Transcript for U.S. EPA's Public Webinar:
Fees for the Administration of the Toxic Substances Control Act under Section 26(b)
February 18, 2021

Opening Remarks from Jeffrey Kohn, U.S. EPA

Good afternoon, everyone. Thank you for joining EPA's Office of Pollution Prevention and Toxics webinar on the Proposed Revisions to the Toxic Substances Control Act Fees Rule. My name is Jeff Kohn. I work for the Stakeholder Engagement Branch in the Office of Pollution Prevention and Toxics. We have 150 people on the line. During the webinar, we will be advancing the presentation slides using WebEx. You can also download the slides from EPA's TSCA Fees Rule webpage. Today's agenda shown on the screen right now is also on that webpage. Today's webinar will start with a presentation from EPA, followed by a public comment period. EPA will not be answering questions during the webinar. Those people who signed up to make remarks will have five minutes per person. Emily, from Abt Associates, will introduce each commenter. If you have registered to make a comment, please be sure you are connected properly through WebEx so Emily can unmute you. Again, if there's any technical issues, you can use the chat function or email Sarah Swenson, swenson.sarah@epa.gov. With that, let's get started. Our first speaker this morning is Tanya Hodge Mottley, Director of EPA's Existing Chemicals and Risk Management Division in the Office of Pollution Prevention and Toxics. Tanya, please go ahead.

Introductory Remarks from Tanya Hodge Mottley, U.S. EPA

Thanks, Jeff. Hello, everyone. It's a pleasure to be here today. My name is Tanya Hodge Mottley and I'm the Director of the Existing Chemicals Risk Management Division. I'm opening today's webinar on EPA's proposed updates to the TSCA Fees Rule. And I'd like to emphasize how much we value your input. This is a useful forum for the Agency to obtain public comment on the TSCA Fees Program.

But before I turn it over to my colleague, Brooke Porter, I want to leave you with a few thoughts. With the amendments to the Toxic Substances Control Act that were enacted in 2016, we've been building a new regulatory program from the ground up. We've taken some big steps to propose amendments to the Fees Requirements established in 2018 and to ensure that the TSCA Fees Rule reflects real world situations, ensures the equitable and fair distribution of these, and reduces the burden on small businesses.

Last month, EPA published the proposed changes to the TSCA Fees Requirements established in 2018, based upon over two years of the implementation experience and with the help of valuable stakeholder input. Today, you will hear about how EPA is meeting the mandate to review and adjust as necessary the fees every three years to ensure EPA is collecting sufficient funds to defray a portion of the costs of carrying out important TSCA functions, including risk evaluations, test orders, and activities under the New Chemicals program.

We look forward to hearing from companies, trade associations, and consortia that represent affected manufacturers and processors directly impacted by these rules, as well as individual organizations and non-governmental groups interested in TSCA Fees. I want you to be aware of our work and through meetings like today, contribute to the TSCA Fees Rulemaking. We'll be using today's webinar to bring you up to speed on the key provisions of TSCA as it relates to TSCA Fees to inform you about the proposed amendments to the TSCA Fees Rule and to outline the next steps in the process.

EPA is committed to an open and transparent dialogue with stakeholders and will be seeking input from you on the best approaches for the TSCA Fees Program and the impact those approaches may have on stakeholders. Your feedback is important as we develop a regulation that is practical and meets the directives set out under TSCA and now is a critical juncture for you to be involved. We need and appreciate your input, expertise and feedback to help finalize a successful TSCA Fees Rule that ensures EPA can collect the appropriate funds to carry out its essential task of protecting humans and the environment.

Thank you again for your interest in TSCA. On behalf of the Agency, I look forward to working with you and we all look forward to working with you. And with that, I will now turn to our next speaker, Brooke Porter. Brooke Porter is a Staff Lead on the TSCA Fees Rule rulemaking. And she will walk us through today's presentation. Thank you, Brooke.

Presentation by Brook Porter, U.S. EPA

Thanks, Tanya. Thank you, everyone, for joining us today. I will start with statutory background. So TSCA, as amended by the Frank R. Lautenberg Chemical Safety for the 21st Century Act of 2016 provides the EPA with authority to establish fees.

