UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

Comments of Safer Chemicals Healthy Families on Improvements to the New Chemicals Review Program under the Amended Toxic Substances Control Act

Submitted via Regulations.gov (January 17, 2017)

Docket ID EPA-HQ-OPPT-2016-0658

Safer Chemicals Healthy Families (SCHF) submits these comments on the efforts of the Environmental Protection Agency (EPA) to strengthen the new chemical review program in response to the newly enacted Frank H. Lautenberg Chemical Safety for the 21st Century Act (LCSA). This Act is the first major overhaul of the 1976 Toxic Substances Control Act (TSCA) and an important step forward in evaluating and reducing the risks of chemicals to health and the environment in the US.

SCHF is a nationwide coalition of national and grassroots organizations including parents, health professionals, advocates for people with learning and developmental disabilities, reproductive health advocates, environmentalists and businesses, committed to assuring the safety of chemicals used in our homes, workplaces and the many products to which our families and children are exposed each day. SCHF and its members were leaders in advocating that Congress enact the most protective and effective legislation possible to reduce the risks of toxic chemicals in commercial use today. If EPA takes forceful and proactive steps to implement the new law, it can deliver significant health and environmental benefits to the American people. However, if EPA rolls back the protections mandated by Congress, the law's promise will not be realized and the threats that chemical risks now pose to our communities and the environment will continue unchecked. SCHF will engage constructively with EPA and other stakeholders on an implementation path that will maximize the health and environmental protections of LCSA but will hold EPA accountable if it fails to carry out the law as Congress intended.

We commend EPA for convening the December 14 public meeting on the new chemicals program and appreciate the opportunity both to share our views at the meeting and submit these follow-up written comments.

The following organizations have endorsed and are supporting the SCHF comments:

Alaska Community Action on Toxics
Alliance of Nurses for Healthy Environments
American Sustainable Business Council
Asbestos Disease Awareness Organization
BlueGreen Alliance
Breast Cancer Action
Breast Cancer Fund
Center for Environmental Health
Clean and Healthy New York
Clean Production Action
Clean Water Action
Earthjustice
Environmental Health Strategy Center
The Ecology Center
Michigan Network for Children's Environmental Health
Healthy Legacy Coalition
League of Conservation Voters
Learning Disabilities Association of America
Natural Resources Defense Council (NRDC)
Physicians for Social Responsibility
Science and Environmental Health Network
Vermont PIRG
Toxic Free Future

Summary of Key Points

From the law's inception in 1976, the pre-manufacture notification (PMN) program for new chemicals has been a bedrock element of TSCA. The program reflects a recognition by Congress that new chemicals require careful review before their introduction in commerce so that potential risks to human health and the environment are identified and addressed before there is widespread exposure and harm. This precautionary goal is now more important than ever as new chemical products continue to replace existing substances in large numbers and account for an ever-increasing portion of public exposure to chemicals. Since EPA can only evaluate and restrict a small portion of the existing chemical universe, the safeguards provided by the PMN program are uniquely important and may be the only opportunity in the life cycle of many chemicals to provide protection against harm.

The LCSA significantly revamps and strengthens the PMN program in section 5 and requires a significantly more protective approach to new chemical review. EPA has made a diligent effort to implement the heightened protections in the law and is off to a strong start. The Agency must stay the course despite the unjustified efforts of industry to attack and weaken the enhanced protections EPA is putting in place.

We will show below that:

EPA's approach to new chemical review implements the letter and spirit of LCSA

- Under section 5(a)(3), EPA now must make an affirmative determination of safety for every new chemical. Thus, EPA can no longer allow the PMN review period to expire without explicitly addressing the chemical's risks. If it concludes that the new chemical does or may present an unreasonable risk, lacks sufficient information for a risk evaluation, or is or may have substantial production volume and exposure, EPA *must issue an order* to restrict the chemical and/or require testing. This obligation is non-discretionary.
- The only instance where no action is required is when EPA determines that the chemical is not likely to present an unreasonable risk. Thus, in contrast to the current law, EPA must have affirmative evidence of a chemical's safety before the PMN submitter is allowed to start production.
- Because the burden is on EPA to show that the PMN chemical presents low risks before manufacture can proceed, the number of orders issued under sections 5(e) and 5(f) will increase and many more chemicals will be subject to limits on human exposure and environmental release and testing requirements. Despite industry claims of EPA "overreaching", this is exactly what LCSA intends.

The claimed PMN "backlog" is a red herring designed to pressure EPA to cut corners in implementing LCSA

- Industry has presented a greatly exaggerated picture of "gridlock" in the new chemicals program and made overblown claims that EPA's approach is threatening new chemical innovation.
- While one-time start-up challenges have created a limited PMN "backlog", delays are diminishing as EPA completes reviewing the hundreds of PMNs pending when the law took effect in June, gains greater experience in interpreting and applying the new requirements and continues to find additional efficiencies in its review process.
- As EPA explained at the public meeting, its internal PMN review timeline has not changed under LCSA: as before, EPA seeks to complete review of the PMN and communicate any concerns to the submitter via an Action Letter by Day 90. What has changed is that EPA is

seeking suspensions of more PMN reviews to negotiate orders and fewer chemicals are being cleared for commercial production in 90 days. This is not an inexplicable departure from EPA's existing process but the natural consequence of applying the new safety determination criteria and concluding that more new chemicals must be regulated under the express terms of the law.

- LCSA encourages EPA to make safety determinations under section 5(a)(3) within the 90-180 day review period but recognizes that this may not always be possible and that EPA can take more time for determinations where necessary. Thus, in contrast to the original law, TSCA no longer imposes an ironclad deadline for completing PMN review whether or not EPA has taken action but conditions the start of production on the Agency making an affirmative safety determination.
- EPA explained at the December 14 meeting that many PMNs contain unnecessary errors or are bare-bones submissions that fail to anticipate and address issues and concerns that will likely arise in EPA's expanded review. Industry can accelerate PMN reviews by preventing avoidable non-compliance with notification requirements and filing more robust PMNs.
- Only about a third of PMN chemicals are in fact commercialized and listed on the Inventory and many of these enter production months or even years after the completion of PMN review. Moreover, many new chemicals have moved forward to commercialization under PMN exemption rules rather than through the PMN process itself and thus are unaffected by the new law. In this context, it is hard to see how taking additional time to negotiate orders on PMN chemicals of concern represents a barrier to innovation.

