WRITTEN STATEMENT OF

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BEFORE

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COMMITTEE ON ENERGY AND COMMERCE
SUBCOMMITTEE ON ENVIRONMENT AND THE ECONOMY

AT A HEARING ON

S. 1009, THE CHEMICAL SAFETY IMPROVEMENT ACT OF 2013

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ONE-PAGE SUMMARY

In May of this year, the bipartisan Chemical Safety Improvement Act (CSIA) was introduced, opening the first viable path toward actually passing TSCA reform legislation. CSIA contains many elements of effective reform – but needs significant changes if it is actually to deliver the promised reforms.

Some of the ways in which CSIA addresses major flaws in the current law include:

- CSIA mandates safety reviews of all chemicals already in commerce.
- CSIA tackles the key problems in TSCA's "unreasonable risk" standard, by clarifying that the standard is to be applied based solely on health and environmental risk, and striking the "least burdensome" requirement that has paralyzed EPA's ability to act.
- CSIA requires a new chemical to be found likely to meet the safety standard before market entry.
- CSIA increases EPA's ability to require testing, by allowing it to issue orders and not requiring EPA to make risk findings to order testing.
- CSIA grants State and local governments and medical personnel access to confidential business information (CBI), subject to confidentiality agreements.

Unfortunately, the bill as drafted also would erect major obstacles that would impede EPA's ability to effectively and efficiently utilize these tools. And it would unduly limit the authority of states to act to address chemical risks, often long before EPA has acted to address those risks.

Among the major concerns that need to be addressed are the following:

- The safety standard must ensure protection of vulnerable populations and require that the multiple sources of exposure to chemicals be taken into account.
- EPA's authority to require testing when reviewing new chemicals and prioritizing data-poor chemicals needs to be restored.
- The bill's sweeping pre-emption of state authority needs to be significantly narrowed.
- The bill's lack of deadlines and its imposition of numerous overlapping procedural requirements, which would delay even the first safety decisions for many years, must be fixed.
- The bill's undue limits on EPA's ability to ensure that information submitted and claimed as confidential actually warrants protection from disclosure must be remedied.

I am convinced that these problems, while serious, are fixable and can be addressed in a manner that ensures protection of public health while retaining bipartisan support critical to passage of the legislation. Congress must seize this opportunity to address an urgent health concern and overhaul an ineffective and obsolete law that everyone agrees needs reform. The health of all Americans hangs in the balance.

FULL STATEMENT

My organization has been working to reform the Toxic Substances Control Act (TSCA) for nearly 20 years and I have personally been engaged in this effort for well over a decade. We have made this investment because we are convinced that this outmoded law is not protecting American families, workers and communities from toxic chemical exposures.

The need for reform is urgent, even more so than when we began this work. Emerging science increasingly links certain chemical exposures to the rising incidence of serious chronic health problems such as infertility, diabetes, childhood cancers and even learning disabilities. So in recent years we have redoubled our efforts to reform TSCA, the core provisions of which have not been touched in nearly 40 years. Today, there is almost universal agreement that the current law simply does not work: It is not protecting American families, workers and communities from toxic chemicals; it is not providing the market with the information needed to inform decisions and drive innovation toward safer chemicals; and it is not providing the consumer confidence and market predictability that companies need to run their businesses.

In May of this year, we saw a breakthrough: For the first time, bipartisan reform legislation was introduced in the Senate, and the bill now enjoys co-sponsorship by one-quarter of the Senate, 12 Democrats and 13 Republicans. EDF welcomed the introduction of the Chemical Safety Improvement Act (CSIA) because it offers the first viable path toward actually passing reform legislation. In addition, the bill as introduced contains many of the elements of *effective* reform – although, as I will explain, as drafted it needs significant changes if it is to actually deliver the promised reforms.

EDF and many others have identified a number of serious concerns with CSIA that must be addressed, a few of which I'll discuss in a moment. But I am convinced that the problems are fixable and can be addressed in a manner that ensures protection of public health while retaining bipartisan support critical to passage of the legislation. Many, if not most, of the improvements we seek will benefit *all* parties by creating an effective and efficient system that protects public health and restores market and consumer confidence in the chemical and related industries and their products. I've attached to my testimony a side-by-side comparison of TSCA and CSIA, highlighting both strengths and weaknesses of the bill (**Attachment 1**).