Fees are used to defray a portion of the costs associated with administering TSCA sections 4, 5, and 6, as well as the costs of collecting, processing, reviewing, and providing access to and protecting from disclosure as appropriate information on chemical substances under TSCA section 14. EPA is required by section 26(b)(4)(F) to review and, if necessary, adjust the fees every three years, after consultation with parties potentially subject to fees, to ensure that funds are sufficient to defray the costs of administering TSCA.

On January 11, 2021, EPA published a proposal to amend the 2018 Fees Rule, including several exemptions and changes to the fee requirements established in the 2018 Fees Rule. So the purpose of the Fees Rule is to collect fees to defray 25% of the Agency's costs to administer: Section 4 which is Testing and Development of Information on Chemicals; Section 5 – New Chemicals Program; Section 6 – Existing Chemicals Program; and collecting, processing, reviewing, providing access to and protecting information about chemical substances from disclosure as appropriate under TSCA section 14, as well as providing EPA with a sustainable source of funding.

So, continuing on the overview on TSCA Fees which is fees for small businesses. TSCA section 26(b)(4)(a) states that EPA must "prescribe lower fees for small business for small business concerns." Small businesses are currently afforded an 80% discount for TSCA section 4, section 5 exemption submission,

and EPA-initiated risk evaluations, as well as an 82.5% discount for TSCA section 5 premanufacture notices, microbial commercial activity notices, and significant new use notices submission. Under the 2018 Fees Rule, EPA finalized an employee-based size definition modeled after the Small Business Administration's standard. EPA is not proposing changes to that definition.

The proposed rule includes three new fee categories: TSCA section 4 Test Order Fee. EPA is proposing to create a new fee for TSCA payable by recipients that elect to resubmit data per request of the Agency if EPA determines that the recipient did not comply with the terms or conditions of the order, such as testing protocols, or if the company later determines that the data submitted under a testing order is incomplete, inconsistent, or deficient.

The second category is a Notice of Commencement of Manufacture or Import Fee. NOC submissions ensure that a chemical substance is manufactured after TSCA section 5(a)(3) review appears on the TSCA inventory. EPA is proposing to collect section 5 fees for NOC submissions.

The third category is a Bona Fide Intent to Manufacture or Import Notice Fee. EPA is proposing to collect TSCA section 5 fees for bona fide notices. A company that intends to manufacture a chemical not listed in the public TSCA inventory may submit a Bona Fide Intent to Manufacture or Import Notice to obtain written notification from EPA, whether the chemical substance is included on the confidential inventory.

The proposed rule also includes proposed exemptions. Proposed exemptions for entities subject to EPA-initiated risk evaluation fees including, importers of articles containing a chemical substance subject to an EPA-initiated risk evaluation; producers of a substance subject to EPA-initiated risk evaluation that is produced exclusively as a by-product; producers or importers of a substance subject to an EPA-initiated risk evaluation that is produced or imported exclusively as an impurity; manufacturers, including importers, of small quantities solely for research and development activities; entities manufacturing, including import, less than 2,500 pounds of a chemical substance subject to an EPA-initiated risk evaluation fee, and manufacturers, including importers, of chemical substances produced as non-isolated intermediate.

Other proposed updates include, update cost estimates for administering TSCA sections 4, 5, and 6 and individual fee calculation methodology, including associated administrative costs for confidential business information activities under TSCA section 14; propose a production volume-based fee allocation for EPA-initiated risk evaluation fees; propose that export-only manufacturers pay fees for EPA-initiated risk evaluations; and propose various changes to the timing of certain activities required throughout the fee payment. Moving on to the timing for fee activities in the proposals and the proposed rule.

So, the 2021 proposal includes extending the initial payment for a manufacturer-requested risk evaluation to 180 days over three payment installments and in the 2018 final rule, this is 30 days over two payment installments.

In the 2021 proposal for EPA-initiated risk evaluations, EPA proposed that payment is collected over two installments and the first payment of 50% is to be collected in 180 days. And the second payment is due

no later than 545 days after the EPA publishes the final scope of the chemical risk evaluation. In the 2018 final rule payment, it is collected in one installment over 120 days. And in the 2021 proposal, 90 days have been proposed to notify EPA of intent to form a consortium from the fee-triggering event. In the 2018 final rule, it is 60 days. And to wrap up, I encourage you to visit the TSCA Fees webpage for more information on the 2021 proposed rule. And with that, I will turn it back to Jeff. Thank you, everyone.