To comply with the new law, PMN reviews must identify and, where warranted, restrict foreseeable uses of new chemicals

- EPA has correctly concluded that the new law requires it to base its safety determinations on the "conditions of use" of the new chemical, a term defined to include "reasonably foreseen" chemical uses. As EPA recognizes, this means evaluating future uses of new chemicals that can be reasonably anticipated – and issuing orders restricting these uses where warranted by the Agency's determinations of safety.
- This approach provides necessary protections against changes in use that will or may present unreasonable risks or warrant additional testing by ensuring that the new chemical does not enter production until these concerns are addressed.

Vulnerable populations must be a central focus of EPA's safety determinations for new chemicals under amended TSCA

- In a significant change from the original law, LCSA expressly directs EPA to identify risks to vulnerable populations and to protect these populations in its risk evaluations and risk management decisions.
- SCHF and its member organizations believe that protecting vulnerable populations is among the most important responsibilities placed on EPA under the new law.
- While EPA has previously addressed some vulnerable populations in PMN reviews, it needs to broaden its efforts under LCSA. As EPA recognized at the December 14 meeting, this includes expanding the range of subpopulations that are addressed in new chemical evaluations; adopting additional scaling factors to adjust risk estimates to reflect differences in susceptibility among groups; and developing more systematic and transparent protocols to identify vulnerable populations and the greater risks they face.

While structure-activity relationships (SAR) remain an important tool, they should not be the sole basis for determining that a new chemical is not likely to present an unreasonable risk but should be supplemented by testing

- EPA's reliance on SAR under original TSCA developed in large part because few PMNs contained test data and SAR was the only way to prioritize new chemicals based on their potential adverse effects and justify restrictions on manufacture and use.
- Over time, SAR's value as a predictive tool has improved but it continues to have significant limitations. For example, the new chemical may not in fact have the same toxicological properties as the analog. Or the scope and quality of the test data on the analog (assuming it is a good surrogate for the new chemical) may be limited.
- Because of these drawbacks, SAR may be valuable in identifying new chemicals that raise concern and require closer evaluation but is generally insufficient to make an affirmative determination of safety.
- In drafting LCSA, Congress gave EPA new authority to require testing where more information about a chemical's effects is needed for informed judgments about risk. In view of this expanded authority, EPA should place limited reliance on SAR as a basis to determine that PMN chemicals are of low concern. Instead, the Agency should in most cases require submitters to develop test data so that it can conduct the reasoned, scientifically sound evaluation of new chemical risks that Congress required.

EPA must establish an accessible public tracking system for its safety determinations and orders under the enhanced PMN program

- As EPA strengthens the new chemicals program under LCSA, it is time for the Agency to adopt enhanced transparency measures so that there can be greater public engagement with and understanding of the implementation of the new chemical program.
- While EPA has begun posting summaries of its findings for chemicals not likely to present an unreasonable risk, it is equally important for the public to understand the basis for its determinations that chemicals require restrictions because they present or may present an unreasonable risk, lack sufficient information for a reasoned risk evaluation, or will have substantial production volumes and potential exposure.
- In these cases, EPA should publish a summary document describing the nature of its concerns and the requirements imposed under sections 5(e) or (f). Also valuable would be a frequently updated tabulation of the Agency's safety determinations and regulatory actions so that the public can monitor the performance of the program as a whole.

EPA must apply the law's more stringent requirements for CBI claims to the new chemicals program

- LCSA imposes significantly more stringent requirements for CBI substantiation, including for many elements of PMN submissions, and precludes CBI claims for general processing and use information.
- EPA has not applied these new requirements to PMN submissions, even though they have been in effect since LCSA was signed. This failure to enforce the law has greatly reduced the transparency to which the public is entitled and must be immediately corrected.

I. EPA's Approach to New Chemical Review Fully Implements the Letter and Spirit of the New Law

Since TSCA's enactment in 1976, EPA's PMN program has achieved modest success in assessing the risks of new chemicals. However, shortcomings in the law have limited the program's effectiveness. As the Senate report on S. 697 noted, "concerns have been raised that [the original law] does not require EPA to make an affirmative finding that a new chemical or a significant new use is not likely to present an unreasonable risk." And it further noted that EPA's limited authority "constrains the Agency's ability to mandate new testing when necessary to support review of a new chemical or significant new use."[1]

Reflecting these shortcomings, only 10 percent of PMN submissions under the old law were subject to controls on human exposure and environmental release or testing requirements under section 5(e).[2] The great bulk of new chemicals entered manufacture without restriction or additional testing since EPA had no obligation to make a safety determination and could only take action on the basis of an affirmative finding of risk. To compensate for the absence of data, EPA used SAR to screen chemicals but its SAR judgments were inherently imprecise and provided a limited basis for determinations of safety. EPA senior officials have acknowledged that chemicals slipped through the section 5 review process that, once in widespread use, posed risks that could have been effectively addressed before the start of production.[3]

LCSA provides EPA with important new tools to strengthen the health and environmental protections it affords for new chemicals submitted for review under section 5. At the December 14 public meeting, industry speakers downplayed these changes as solely intended to increase transparency, but in fact they place obligations on EPA that significantly enhance how the risks of new chemicals are assessed and addressed.

The strengthened requirements for PMN review are spelled out explicitly in LCSA and are not discretionary. Industry has complained about EPA "overreaching" but the simple fact is that the Agency is merely following the law. Indeed, if the Agency were to cut corners on the new requirements imposed by Congress – as industry apparently would like – it would be acting outside its authority.