Let me now highlight some of the ways in which CSIA addresses major flaws in the current law.

- **CSIA mandates safety reviews of all chemicals already in commerce:** When TSCA passed in 1976, it grandfathered in some 62,000 chemicals already in commerce – which still account for the bulk of chemicals in active use today – and gave EPA no mandate to review them for safety. As a corollary, it falsely equated the lack of any safety data on the great majority of those chemicals with a lack of risk.

  CSIA for the first time would require EPA to review the safety of all chemicals in active commerce. And it makes a lack of safety data a basis for designating a chemical high-priority, which triggers EPA's authority to require testing and a mandate to conduct a formal safety assessment and safety determination for the chemical.

- **CSIA tackles the key problems in TSCA's "unreasonable risk" standard**: TSCA's "unreasonable risk" cost-benefit standard is widely regarded to have failed for two main

reasons. First, it blurs together what should be two distinct decisions: a science-based decision as to *whether* a chemical poses a significant risk; and a risk management decision as to *how* to address such risks where they are found. Second, it forces EPA to engage in paralysis-by-analysis by requiring it to prove that any action it proposes to take is the "least burdensome" of all possible options for each and every use of a chemical.

CSIA tackles both problems: It clarifies that the "unreasonable risk" standard is to be applied "based solely on considerations of risk to human health and the environment;" except in the case of complete bans or phase-outs, consideration of costs and benefits is relegated to a separate risk management stage. And it strikes the paralyzing "least burdensome" provision.

- **CSIA requires that a new chemical be found likely to meet the safety standard before market entry:** Under TSCA, new chemicals undergo a cursory pre-manufacture review, and no affirmative safety decision is required before they can enter the market. And in the review, the burden is on EPA to find a concern – hard to do when safety data are not required – in order to halt, slow or limit market entry.

  CSIA for the first time would require EPA to make an affirmative finding of likely safety as a condition for the manufacture of a new chemical to commence. And while EPA still could not directly require safety testing of new chemicals, it could suspend its review pending submission of needed data, or impose conditions needed to provide the requisite assurance of likely safety in the absence of such data.

- **CSIA allows EPA to require testing by issuing orders:** Under TSCA, EPA must promulgate a regulation in order to require a company to conduct safety testing of a chemical it makes or uses. Moreover, to require testing, EPA has to show potential risk or high exposure – a *Catch-22*, given that testing would typically be the way EPA would get the data needed to make such findings! This process is resource-intensive and typically takes many years.

  CSIA would authorize EPA to issue orders to require testing. Using orders avoids the onerous rulemaking process and subsequent court challenges. While EPA would have to justify why it is using an order rather than a rule or consent agreement, it would not need to make risk findings to order testing of a chemical.

- **CSIA grants State and local governments and medical personnel access to confidential business information (CBI), subject to confidentiality agreements:** Under TSCA, EPA is forbidden from sharing CBI with other levels of government, denying them access to information vital to their ability to assure the health and welfare of their citizens. And even in emergency situations, TSCA denies doctors, nurses, even staff in poison control centers, access to information – such as the confidential identity of a chemical to which a child or worker has been exposed – that could literally save lives.

  CSIA would for the first time grant access to such information to those outside the Federal government who need it most.

That's the good news.

Unfortunately, the bill as drafted also would erect major obstacles that would impede EPA's ability to effectively and efficiently utilize these tools. And it would unduly limit the

authority of states to act to address chemical risks, often long before EPA has acted to address those risks.