Public Comment Period

James Cooper

Thank you and good afternoon, everybody. And thank you EPA for, again, hosting another TSCA webinar. I think these are very important for the transparency of the program and also to create that spirit of cooperation among the various stakeholders, so I appreciate the opportunity. First and foremost, generally, TSCA Fees should be based on actual services provided and follow the OMB Circular Number 825, especially the revised version. TSCA Fees should be based on market prices. That's under section 6 (a)(2)(b) of the circular. And EPA probably needs to conduct a benchmarking study that includes non-governmental service providers to really gauge what the actual market prices are. And I've not seen such a study conducted thus far. And also, fees really should vary according to the number of conditions that we use that are to be considered where an intermediate that has made one or two uses. That's far different from, let's say, something that's used commercially or a consumer product that may have any different number of users. And so the actual amount of work that goes into that service is going to be quite different.

More specifically, EPA does ask some questions, but AFPM believes that EPA should use ranges based on average production and import volumes. That way, CBI won't be disclosed. And still, it's probably the most equitable way to split the cost if the companies can't figure out how they're going to divide the costs on their own. AFPM does not believe the fees should be collected for section 4 actions, primarily because the reviews of the data that are submitted under section 4 actions are going to be conducted under section 5 and section 6 and fees are already charged for those reviews. And so, it's actually resulting in a double charging when you're charging them to submit data and then you're also charging them to review under different sections. Do one or the other, but not both.

Let's see. Just bear with me for a moment. I didn't expect to be coming up that quickly since my name begins with a J. The Bona Fide Intent, we do support the Agency's proposal to collect a fee for that. There is a service that is provided. Regarding the Notice of Commencement, I don't know if the same fees should be collected. Maybe it should be at least a reduced fee because the Notice of Commencement doesn't require the same level of service that a Bona Fide Intent entails. Basically, with the Notice of Commencement, EPA is primarily going to chemical abstracts service and then placing it on the Inventory. Let me see what else I've got here.

Regarding exports, TSCA is quite clear and has been since its inception that TSCA authorizes the Agency to regulate chemicals in commerce and that means US commerce. If a substance is manufactured solely for export, even if it's sold into commerce by other market players, that's really not subject to a lot of

other provisions at TSCA and it shouldn't be subject to TSCA Fees as well because it's not sold into commerce, thereby not presenting any kind of risk in the United States. So that's kind of outside EPA's jurisdiction.

When it comes EPA's justification on the containers, I think maybe there was a misinterpretation of the phrase "bears the stamp of labeling stating that such substance makes your article or articles intended for export." Basically, all containers, they go for export. If they are going for export, they have to bear – certainly, there are clear regulations on that. And other containers aren't subject to the same thing. And so, it basically would be far simpler just to exclude export-only substances, if that's the case. In conclusion, AFPM has always supported - even when doing the TSCA revisions on the Hill, we advocated that the EPA should be authorized to collect fees for the services. But one thing that concerns us is how EPA is estimating those fees and whether or not there's been actual benchmarking done and AFPM would appreciate if EPA, in the future, conduct a benchmarking study and base these fees on the realistic market conditions. And also, maybe even providing options where if a full-risk evaluation is to be conducted, perhaps the regulated community can use the same type of service providers that EPA uses as contractors to conduct those risk evaluations and submit a more complete dossier that includes the risk evaluation to EPA. EPA's only task would be to review that information and render its opinion with that information. And again, thank you for the opportunity.

Julia Rege

This is Julia Rege with the Alliance for Automotive Innovation. Auto Innovators is a trade association that represents automakers that sell about 90% of the new vehicles in the US, as well as suppliers and technology and mobility companies. Innovators fully supports EPA's goals of ensuring a sustainable resource base to continue the effective implementation of TSCA as in the Lautenburg Chemical Safety Act of 2016. Assessing fees on the primary manufacturers of chemicals places the responsibility on the first step in the supply chain and provides EPA with a predictable and sustainable set of responsible parties. In exempting processors in the original rule, EPA recognizes the pitfalls of charging duplicative fees up and down the supply chain, as well as the complexities associated with data collection from the numerous and multi-tiered systems of downstream users. Since EPA began its Implementation of the Lautenburg Act, our association and our members have had the opportunity to learn from EPA about the types of data and information that they need from our sector to conduct accurate risk evaluations.