The most important change in the law is that, under section 5(a)(3), EPA now must make an affirmative determination of safety for every new chemical on which a PMN is submitted. Thus, EPA can no longer allow the PMN review period to expire without explicitly addressing the chemical's risks but must make a considered judgment about these risks and then take action as prescribed in the law.

The June 7, 2016 statement of several Democratic Senators on the final TSCA legislation underscores the importance of making a safety determination for every PMN:

> While existing TSCA does not preclude EPA from reviewing new chemicals and significant new uses following notification by the manufacturer or processor, it does not require EPA to do so or to reach conclusions on the potential risks of all such chemicals before they enter the marketplace. EPA has authority to issue orders blocking or limiting production or other activities if it finds that available information is inadequate and the chemical may present an unreasonable

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[1] S. Rep. No. 114-67, 114th Cong., 1st Sess. (June 18, 2015) at 3.

[2] EPA, Statistics for the New Chemicals Review Program under TSCA, updated through September 30, 2015. https://www.epa.gov/reviewing-new-chemicals-under-tsca/statistics-new-chemicals-review

[3] http://www.ceh.org/news-events/blog/give-that-tiger-some-teeth-a-historic-milestone-in-protecting-americans-from-toxic-chemicals/

> risk, but the burden is on EPA to invoke this authority; if it fails to do so within the 90– 180 day review period, manufacture of the new chemical can automatically commence. *This bill makes significant changes to this passive approach under current law: For the first time, EPA will be required to review all new chemicals and significant new uses and make an affirmative finding regarding the chemical's or significant new use's potential risks as a condition for commencement of manufacture for commercial purposes . . .* [4]

LCSA provides that EPA's safety determination must fall into one of five categories:

(1) The chemical or significant new use "presents an unreasonable risk of injury to health or the environment" ((a)(3)(A));
(2) The available information "is insufficient to permit a reasoned evaluation of the health and environmental effects" of the chemical or significant new use ((a)(3)(B)(i));
(3) In the absence of sufficient information, the "manufacture, processing distribution in commerce, use or disposal of such substance, or any combination of such activities, may present an unreasonable risk of injury to health or the environment"((a)(3)(B)(ii)(I));
(4) The substance "is or will be produced in substantial quantities" and either will or may "enter the environment in substantial quantities" or will or may result in "significant or substantial human exposure" ((a)(3)(B)(ii)(II)); or
(5) The substance or significant new use "is not likely to present an unreasonable risk of injury to health or the environment" ((a)(3)(C)).

These determinations must be strictly risk-based: in contrast to the previous law, EPA cannot consider "costs or other nonrisk factors" in deciding whether a new chemical does, may or is not likely to present an unreasonable risk.

If EPA makes any of the first four determinations, it is *obligated* to issue an order restricting the chemical under sections 5(e) or 5(f).[5] The order *must* prohibit or limit manufacture or other commercial activities "to the extent necessary to protect against unreasonable risk."

The only instance where no action is required is when EPA has a basis to make the fifth finding -- that the chemical is not likely to present an unreasonable risk. Thus, in contrast to the current law, EPA must have affirmative evidence of a chemical's safety before the PMN submitter is allowed to start production. As the statement of Democratic Senators explains

> [I]n the absence of a finding that the chemical or significant new use is not likely to present an unreasonable risk, manufacture will not be allowed to occur. . . . Only chemicals and significant new uses that EPA finds are not likely to present an unreasonable risk can enter production without restriction. This affirmative approach to better ensuring the safety of new chemicals entering the market is essential to restoring the public's confidence in our chemical safety system.

One corollary of this approach is that, in contrast to original law, the burden of producing sufficient information to support a finding of likely safety now rests with the manufacturer: where the data in the PMN is inadequate or non-existent, EPA must issue an order requiring testing to assure that its risk determinations on new chemicals are informed by sufficient information. As the Senate report notes, "new chemicals may not have as robust a data set as existing chemicals [and] the testing authority

[4] Congressional Record – Senate, S3516 (June 7, 2016).
[5] The original law provided that, upon making risk findings, EPA "may" issue an order regulating the new chemical but, as amended, section 5(e) states that EPA "shall" issue such orders.

provided to EPA under section 5 of S. 697 is intended to ensure EPA can obtain necessary information to review a PMN application . . . without having to demonstrate potential risk to require testing."[6]

At the December 14 public meeting, EPA explained its approach to making the determinations required under section 5(a)(3) and provided several case studies illustrating how the criteria in the new law would apply to representative chemicals. The Agency was explicit that the new law will necessarily result in an increase in the number of orders issued under sections 5(e) and 5(f) and that more chemicals will be subject to limits on human exposure, environmental release and production volume and to testing requirements.

Far from representing "over-regulation," this increase in orders is necessary to comply with LCSA's requirement that EPA make an affirmative finding that a chemical is not likely to present an unreasonable risk before allowing commercialization, and EPA's obligation to issue orders restricting such chemicals where this finding cannot be made. To adhere to the new law, EPA must stay on its current course and continue to provide the enhanced protection of health and the environment that the law requires for new chemicals.

II. The Claimed PMN "Backlog" Is a Red Herring Designed to Pressure EPA to Cut Corners in Implementing the New Law

At the December 14 meeting and separately, industry has claimed that the PMN program is "gridlocked" because of a large "backlog" of new chemical reviews that are dragging on beyond the 90-day deadline in the law. This claim has been accompanied by warnings that new chemical innovation (the "lifeblood" of the industry) is at risk because of a broken PMN process.

The picture that industry has painted is misleading and inaccurate on several counts.