Among the major concerns that need to be addressed as the bill moves through the legislative process are the following:

- **The safety standard must ensure protection of vulnerable populations and require that the multiple sources of exposure to chemicals be taken into account**. One thing we have learned since TSCA first passed in 1976 is that certain individuals and populations are either more heavily exposed to chemicals or more susceptible to their effects than the population as a whole. These include the developing fetus and infants, as well as workers or those with pre-existing medical conditions. And they include "hotspot" communities that have disproportionately high exposure, often because they are exposed to chemicals from multiple sources.
- **EPA's authority to require testing when reviewing new chemicals and prioritizing data-poor chemicals needs to be restored.** As noted earlier, CSIA would reduce the procedural and evidentiary burdens on EPA to require testing. However, it would severely limit the purposes for which testing could be required: Testing could only be required to inform safety assessments and determinations for existing chemicals, and EPA is explicitly barred from requiring testing of new chemicals and to inform prioritization of existing chemicals. This is a major step backward from current TSCA. The arbitrary restriction on testing in CSIA would lead to one of two outcomes that would be good for no one: either EPA would be forced to allow chemicals for which insufficient data exist to assess their safety to enter or

remain on the market; or it would have to deny market access to or waste resources assessing chemicals that more data would show pose little or no risk.

- **The bill's sweeping pre-emption of state authority needs to be significantly narrowed.** Foremost among the concerns about the bill as drafted is that by EPA merely designating a chemical as high- or low-priority, all States would be precluded from imposing a <u>new</u> requirement on the chemical. For a high-priority chemical, this pre-emption of State authority would happen long before, likely many years before, EPA took any action to address risks posed by that chemical. And for a low-priority chemical, States that disagree with EPA's decision would have no recourse because even though the low-priority designation would effectively be a final agency action, it would not be subject to judicial challenge. That's not only bad policy, it's bad for the practice of government.

  Under the bill as drafted, pre-emption of <u>pre-existing</u> state requirements is triggered merely by EPA's issuance of a safety determination. For a chemical EPA finds does not meet the safety standard, State requirements would be voided well before EPA takes final action to address the risks of the chemical.

  Long-standing authorities of states to enact requirements identical to those of Federal agencies for purposes of co-enforcement would also be eliminated, as would state requirements imposed for entirely different purposes such as to reduce emissions of greenhouse gases.

- **The bill's lack of deadlines and its imposition of numerous overlapping procedural requirements, which would delay even the first safety decisions for many years, must be fixed.** One area of agreement across all stakeholders is the desire for an efficient system

that gets up and running quickly, transitions smoothly from the current system, and makes timely decisions on the large number of chemicals in active commerce. As drafted, the bill would frustrate that shared objective by requiring EPA to take years just to establish the new system, and years more to make decisions and take action on specific chemicals. And it would all but invite legal challenges by parties unhappy with one or another aspect.

I have done a detailed analysis of the bill's procedural requirements, which I've attached to my testimony (**Attachment 2**). It shows that even by a very conservative estimate, the first list of prioritized chemicals would take more than three years to develop, and the first safety determination on a chemical not made until more than seven years after enactment, with any needed risk management actions requiring even longer to implement.

Solutions to these problems are, however, evident: Among them are adding aggressive but realistic deadlines; ensuring EPA can incorporate and build on the work it has done to date as it transitions to the new system the bill would establish; and streamlining the bill's "red tape" to eliminate redundant requirements and procedures.

- **The bill's undue limits on EPA's ability to ensure that information submitted and claimed as confidential actually warrants protection from disclosure must be remedied.** For example, the bill places a blanket restriction on EPA's authority – which it has under current TSCA – to examine and require documentation of past confidentiality claims – even when it has reason to believe the information does not or no longer constitutes a trade secret. Given the widespread overuse of CBI allowances over the history of TSCA – a fact acknowledged even by industry witnesses appearing before this Subcommittee earlier this

year – this restriction is unwarranted and could even preclude EPA from complying with requests its receives under the Freedom of Information Act (FOIA).

Let me end by returning to what I believe is the good news here: First, we have a major political opening to address an urgent health concern and overhaul an ineffective and obsolete law that everyone agrees needs reform. Second, we have a bill that has many of the elements needed for effective reform and can serve as a basis for negotiations. Third, while its deficiencies are serious, they are fixable: many of the changes needed I believe will benefit all parties, and the others, while tougher, can be solved if we can muster the political will and negotiate in good faith to balance competing objectives. I am encouraged that the informal negotiations on the bill that have occurred to date appear already to be moving it in the right direction.