EPA staff have, likewise, the opportunity to learn about the supply chains associated with the import of articles that may contain any of the high priority chemicals. This work is critical to the EPA's goals of protecting workers, the public, and the environment. I have four items to briefly address today regarding the proposal. First, we'd like to express appreciation for EPA's proposed tiered fee structure. This recognizes that not all uses are the same or even in the same amounts. It also continues to meet EPA's funding needs without overburdening smaller manufacturers or users covered by the rule.

Second, in addition to the challenges and undue burden presented by data collection impacting thousands of imported articles, inclusion of downstream users, officers, importers of articles, R&D users, etc. will double count fees in the supply chain and detract from the overarching need to conduct risk assessments. It is important to recognize that the exemptions EPA has proposed in this Fees Rule in no

way constrain EPA from assessing these activities in its risk evaluation. These assessments – not the fees – are the primary tool for assessing health and environmental impacts, leading to actions to manage risks throughout the supply chain from manufacturer to processor to user to consumer to environment. And third, as we will detail in our comments, some additional clarification and process improvements are likely due to the certification, identification, and exemption provisions to clearly outline responsibilities by user type.

And then finally, we do have one question for EPA today, and that is about how today's webinar and public comments will be considered in the context of the upcoming comment deadline? We are wondering if there's any plans to extend that comment deadline based on today's event. Thank you so much for your time today.

Kat Gale

Good afternoon. My name is Kat Gale and I'm a manager of the Regulatory and Technical Affairs Department for the American Chemistry Council. ACC appreciates the opportunity to provide feedback on the approach to the administration of the Toxic Substances Control Act Rule. I would like to note that ACC has submitted a request for extension of the public comment period by 30 days from its current deadline to March 27, 2021. In this comment, I'd like to highlight several points which will be discussed further in our written comments on the proposal.

First, the proposal would increase the TSCA section 6 fixed program fees, which includes increasing the fees we've collected for the EPA-initiated risk evaluation by approximately 87.6% without providing a thorough economic analysis to substantiate that increase. ACC appreciates the Agency's need to recoup the costs associated with creating a positive program based on experience, recent risk evaluation, and prior risk management. However, the Agency is proposing to do so without having provided a detailed economic analysis sufficient to substantiate that the proposed increase is warranted. The proposed increase is substantial and would have a significant impact on the stakeholders. The current fees cycle revealed that in some instances, a single manufacturer responsible for only a small quantity of production could be responsible for the full fee associated with the risk evaluation. This is not an equitable outcome.

Second, the proposed methodology for calculating fees for the EPA-initiated risk evaluation, with the potential confidential business information concern, places an excessive reporting burden on the stakeholders and additional burdens on EPA. The methodology proposed uses an average actual production value which would present CBI concerns for stakeholders that claim the sensitive information is confidential. Stakeholders are business competitors and those that choose to maintain their production volume as confidential could be forced into involuntary disclosure of CBI as the fee calculations are based on volume and in the manner proposed.

Further, the collection of production volume data is a detailed and time-consuming process. If a chemical is identified during an off chemical data reporting year, obtaining and reporting the data presents an excessive burden on stakeholders. Finally, the calculation of numerous fees based on numerous factors also presents a significant burden on EPA. ACC is developing and plans to present

alternative methodologies in our written comments. These alternatives might include using tonnage bands instead of actual volumes and/or set fees for section 6 evaluation based solely on the company's tonnage, i.e., regardless of how many participants are active manufacturers or importers. Third, manufacturers and importers that have not paid the TSCA Fee for a substance should be restricted from entering the market for a period of five years or the manufacturers and importers that have otherwise left the market should have a path back into the market. These "new markets entrants" and "market re-entrants" should be required to pay a portion of the TSCA Fee prior to entering. The current "free market/free rider" system where manufacturers can enter the market as soon as the TSCA Fee [poor audio quality] is unfair to those manufacturers [poor audio quality]. Further, barring manufacturers from participating in the market for a period of five years especially in light of the proposed research and development exemption utilizes EPA support in a manner that might impede unduly or create unnecessary economic barriers to technical or logical innovation contrary to Congressional intent.