A. One-time Start-Up Challenges Have Imposed Unique Burdens on EPA

As EPA pointed out at the December 14 meeting, it faced unusual start-up challenges when the President signed the LCSA into law on June 22, 2016. Since the law was immediately effective, EPA concluded that it needed to restart the review period for several hundred pending PMNs and evaluate them under the law's more stringent criteria. Around 200 of these chemicals had already been identified as raising concerns under the old law and the submitters agreed to continue ongoing suspensions of the review period for additional evaluation and negotiation of consent orders. An additional 115 PMNs without suspensions also required re-review under the new law, and EPA made determinations on these chemicals by Day 90 of the restarted review period, with appropriate suspensions to develop orders where warranted. In parallel with these actions, EPA began reviewing new PMNs submitted after the new law took effect.[7]

As EPA has explained,[8] the spike in submissions requiring review occurred when EPA simultaneously needed to devote time and resources to analyzing the requirements of LCSA and deciding what criteria and processes it would use to apply them. For example, it had to determine what data it would need to support a finding that a chemical was "not likely to present an unreasonable risk" and when available

[6] S. Rep. No. 114-67, supra, at 15.
[7] EPA, The Frank R. Lautenberg Chemical Safety for the 21st Century Act: Frequent Questions, Answer to Q 23, available at https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/frank-r-lautenberg-chemical-safety-21st-century-act-0#newchems
[8] Id.

information would be deemed "insufficient" for a "reasoned evaluation." Over time, these decisions will become routine but initially EPA proceeded with care and caution, as would any responsible agency.

EPA expects that future delays will be reduced given the progress it has made in reviewing the hundreds of PMNs pending on June 22, 2016, its growing experience in interpreting and applying the new law and its continuing efforts to find additional efficiencies in the review process. To declare the program "broken" on the basis of one-time start-up problems is unwarranted.

B. Properly Implemented, the Law Will Require More Orders and More PMN Suspensions and this will Benefit Health and Environment

As EPA explained at the public meeting, its internal PMN review process and timeline has not changed: as before, EPA seeks to complete review of the PMN and communicate any concerns to the submitter via an Action Letter by Day 90. Where EPA concludes during its review that a chemical meets the criteria for action under sections 5(e) or 5(f), its standard practice (as under the old law) is to ask the submitter to suspend the PMN review period to allow for the negotiation of a consent order. Almost without exception submitters have granted such requests (as they did under original TSCA). .

It is to be expected that, with LCSA compelling greater use of section 5(e) and 5(f) authorities, EPA will seek suspensions of more PMNs and fewer chemicals will be cleared for commercial production in 90 days (or 180 days where the review period is extended under section 5(c)). This does not reflect a deviation from the Agency's well-established internal process (as was asserted at the public meeting) but is rather the natural consequence of applying the new safety determination criteria in section 5(a)(3) and concluding that more new chemicals must be regulated under the express terms of the law. In short, the law demands greater protection of public health and the environment and EPA is attempting to meet that expectation. .

C. LCSA Allows EPA to Make Determinations and Issue Orders After the Close of the 90-180 Day Review Period

The new law encourages EPA to make determinations under section 5(a)(3) within the 90-180 day review period but recognizes that this may not always be possible and that EPA can take more time for determinations where necessary. Under section 5(a)(4)(A), EPA "shall not be relieved of any requirement to make" a determination where it "fails to make a determination . . . by the end of the applicable review period." As an incentive to avoid delays, paragraphs (A) and (B) provide that EPA must refund any applicable fees to the submitter where the determination is late,[9] but subparagraph (B)(iii) is explicit that "[n]othing in this paragraph shall be construed as relieving [EPA] or the submitter of the notice from any requirement of this section." Thus, regardless of the timing, EPA remains obligated to issue an order where required by its safety determination and the PMN submitter remains obligated to comply with its restrictions. Indeed, in a significant departure from the original law, section 5(a)(1)(B) states that submitters can only commence production of a new chemical if EPA has made a safety determination on the chemical and taken the actions associated with that determination and the submitter is in compliance with applicable requirements, including those imposed under 5(e) or 5(f) orders.

In sum, in contrast to the original law, TSCA as amended no longer imposes an ironclad deadline for completing PMN review and initiating production unless the Agency has taken affirmative action to block it. Rather, the review period is now structured so that EPA can take more time where needed to make a

[9] Under section 5(a)(4)(B), a fee refund is not automatic. Rather, EPA cannot make a refund if the Agency "certifies that the submitter has not provided information required under subsection (b) or has otherwise unduly delayed the process such that the Administrator is unable to render a determination within the applicable period of review."

safety determination and issue a follow-up order. Thus, Congress recognized that, while timely decision-making remains important, EPA must not sacrifice the quality of its assessments to a rigid schedule and can exceed the 90 (or 180) day review period in order to make thoughtful and careful determinations of risk.

D. Industry Can Accelerate PMN Reviews by Preventing Avoidable Non-Compliance with Notification Requirements and Filing More Robust PMNs

Greg Schweer, EPA PMN Branch Chief, explained at the December 14 meeting that EPA's review process is often hampered by avoidable mistakes and omissions in PMN submissions.[10] These include providing descriptions of chemical identity that lack key elements required under the PMN regulations (a problem with 5 percent of PMN submissions) or failing to identify the physical-chemical properties of the new chemical (essential information for SAR analyses and modeling of biological activity and environmental fate). The effort required to correct these deficiencies inevitably diverts EPA time and resources from evaluating the substance's potential risks and slows down the review process.[11]

Based on EPA's extensive descriptions of its review process and the factors that influence risk evaluations,[12] the industry is well positioned to develop PMNs that anticipate and address issues and concerns that will likely arise during PMN review. Yet as explained by Mr. Schweer, many PMNs are bare-bones submissions that provide the minimum information necessary to complete EPA's PMN form and nothing more. For example, numerous submitters do not identify analogs to the new chemical and describe toxicity studies on these analogs; provide modeling of the chemical's fate and distribution in the environment; offer detailed descriptions of the conditions of manufacture and downstream use that address the physical form of the PMN substance, the size of the exposed population, the intensity of exposure, and the protective equipment and other controls proposed to safeguard workers and other exposed groups; or identify the nature and magnitude of environmental releases and the equipment used to control them. Even more critically, some submitters do not conduct any toxicity testing, even though a few inexpensive studies for a limited number of end-points might rebut worst-case assumptions that EPA must make in the absence of data.