I urge this Subcommittee and all stakeholders to build on the foundation laid by a bipartisan group of Senators earlier this year and work to pass meaningful TSCA reform legislation in this Congress.

The task will not be an easy one, but we simply can't afford to waste this opportunity. If done right, the bill could pave the way to an effective and efficient system that fully protects public health, restores lost confidence in the safety of chemicals and chemical products, and provides incentives and the information needed for the market to avoid dangerous chemicals and innovate safer and greener ones.

The health of all Americans hangs in the balance.

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ATTACHMENT 1

The Chemical Safety Improvement Act of 2013 (S. 1009): How it seeks to address key flaws of TSCA, along with key tradeoffs and concerns

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The Chemical Safety Improvement Act of 2013 (CSIA, S. 1009) would amend the core provisions of the Toxic Substances Control Act (TSCA) for the first time since TSCA's passage in 1976. Over the years, key flaws in these core provisions have been identified by many observers. **Table 1** below shows how these key flaws in each core area of current TSCA would be addressed by the new legislation. It also identifies some of the main trade-offs and remaining concerns raised by these provisions of the legislation. **Boldfaced entries** are those I consider to be most central to addressing the question of how and to what extent the new legislation fixes the key flaws of TSCA.

The bill would significantly expand TSCA's currently limited pre-emption of state authority, which has largely been moot due to how few actions EPA has undertaken. **Table 2** below presents the key pre-emption provisions of current TSCA and CSIA are presented along with key issues and concerns raised by the bill's expanded provisions.

This analysis does ***not*** address other critically important aspects of the debate over TSCA reform, including the absence from the new legislation of provisions – which I and many others support – that would extend the scope of TSCA beyond its core provisions, including those relating to: (1) "hot spots" – areas with disproportionately high chemical exposures; (2) expedited exposure reduction for chemicals of very high concern, such as PBTs; and (3) green chemistry and alternatives assessment.

TABLE 1	*Key flaws in TSCA*	*Key changes in CSIA*	*Trade-offs/remaining or new concerns*
Safety standard/ determination ***(Section 6)***	• **Standard requires cost-benefit analysis** • **Imposes "least burdensome" requirement on any regulation** • No definition or specific criteria to identify chemicals of concern	• **Standard is applied based on health/ environment impacts only** • **Strikes "least burdensome" requirement** • Requires EPA to consider exposures of vulnerable populations • Requires EPA to consider multiple exposures to a chemical • Requires EPA to use "best available science"	• Bans still must be based on cost-benefit • No explicit inclusion in standard of protection of vulnerable populations or need to assess aggregate exposure • "Best available science" does not reference NAS recommendations
Existing chemicals ***(Section 6)***	• **No mandate to review existing chemicals for safety** • **Lack of data is presumed to indicate lack of risk** • No criteria for triggering review of an existing chemical	• **Requires a safety review of all chemicals in active commerce** • **Lack of data is basis for high-priority designation** • High hazard or exposure sufficient for high-priority designation • Requires safety determinations for all high-priority chemicals • Requires risk management to be imposed on chemicals found not to meet the safety standard	• Initial review (prioritization) is based only on existing data, and lack of data does not assure high-priority ranking • Pace of review is unspecified, with virtually no deadlines for EPA actions • Prioritization decisions not subject to court challenge (cuts both ways) and can trigger pre-emption of state authority • Overly prescriptive and redundant frameworks and criteria must be developed and followed
New chemicals ***(Section 5)***	• **No affirmative safety decision is required before market entry** • **Burden is on EPA to find concern even when safety data are lacking** • Decisions are largely a "black box" because consent orders need not be made public	• **An affirmative decision of "likely safety" is required for market entry** • Prohibitions or restrictions can be imposed by order • All new chemical notices and orders and submitted data must be made public (subject to CBI provisions)	• EPA cannot require testing of new chemicals (but can suspend review or impose conditions, as in status quo) • No means provided to ensure compliance for chemicals "likely" to meet safety standard (unless EPA issues a Significant New Use Rule, or SNUR)
Testing ***(Section 4)***	• **EPA must promulgate a regulation to require testing** • **EPA has to show potential risk or high exposure to require testing, a Catch-22** • Testing done by consent orders is non-transparent, not always made public	• **EPA can use orders to require testing (must justify why it is using an order rather than a rule or consent agreement)** • **Testing orders avoid lengthy rulemaking and court challenges** • **EPA does not need to make risk findings to require testing** • Testing agreements and orders and all test data must be made public (subject to CBI provisions)	• Testing can only be required for use in safety assessments or determinations, hence limited to chemicals in commerce deemed high-priority • No minimum information sets are required; all testing is on the basis of EPA demonstrating specific need • An overly prescriptive tiered testing framework must be followed