ACC will provide further details on this recommendation in written comments. Finally, the exemptions proposed should apply to both the manufacturer or the importer of the high-priority substance. ACC appreciates EPA's addition of the five exemptions and a proposed rule. The proposed exemptions specifically differentiate between production of the substance and the import of a substance, as well as the manufacturers of the substance and importers of a substance. ACC recommends that the exemptions be revised to include both manufacturers and importers of the substance and substances that are both produced and imported. We want to thank you for your time and continued engagement with stakeholders on this important issue.

Richard Denison

Good afternoon. I'm Dr. Richard Denison. I'm a Lead Senior Scientist with Environmental Defense Fund. Among the key reforms made to TSCA in 2016 was the expansion of EPA's authority to collect fees from the industry. You have the freight costs in implementing the law. There was widespread agreement, including by industry, that EPA needed more resources to faithfully execute TSCA and that industries should significantly contribute financially.

Unfortunately, that purpose has disappeared almost entirely from the current proposal, which is metamorphosed into a new purpose entirely divorced from TSCA to reduce asserted burdens on industry, without regard to the impacts that will have on EPA's implementation of the law or helping environmental protection from chemical exposures. The EPA repeatedly invokes industry burden reduction as justification for proposed changes to the rule citing no evidence other than industry complaints that the fees actually impose on due burdens.

The EPA's proposed changes also fail even to acknowledge, let alone assess, the effects of the reduced or the delayed fees that would result from its proposed changes on EPA's ability to carry out its duties under TSCA. Let me address specifically the exemptions from fee paying. EPA has proposed no fewer than six exemptions from the payment of fees for companies whose chemicals are undergoing risk evaluations. There are many problems with this approach. These activities constitute forms of manufacturing under TSCA. They are activities that TSCA requires EPA to include in the scope of a risk evaluation and hence, EPA will incur costs in evaluating those activities. Neither TSCA nor

EPA's final 2018 Fees Rule provides any basis for these exemptions. Indeed, in their comments on the 2018 proposed Fees Rule, numerous industry stakeholders requested EPA to include some of these and many other exemptions from the fees. In the final rule, EPA firmly rejected those requests, issuing a final rule without any of the exemptions and noting that TSCA requires EPA to evaluate chemicals under these conditions of use.

In theory, exempting some manufacturers of a chemical would simply mean that the remaining manufacturers would have to pay more. There is real concern that exemptions could result in no companies being left to pay fees and will otherwise create inequities. This is not theoretical. After EPA applied these exemptions to its list of manufacturers of the 20 chemicals now undergoing risk evaluations, which they did with no transparency, the number of subject chemicals dropped dramatically and in one case, left no - zero companies - that meant that EPA and hence, the taxpayer would have to pay the full $5.7 million for that assessment.

EPA never addresses what will happen if the basis for a company's claimed exemption changes or if its certification is found not or no longer to be true. These clearly should be considered violations of TSCA. EPA has also not addressed what the situation would mean for the fees other companies have paid for that chemical. The policy basis for these exemptions is highly questionable. On what reasonable basis, for example, would a company not know that a product or a chemical it makes or imports is contaminated with an impurity or a by-product. Knowledge about the composition of one's products was long ago identified as a pillar of extended product producer responsibility policies that the industry purports to have embraced years ago.

EPA has further proposed spreading out and delaying the payment of fees for risk evaluations, yet it fails to acknowledge, let alone assess, this proposal's impact on EPA's ability to conduct risk evaluations. EPA's ability to hire staff and engage contractors to do the necessary work requires stability in its budget and advanced planning, both of which will be adversely affected if you do not receive fees on time and early. Some of the same companies that pressed EPA for this accommodation are adding to EPA's burden by requesting that it conduct risk evaluations of their chosen chemicals. If cash were really so tight, they could save some by pulling back those requests and avoid paying the fees to cover their share of those risk evaluations. Finally, if fees are lost or delayed due to EPA's accommodation of industry concerns, that reduces EPA's capacity to conduct timely, robust risk evaluations. The TSCA clock is already ticking on the next 20 evaluations and EPA is already well behind schedule. In sum, EPA should not introduce exemptions from fee paying in updating the Fees Rule. Thank you for your time.