As Mr. Schweer noted, the less information PMNs contain, the more time EPA reviewers need to spend requesting additional information from the company or doing calculations and modeling to compensate for the lack of data. If industry is so concerned about delays in the PMN process, it would be well served by providing more robust and informative PMNs.

E. The Innovation "Crisis" Described by Industry is Overblown

Industry's presentations on December 14 created the impression that innovation in new chemistries will come to a standstill if more PMNs are subject to orders and the review process is extended while EPA completes risk evaluations and negotiates order provisions. This ignores the larger context for new product development and regulatory review under TSCA.

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[10] Greg Schweer, Chief, New Chemicals Management Branch Office of Pollution Prevention and Toxics, *How to Make the Review Process More Efficient,* December 14, 2016

[11] As described by Mr. Schweer, some of the deficiencies are even more rudimentary – for example, failing to provide a clear and complete list of all the studies and other information included in the PMN or submitted later in the review process or incorrectly identifying the technical contact that EPA should reach out to in order to obtain more information.

[12] https://www.epa.gov/reviewing-new-chemicals-under-toxic-substances-control-act-tsca

Under the original law, the completion of PMN review allowed submitters to commence commercial production without delay. This was (and is) accomplished by filing a notice of commencement of manufacture (NCOM), which results in placing the substance on the TSCA Inventory. Yet the great majority of submitters have not filled NCOMs. According to EPA's most recent tabulation,[13] 39,962 PMNs were filed from 1979 through September 2015 but only 13,933 NCOMs were submitted. Thus, only about a third of PMN chemicals are actually commercialized. And in many cases, production does not in fact begin until weeks, months or even years after the completion of PMN review. This shows that a more deliberative and thorough PMN process that adds modestly to the review period will have minimal commercial impacts.

Moreover, the PMN process only captures a share of the new chemical universe; many new chemicals bypass the process and follow other routes to commercialization. According to EPA's latest data for the 1979-2015 period, 12,919 new chemicals were the subject of low volume exemption notices (LVEs); 106 were covered by the low release/low exposure exemption (LoRex); and 883 were produced under test marketing exemption applications (TMEAs). Although EPA has not tracked chemicals produced under its polymer exemption rule since 1995, such polymers undoubtedly number in the hundreds or even thousands.

In short, a large portion of the new chemical universe has moved forward to commercialization outside the PMN process rather than through that process. This will likely continue since the new law leaves in place EPA's various exemption rules. With the continued availability of exemptions, the more stringent PMN process created by the new law will be largely focused on higher volume chemicals with the potential for exposure and release and the ability to pass through cell membranes – the very chemicals to which the strengthened PMN process *should* apply. The remaining new chemicals will face no new barriers to commercialization.

Industry has touted the superior environmental and toxicity profile of many new chemicals that replace existing chemicals of known concern. But the only assurance that these substitute chemistries are in fact superior is the availability of sufficient toxicity and exposure data to conduct strong risk evaluations. LCSA is intended to create incentives for this to occur. Thus, the extra effort to develop robust PMNs, and the additional time to conduct further testing or negotiate controls on exposure and release, will better position such chemistries to succeed in the marketplace, enabling rather than blocking environmentally sustainable innovation. In short, it is in everyone's interest (industry, the public, the environment) to have EPA confirm likely safety before a new chemical is introduced into commerce.

III. To Comply with the New Law, PMN Reviews Must Identify and, Where Warranted, Restrict Foreseeable Uses of New Chemicals

As amended, section 5 expressly provides that safety determinations and orders under section 5 must address and, where warranted, restrict the new chemical's "conditions of use." For example, section 5(a)(3)(C) specifies that a determination that a substance is not likely to present an unreasonable risk of injury must be "under the conditions of use." Similarly, section 5(e)(1)(B), which describes the orders that EPA must issue where it makes one of the determinations in sections 5(a)(3)(B), requires that such orders shall –

> prohibit or limit the manufacture, processing, use, distribution in commerce, or disposal of such substance or to prohibit of limit any combination of such activities to the extent necessary to

[13] EPA, Statistics for the New Chemicals Review Program under TSCA, supra.

> protect against an unreasonable risk of injury to health or the environment . . . *under the conditions of use* (emphasis added).[14]

Section 3(4) defines the term "conditions of use" as –

> the circumstances, as determined by the Administrator, under which a chemical substance is intended, known or *reasonably foreseen* to be manufactured, processed, distributed in commerce, or disposed of (emphasis added).

Based on this clear statutory language, EPA has been assessing new chemicals under section 5(a)(3) not just based on intended or known uses described in the PMN but also based on reasonably foreseeable additional uses that are outside the scope of the PMN. And it has been issuing orders restricting reasonably foreseeable uses, along with intended and known uses, where warranted by the Agency's determinations of safety. This approach is not only required by LCSA but provides necessary protections against changes in use that will or may present unreasonable risks to health or the environment or warrant additional testing to assure an informed evaluation of safety.

