreseen" conditions of use that "may present an unreasonable risk." The law expressly requires that where EPA finds a new chemical presents or may present an unreasonable risk under its conditions of use – defined in the law to include both intended and reasonably foreseen uses– it *must* issue an order imposing conditions sufficient to mitigate such risk. It appears that EPA has taken just such action in some cases by limiting a PMN submitter to its identified intended conditions of use. This is necessary to support an affirmative finding that the new chemical is not likely to present an unreasonable risk under such conditions and allow market entry. If EPA were only to examine intended uses, as was the case in the past, it may very well miss real concerns that could arise from uses beyond those identified. The new law's requirement that EPA explicitly consider how else a new chemical might be used is sound policy and necessary to provide a reasonable assurance of safety. Some have suggested that rather than issuing a consent order, EPA should instead be issuing a non-5e SNUR. However a non-5e SNUR is not applicable in the context of making an initial determination on a PMN. The new law requires that EPA

make a finding about the PMN submission itself—that the chemical presents, may present, or is not likely to present an unreasonable risk under its conditions of use, again to include reasonably foreseen uses. In the past EPA could have dealt with a situation where the PMN submitter's intended uses were ok but other uses might not be by issuing a non-5e SNUR, but the new law changes the baseline requirements of a PMN review by mandating that EPA consider reasonably foreseen uses. EPA will presumably still use non-5e SNURs as a follow-up to consent orders because it is the only way to extend conditions imposed to other companies – as the consent order applies only to the PMN submitter.

Fourth, EPA has identified a number of new chemicals the characteristics of which raise particular concern for workers, especially with regard to the potential for adverse chronic health effects associated with long-term exposures to contaminated air in the workplace. In such cases, we understand EPA is requesting that companies conduct additional testing to determine whether the chemical presents, may present, or is not likely to present, an unreasonable risk. Based on information available to us, EDF believes this is a prudent approach and in fact could and often should have been done under the old law. It's even more called for now with EPA's new authority and mandate to explicitly consider workers as a "potentially exposed or susceptible subpopulation."

Thank you for the opportunity to comment.