Lindsay McCormick

Hi, my name is Lindsay McCormick and I'm a program manager with Environmental Defense Fund. I'd like to start by saying there are several aspects of the proposed Fees Rule that we support, including the introduction of three new fee categories and the addition of fee requirements for manufacturers that exclusively export chemicals subject to EPA-initiated evaluations. However, we are concerned that EPA is continuing to underestimate the agencies baseline cost to administer TSCA, which will ultimately result in recouping fewer fees than warranted.

In the proposal, EPA both underestimated the Agency's costs for many of the activities it did include and omitted altogether the cost of other activities it must undertake, in which the fees to be collected are to help defray. I will briefly describe some examples of these underestimates and omissions under five sections of the law.

First, with respect to section 4 – Testing, EPA continues to grossly underestimate the amount of testing it needs to conduct to robust risk evaluations and instead over-rely on voluntary information submissions, as exemplified by its recent proposed section 4, Involuntary Information Collection Request. Second, with respect to section 5 – New Chemicals, while the Agency has proposed some new fees, it fails to adequately address costs of developing consent orders and significant new use rules, omitting mention of them in its proposal on the supporting economic analysis.

Third, with respect to section 6 – Existing Chemicals, EPA states it estimated the costs of conducting risk evaluations based on the hours staff reported working on the first 10 risk evaluations. Given that those risk evaluations included or excluded or omitted major known sources of exposure, there is little doubt that EPA's estimates significantly understate the cost of conducting the comprehensive evaluations TSCA and sound science require.

Proposed prioritization and risk management actions under section 6. It is far from clear whether or how EPA included the cost of these activities in its estimates of cost. EPA has provided no line item costs, let alone a break down for the component steps each activity entails. EPA says it estimates costs per risk management based on prior actions, but with one partial exception. These actions were never finalized and were recently abandoned altogether. Moreover, they were far narrower in scale than the risk management rules EPA is now undertaking. Finally, EPA's estimated cost for administering section 6 has actually gone down by nearly $2 million through the 2018 Rule, which seems highly questionable given EPA's greatly increased risk evaluation and risk management workload.

Fourth, with respect to the cost of collecting, processing and reviewing the information based on a continued misreading of the law, EPA has failed to include any estimates beyond the cost of reviewing confidential business information or CBI claims under section 14. For example, EPA did not include any costs for developing reporting rules under section 8, which may be critical in providing information needed to inform section 6 prioritization, risk evaluation, and risk management activities. Indeed, EPA is reportedly developing the first such rule now since TSCA was amended. And finally, for section 14 – Confidential Information, EPA's estimated costs are unreasonably low, as much as fivefold lower than EPA's prior 2016 budget estimate for the much narrower set of activities carried out under the old law.

EPA has failed to provide a breakdown of costs for many new duties under this heavily amended section of TSCA. EPA provided no estimate of how many CBI claims it received or must review and omitted any estimate of its cost to provide access to CBI to qualified persons or to provide public access to information that does not qualify for protection from disclosure. EPA also grossly understated its cost for faithful and timely review of confidentiality claims under TSCA. EPA has failed to carry out its new obligations under amended TSCA in this area, which it repeatedly blames on insufficient resources. Just one example, EPA has failed to review on time a third of the Notices of Commencement of

Manufacturing it had received in the past four years that claim the identity of the chemicals to be confidential, or to assign a unique identifier the law requires in cases where it approves such claims.

In summary, as a result of these underestimates and omissions, EPA is proposing fees below the levels required by TSCA and insufficient to recoup the allowable cost. We urge EPA to remedy these deficiencies in its final Fees Rule. Thank you for the opportunity to comment.

Closing Remarks from Jeffery Kohn, U.S. EPA

Thank you for all the wonderful comments and for the participation in today's webinar on the Proposed Revisions to the TSCA Fees Rule. An audio recording and a transcript of this webinar will be available on the TSCA Fees website. The team here in the Office of Pollution Prevention and Toxics looks forward to continued dialogue on this issue and other issues such as risk management under TSCA. Thank you again for joining us.