EPA made clear at the December 14 meeting that, notwithstanding the assertions of some in industry, the identification of reasonably foreseeable uses is not an exercise in guesswork but the result of careful analysis. For example, in her slide presentation,[15] Maria Doa, Director of the Chemical Control Division, explained that EPA accesses the following sources of information to determine foreseeable uses:

- EPA uses the information on the chemical substance, including information provided by the submitter, information in the literature, attributes of the chemical substance (e.g., physical-chemical properties)
- EPA also uses information on analog(s) for the chemical substance, including available data, information in the literature, attributes of the analog (e.g., physical-chemical properties) and any difference in these attributes from the subject chemical substance
- Information on downstream processing and use of the chemical substance and analogs

Ms. Doa then provided the following example of EPA's approach:[16]

- A PMN is submitted for a chemical substance. The PMN chemical substance is made with a reactive moiety, which has been shown to cause a variety of adverse effects including respiratory effects. These chemicals may be sensitizers after either inhalation or dermal exposure. Sensitization results from very low exposures.
- The PMN substance is made in such a way that there are no "free" reactive moiety in the chemical substance. However, once on the TSCA inventory the chemical substance can

[14] While the corresponding provision of section 5(a) – paragraph (3)(B) – does not expressly mention conditions of use, the presence of this phrase in the order language in section 5(e) is clear evidence that Congress intended conditions of use to be within the scope of "may present" determinations. Nor is it logical to assert – as some stakeholders have done – that conditions of use are only relevant to potentially exposed or susceptible subpopulations but not to the general population. This tortured reading of the statutory text is based on the omission of a comma in section 5(a)(3) that appears in identical language found in section 6(b)(4)(A). All indications are that the comma omission was a drafting error without any substantive intent. Clearly, there is no rational risk-based justification for why Congress might limit the role of "conditions of use" to vulnerable populations in section 5 but not section 6.

[15] *Reviewing New Chemicals under the Toxic Substances Control Act,* Maria J. Doa, Ph.D. Director, Chemical Control Division, at 19 (Dec. 14, 2017).

[16] Id at 31-32.

be made in a way in which there will be "free" reactive moieties. This use is foreseen given the information on chemicals with this reactive moiety
- Manufacture, processing and use associated with the foreseen uses will result in worker and consumer exposure

As Ms. Doa explained, manufacture of the substance with the free-reactive moiety "may present an unreasonable risk" given the potential for exposure and possible sensitization and, therefore, EPA would be required to issue an order under section 5(e). This order would impose a limit of no greater than 0.1% free reactive moiety and require toxicity testing if the company were to change its process to make the chemical substance with higher levels of free moiety.

This example illustrates how changes in use after PMN review can increase risks and simple, easily implemented restrictions in a 5(e) order can provide meaningful protection against such risks. It's thus perfectly understandable why Congress would bring reasonably foreseeable uses within the scope of the Agency's safety determinations and risk management actions for PMNs under section 5.

EPA speakers at the December 14 meeting noted that, even before enactment of LCSA, PMN reviewers routinely attempted to identify potential uses of new chemicals not described in the PMN that raised health or environment concerns. If there is a change in Agency practice, it is that EPA is imposing restrictions on reasonably foreseeable uses that may present unreasonable risks through section 5(e) orders -- and not, as before, allowing the new chemical to be commercialized and later following up with a significant new use rule (SNUR) applicable to all manufacturers.[17]

This change is compelled by the statute, which requires consideration of "conditions of use" in making safety determinations for new chemicals and imposition of any necessary restrictions under Section 5(e). Moreover, while greater use of section 5(e) may have some effect on the length of PMN review, it will have no impact on the ultimate outcome of the review process: the submitter will be subject to the same restrictions whether or not they are incorporated in a 5(e) order or solely in a SNUR. The submitter may even benefit by the ability to negotiate the restrictions upfront with the Agency; in this event, the submitter will have greater ability to shape them and the later SNUR rulemaking will be more efficient and raise fewer issues.

Most important, from a public protection standpoint, a more comprehensive use of section 5(e) will prevent new uses of concern from falling through the cracks – *i.e.* being introduced following the completion of PMN review but before a final SNUR is in place, thereby becoming grandfathered from the SNUR. This will help achieve the higher standards of health and environmental protection that LCSA requires.[18]

IV. Vulnerable Populations Must be a Central Focus of EPA's Safety Determinations for New Chemicals under LCSA

In a significant change from the original law, LCSA expressly directs EPA to identify risks to vulnerable populations and to protect these populations in its risk evaluations and risk management decisions. This

[17] 40 CFR Part 721 establishes a process for issuing SNURs to codify restrictions in section 5(e) orders and to place limits on other PMN substances (so-called non-5(e) SNURs).

[18] To address the gap between the completion of PMN review and issuance of a SNUR, section 5(f)(4) of the amended law provides that, within 90 days after issuing a section 5(e) order, EPA must decide whether to incorporate the order's restrictions in a SNUR and, if so, must initiate a SNUR rulemaking. There is no comparable timeline for non-5(e) SNURs and thus no express requirement for EPA to promulgate a SNUR for PMN chemicals that have not been regulated through the safety determination and order process.

focus on vulnerable populations (or "potentially exposed or susceptible subpopulations" as they are called in the law) is central to the enhanced PMN process and reinforced throughout revised section 5.

In making all of the five safety determinations described in section 5(a)(3), EPA must explicitly evaluate whether the new chemical does or may present "an unreasonable risk to a potentially exposed or vulnerable subpopulation identified as relevant by the Administrator." EPA may only avoid restricting the chemical if it determines under section 5(a)(3)(C) that a potentially exposed or susceptible subpopulation is "not likely" to be at risk. Chemicals that do or may present such risks must be regulated under sections 5(e) or 5(f). As these provisions explicitly state, manufacture of the chemical and other commercial activities must be limited "to the extent necessary to protect against . . . an unreasonable risk to a potentially exposed or susceptible subpopulation." Thus, these populations must receive full protection against the identified risk.

Section 3(12) of amended TSCA broadly defines "potentially exposed or susceptible subpopulation" as –

> a group of individuals within the general population identified by the Administrator who, due to either greater susceptibility or greater exposure, may be at greater risk than the general population of adverse health effects from exposure to a chemical substance or mixture, such as infants, children, pregnant women, workers, or the elderly.

Significantly, this definition applies whenever a group "may be at greater risk than the general population" because of unique biological characteristics (pregnant women or infants) or because of higher levels of exposure (workers or consumers using a particular product). Moreover, while the definition includes examples of such populations, they are not all-inclusive. All other groups with attributes that "may" place them at greater risk must also be identified and addressed in safety determinations under section 5.