TABLE 1	*Key flaws in TSCA*	*Key changes in CSIA*	*Trade-offs/remaining or new concerns*
Confidential business information ***(Section 14)***	• **Companies can claim any information they submit to be CBI** • **Substantiation of CBI claims is typically not required** • **EPA reviews very few CBI claims and must challenge them case-by-case** • **EPA cannot share CBI with state and local governments** • Health and medical professionals cannot be given access to CBI • CBI claims do not expire	• Information never eligible (as well as eligible) for CBI is delineated • **All other CBI claims must be substantiated at the time asserted** • Resubstantiation can be required for any CBI claim upon designation of a chemical as high-priority • **EPA must review CBI claims (all or representative subset)** • **States and localities have access to CBI, subject to confidentiality agreements** • Health professionals can access CBI under confidentiality agreements • For chemical identity CBI claims: ▪ Redocumentation can be required at any time ▪ Ready capability for reverse engineering disallows such claim ▪ A time period must be specified for each such CBI claim and found by EPA to be reasonable	• Only health and safety data on existing – not new – chemicals is precluded from being claimed CBI • Notifications to submitters prior to release of CBI are generally required • A new appeals process is provided under which claimants can challenge EPA's intention to release CBI • Except as noted for chemical identity and high-priority chemical CBI claims, EPA cannot require documentation or redocumentation of a CBI claim made prior to the date of enactment
Chemical information reporting ***(Section 8)***	• The full range and identity of chemicals in active commerce, and their producers and processors, is not known • **Information on use of chemicals is collected only from chemical manufacturers with limited knowledge of downstream use**	• Companies must notify EPA of all chemicals on the TSCA Inventory they are producing or processing (used to "reset" the Inventory) • Chemicals not notified as active are placed on an inactive list; a company must notify EPA before making them • **Processor reporting is required for the first time for all chemicals in active commerce**	• Chemicals on the confidential portion of the TSCA Inventory can remain so if reasserted (though EPA can require (re)substantiation – see above) • The scope of manufacturer and processor reporting programs is left to EPA to develop through rulemaking

TABLE 2	***TSCA***	***CSIA***	***Issues/concerns***
Pre-emption ***(Section 18)***	• States can't require testing of a chemical "for purposes similar to those" for which EPA requires testing • If EPA regulates a chemical by rule, States can only: (a) have the identical requirement or (b) regulate it under a different Federal law or (c) entirely prohibit the chemical in the State • Only final rules or orders have a pre-emptive effect • Waivers available for State requirements that are more protective and don't unduly burden interstate commerce	• States can't require testing "reasonably likely to produce the same data" as EPA requires, or require notification of uses of a chemical for which EPA requires the same notification • States can't establish or continue to enforce a requirement that restricts a chemical once EPA has completed a safety determination on the chemical • States can't impose a <u>new</u> restriction on a chemical once EPA has: (a) designated it low-priority, or (b) for high-priority chemicals, upon publication of EPA's schedule for conducting a safety assessment and determination • Waivers available if State cannot wait for EPA to act or EPA finds its actions are being unreasonably delayed	• States need to be able to enact requirements identical to EPA's to allow for co-enforcement • "Restriction" can be read broadly to apply to warning labels, etc. (e.g., CA Prop 65) • The safety determination doesn't regulate a chemical found not to meet the safety standard; the trigger for any preemption should be the final risk management rule required for such chemicals • Low-priority designations can't be challenged in court as final EPA actions • The trigger for any preemption should only be (a) a determination that a chemical meets the safety standard or (b) the risk management rule required for chemicals found not to meet the standard • States must also show "compelling local" conditions or interests and sufficient scientific basis to obtain waivers