At the December 14 public meeting, Dr. Tala Henry of EPA acknowledged that, while EPA has previously addressed some vulnerable populations in PMN reviews, it needs to broaden its efforts to meet the requirements and objectives of LCSA. According to her presentation, this includes expanding the range of subpopulations that are addressed in new chemical evaluations; adopting additional scaling factors to adjust risk estimates to reflect differences among groups; and developing more systematic and transparent protocols to identify vulnerable populations and the greater risks they face.[19]

We strongly encourage these efforts: SCHF and its member organizations believe that protecting vulnerable populations is among the most important responsibilities placed on EPA under the new law.

We also request that EPA explicitly describe its consideration of vulnerable populations in all statements it publishes under section 5(g) describing its basis for determining that a PMN chemical is "not likely to present an unreasonable risk" under section 5(a)(3)(C). As noted below, for chemicals that EPA determines will or may present an unreasonable risk, EPA should similarly describe publicly how it took into account and addressed risks to potentially exposed or susceptible subpopulations.

V. While Structure-Activity Relationships (SAR) Remain an Important Tool, They Should Not be the Sole Basis for Determining That a New Chemical is of Low Concern But Should Generally be Supplemented By Testing

[19] *Reviewing New Chemicals under the Toxic Substances Control Act — Science Issues —,* Tala R. Henry, Ph.D. Director, Risk Assessment Division Office of Pollution Prevention and Toxics (December 14, 2016) at 12.

EPA's reliance on SAR under original TSCA developed in large part because few PMNs contained test data and the Agency lacked authority to require testing unless it had some basis for concern about a new chemical's risks to health or the environment. In the absence of data, SAR was the only way to prioritize new chemicals based on their potential adverse effects and justify restrictions on manufacture and use.

Over time, SAR's value as a predictive tool has improved due to the efforts of EPA scientists and engineers and the contributions of the scientific community. Nonetheless, SAR has significant limitations and LCSA now makes it easier for EPA to require testing where greater certainty about a chemical's effects is needed for informed judgments about risk. Specifically, EPA can make a determination under section 5(a)(3)(B)(i) that "the information available . . . is insufficient to permit a reasoned evaluation of the health and environmental effects of the relevant new substance . . ." Once this determination is made, EPA is obligated to issue an order under section 5(e) requiring testing to fill the identified information gaps.

As described at the December 14 public meeting, EPA uses SAR for judgments about potential health and ecological hazards where it has identified an appropriate analog to the new chemical *and* available toxicity data on the analog provide a quantitative benchmark for predicting the new chemical's effects under its conditions of use. As EPA well knows, while sound in theory, there are significant uncertainties at both stages of this analysis.

For example, the new chemical may not in fact have the same toxicological properties as the analog. There are many examples of seemingly minor changes in the molecular structure of substances in a defined chemical class resulting in significant differences in toxicity. The predictive value of SAR is particularly weak when testing of different chemicals within a class is limited and therefore understanding of how toxicity varies among structural subgroups within the class is poor. In such cases, data on the analog may be a false positive or negative as applied to the PMN substance and testing of the substance itself (or of a representative subset of molecular structures within the class) would be necessary for a "reasoned evaluation of the health and environmental effects" of the new chemical.

Moreover, the scope and quality of the test data on the analog (assuming it is a good surrogate for the new chemical) may be limited. For example, data may be available on some endpoints (chronic toxicity) but not on others (reproductive or developmental toxicity). Or while data for an end-point is available, it may be of limited value in predicting effects at different exposure levels (because of the doses tested) or for different routes of exposure (because inhalation but not dermal testing was conducted). Similarly, where the only available data is from a short-term screening assay, the absence of dose-response information may preclude applying the test results across a range of exposure scenarios.

In light of these drawbacks, SAR may be valuable in identifying new chemicals that raise concern and require closer evaluation but is often insufficient to make an affirmative determination of safety because of the inherent uncertainty of such judgments in the absence of data. Under the old law, EPA could not require testing on chemicals lacking any basis for concern and thus SAR was often the only way to conclude that a chemical was low risk. However, LCSA gives EPA authority to require testing solely because more information about a chemical's effects is needed for informed judgments about risk. In view of this expanded authority, EPA should place limited reliance on SAR as a basis to determine that PMN chemicals are not likely to present unreasonable risks. Instead, the Agency should generally require submitters to develop test data to supplement SAR-based predictions so that it can conduct the reasoned, scientifically sound evaluation of new chemical risks that Congress required.

At the December 15 meeting, several industry speakers complained that some recent PMN reviews have been suspended to allow EPA to develop orders requiring 90-day inhalation studies. However, EPA's rationale for seeking these studies is an excellent example how the new law is intended to work in the

absence of reliable SAR. As Dr. Tala Henry explained, a number of chemical and physical characteristics (particulate overload, cationic binding, surfactancy and water-proofing) are risk factors for inhalation toxicity but SAR based on the current database is not sufficient to predict when lung effects will occur. According to Dr. Henry, additional testing of new and existing chemicals, together with further scientific assessments, would better support predictions of lung effects, but for now, the basis for evaluating this group of new chemicals is inadequate, This is clearly a circumstance in which EPA must make a determination that available information is "insufficient. . . for a reasoned evaluation of the health and environmental effects" of the new chemical under section 5(a)(3)(B)(i) and testing must be required under section 5(e).

We urge EPA to remain firm in following the law and insisting on testing where the limitations of SAR preclude reasoned, scientifically sound evaluations of new chemical risks. EPA can make testing requirements more manageable by authorizing limited commercialization while testing is conducted (assuming protections are imposed against potentially unsafe exposures and releases under section 5(e)), and allowing the use of lower cost test systems once validated (such as the alternative methods for assessing dermal and respiratory sensitization which EPA is helping to develop under domestic and international programs).