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Attachment 2

Conservative timeline for implementation of the Chemical Safety Improvement Act (S. 1009)

Date of enactment to first prioritized chemicals = 39 months or 3.25 years
Date of enactment to first final safety determination = 86 months or 7.17 years
Date of enactment to first final rule imposing restrictions = 104 months or 8.67 years

Process step or activity	**Minimum time required** (Conservatively assumes: (1) no additional data needed; (2) process timelines overlap or run concurrently wherever plausible; and (3) rules can be finalized in 18 months)	**Minimum cumulative time (months)**	**Bill section**
1. Promulgate reporting rule, guidance	18 months (may be done within timeframe of #4)		8(a)(4), (5)
2. Develop candidate list of active chemicals	6 months (may be done within timeframe of #4)		8(b)(4)(A)
3. Issue guidance on active chemical reporting	6 months (may be done within timeframe of #4)		8(b)(4)(B)
4. Promulgate rule requiring reporting of active chemicals	18 months	18	8(b)(4)(C)
5. Propose designations of each chemical as active/inactive	6 months	24	8(b)(5)-(7)
6. Provide an opportunity to comment/claim CBI	3 months	27	8(b)(8)
7. Modify active/inactive lists based on comments	3 months	30	8(b)(8)
8. Develop chemical assessment framework	12 months (concurrent with above activities?)		4(a)(1)
9. Develop policies and procedures for the framework	12 months (concurrent with #8?)		4(a)(2)
10. Develop data quality criteria	6 months (concurrent with #8?)		4(b)(1)
11. Develop structured evaluative framework	6 months (concurrent with #8?)		4(b)(5)
12. Develop prioritization screening process	12 months (concurrent with #8?)		4(e)(1), (2)
13. Propose prioritization criteria	3 months (concurrent with #12?)		4(e)(2)(A), (C)
14. Take public comment on the process and criteria	3 months (concurrent with #12?)		4(e)(2)(A)
15. Propose initial list, prioritization decisions for comment	3 months (concurrent with #12?)		4(e)(2)(B)
16. Request data submission on the initial chemicals	3 months	33	4(e)(1)(F)(ii)
17. Finalize priority designations for initial list	6 months	***39***	4(e)(3)(B)
18. Take public comment on subsequent high/low decisions	3 months (not included in initial timeline)		4(e)(3)(G)
19. Publish subsequent lists of high/low priority chemicals	3 months (not included in initial timeline)		4(e)(3)(J)
20. Promulgate procedural rules for safety assessments	18 months (partially concurrent with #8?)	45	6(b)(2)
21. Develop safety assessment methodology	18 months (partially concurrent with #8?)		6(b)(4)
22. Take public comment on and peer review methodology	12 months	57	6(b)(4)(A)(ii)
23. Seek input on first high-priority chemicals to be assessed	3 months (concurrent with #22?)		6(b)(2)(B)(i)(III)
24. Draft safety assessments on first high-priority chemicals	12 months	69	6(b)(1)
25. Take public comment on draft safety assessments	6 months	75	6(b)(2)(B)(i)(IV)(bb)
26. Publish final safety assessments on first chemicals	6 months	81	6(b)(2)(B)(i)(IV)(cc)
27. Propose safety determinations on assessed chemicals	1 month	82	6(c)(1)
28. Take public comment on draft safety determinations	2 months	84	6(c)(6)
29. Publish final safety determinations on first chemicals	2 months	***86***	6(c)(7)
30. Promulgate rules for chemicals not meeting standard	18 months	***104***	6(c)(9)