Minimizing use of vertebrate test animals is also an important consideration under TSCA section 4(h), as speakers from animal rights groups stressed at the December 14 meeting. However, this provision does not in any way weaken EPA's responsibility under sections 5(a)(3) and (e) to assure that sufficient scientifically reliable information is available for evaluating new chemical risks. Nor does it allow EPA to reduce the use of traditional animal test methods in the absence of non-animal methods that are "scientifically reliable, relevant and capable of providing information of equivalent or better scientific reliability and quality" (section 14(h)(2)(C)). EPA has not identified such methods to date, although it will have an occasion to examine their availability when it develops the strategic plan for non-animal that TSCA section 14(h)(2) calls for within two years of LCSA's enactment.

VI. EPA Must Establish an Accessible Public Tracking System for its Safety Determinations and Orders under Strengthened Section 5

Historically, the public has had limited access to information about the basis of EPA's decision-making in the PMN program. Although section 5(d)(2) required (and still requires) publication of general information about PMNs in the Federal Register, there has been no mechanism for tracking the substance of EPA's risk evaluations, the chemicals subject to orders under section 5(e), the exposure restrictions and testing required under such orders, and the results of studies conducted by PMN submitters. In addition, while EPA has identified the chemical classes it uses for SAR screening, there is no generally available database on the SAR predictions EPA has made for individual new chemicals.

Section 5(g) requires EPA to publish a statement of its findings when it has concluded that a new chemical is not likely to present an unreasonable risk of injury under section 5(a)(3)(C). The evaluation summaries EPA is posting in response to this requirement represent a welcome step toward greater transparency. However, it is equally important for the general public and impacted communities to understand the basis for EPA determinations under sections 5(a)(3)(A)-(B) that a chemical presents or may present an unreasonable risk, lacks sufficient information for a reasoned evaluation of risk, or is or may be produced in substantial volumes and has substantial or significant exposure potential.

To provide this transparency, EPA should expeditiously post summary documents describing the rationale and supporting information for its safety determinations on such chemicals and the requirements it has

imposed under sections 5(e) or (f) to protect communities where the chemical will be produced or used. Also valuable would be a frequently updated tabulation of the Agency's safety determinations and regulatory actions so that the public can monitor the performance of the program as a whole.[20]

We would be pleased to discuss these transparency measures in greater detail with the Agency.

With the PMN program entering a new phase as a result of LCSA, it is time for the Agency to adopt enhanced transparency measures so that there can be greater public oversight of the program's implementation. This will enable stakeholders and Congress to make an informed assessment of EPA's progress in carrying out the new safety determination requirements and provide more meaningful feedback on the effectiveness of the strengthened review process and how it can be improved.

VII. EPA Must Apply the Law's More Stringent Requirements for CBI Claims to the New Chemicals Program

One obstacle to increasing the transparency of the PMN program has been industry's excessively broad claims of Confidential Business Information (CBI) for large portions of PMN submissions, ranging from the identity of the new chemical to all aspects of manufacturing, use, environmental release and exposure. Reduction of unwarranted CBI claims would greatly enhance the public's ability to track the health and environmental impacts of new chemical production and use and the basis for the Agency's safety determinations.

LCSA is intended to accomplish this objective. As amended, TSCA section 14(c)(3) provides that "a person asserting a claim to protect information under this section *shall substantiate* the claim . . ." (emphasis added). All information submitted to EPA is subject to this requirement unless it falls within the narrow categories of information listed in section 14(c)(2). As a result, a broad range of previously unsubstantiated claims must now be specifically justified at the time the submitter requests CBI protection. This includes, for example, the identity of the submitting company, the site of manufacture, processing or use, the number of workers and types of worker protections, and the nature and magnitude of environmental releases and the controls used to limit such discharges. Such information is contained in several sections of the PMN form and therefore submitters should be providing significantly greater substantiation of CBI claims. Once submitted, this substantiation must then be reviewed expeditiously by EPA and approved or rejected under section 14(g)(1).

In addition, section 14(b)(3) identifies certain types of information that is "not protected from disclosure", including:

> (A) *any general information* describing the manufacturing volumes, expressed as specific aggregated volumes or . . . in ranges; or
> "(B) *a general description* of a process used in the manufacture or processing and industrial, commercial or consumer functions and uses of a chemical, substance, mixture or article containing a chemical substance or mixture . . . (emphasis added).

PMN submitters provide considerable information that falls in these categories and, under LCSA, it should now be ineligible for CBI protection.

[20] EPA has prepared such tabulations in the past but updated them at infrequent intervals. In addition, while they contain useful statistics about the program, additional measures of program performance could be included.

Unfortunately, EPA has not applied these new requirements to PMN submissions, even though they have been in effect since the law was signed. This failure to enforce the law has greatly reduced the transparency to which the public is entitled under LCSA and should be corrected immediately.

SCHF supports EPA's efforts to strengthen the public health and environmental protections delivered by the PMN program as required by LCSA. We appreciate the opportunity to participate in the December 14 public meeting and to submit these follow-up comments. We look forward to continued engagement with the Agency as it further strengthens the PMN program and would be pleased to answer any questions on our comments.

Respectfully submitted,

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On behalf of:

Alaska Community Action on Toxics
Alliance of Nurses for Healthy Environments
American Sustainable Business Council
Asbestos Disease Awareness Organization
BlueGreen Alliance
Breast Cancer Action
Breast Cancer Fund
Center for Environmental Health
Clean and Healthy New York
Clean Production Action
Clean Water Action
Earthjustice
Environmental Health Strategy Center
The Ecology Center
Michigan Network for Children's Environmental Health
Healthy Legacy Coalition
League of Conservation Voters
Learning Disabilities Association of America
Natural Resources Defense Council (NRDC)
Physicians for Social Responsibility
Science and Environmental Health Network
Vermont PIRG
Toxic Free Future