Transcript for the April 16, 2020 EPA call on TSCA Fees

This is conference #: 2881669. OPERATOR:

Ladies and gentlemen, thank you for standing by and welcome to the TSCA Operator:

Fees for EPA-Initiated Risk Evaluations Conference Call. At this time, all

participants are in a listen-only mode.

After the speakers' presentation, there will be a question and answer session. To ask a question during this session, you will need to press "star," "1" on your telephone. Please be advised that today's conference is being recorded. If at any time during the conference you need to reach an operator, please press "star," "0."

I would now like to welcome your speaker today, Mr. Ryan Schmit. Please go ahead, sir.

Ryan Schmit: Yes, thank you. And hello, everyone. Thank you for joining the conference

> call today. My name is Ryan Schmit. I work in the immediate office of EPA's Office of Pollution Prevention and Toxics on a wide variety of TSCA

and matters, including TSCA fees.

I'm also joined today by Madison Le, who's the new director of the Chemical Control Division in OPPT. Madison and her staff will be working closely on TSCA fees matters moving forward, including the rulemaking efforts that

we'll discuss today. I don't know if you wanted to say hello, Madison?

Madison Le: Thanks, Ryan. I just wanted to say hello to everyone and that I look forward

to working with each of you in the near future. Back to you, Ryan.

Ryan Schmit:

Great. Thanks. So, we also have a number of other EPA staff in OPPT to implement various aspects of the TSCA fees rule, along with some of our colleagues in the Office of Enforcement and Compliance Assurance and our Office of General Counsel.

So, today, I'm calling from my home. My colleagues are calling from their homes. I'm sure many of you are doing the same in light of the ongoing public health situation. I appreciate your patience with us with any technical challenges or disruptions we might have during today's call.

Today, we plan to talk about the requirements associated with the 2018 TSCA fees rule, and specifically, the requirements that are associated with EPA-initiated risk evaluations. We've developed some slides to help follow along with the presentation, which you should have received in an e-mail from EventBrite.com(eventbright.com) following registration.

If, for some reason, you have not received those slides, they're also available on EPA's web site if you're able to go there now, www.epa.gov/tsca-fees. You'll find on the right-hand side of that page a link to the slides for today's call.

As we've done before with other calls on this topic, we solicited questions from you in advance. Greatly appreciate those who took advantage of the opportunity. It really helps us to prepare for these calls.

So, we'll try to answer as many of the questions as possible during the presentation. And, rest assured, this is not the first and last chance that you'll have to get your questions answered. As time allows at the end of the call, we'll also take questions from folks on the line who might have additional questions.

I'd encourage everyone to review the TSCA Fees web site, which continues to be updated with useful guidance and information. Somewhat new to the TSCA fees webpage is the dedicated page describing the process and requirements that are associated with EPA-initiated risk evaluations.

There's new guidance on how to complete the self-identification and other certifications in EPA's central data exchange system and there is a new webpage dedicated to frequently asked questions which we continue to supplement. There's new guidance on how to complete the self-identification and other certifications in EPA's Central Data Exchange system and there is a new webpage dedicated to frequently asked questions which we continue to supplement.

We're committed to helping all of you understand the requirements associated with the rule. Appreciate your patience with us thus far. And we'll certainly continue to engage with all of you after this call to the extent you have additional questions or concerns.

Moving on to slide two, this is just a quick preview of what we'll be discussing during today's presentation. I'll quickly cover some of the backgrounds on the TSCA fees rule itself, as well EPA-initiated risk evaluations and what those entail, and then, the fees that are specific to EPA-initiated risk evaluations.

We'll talk about the recent announcement and no-action issuance and the implications of those recent actions for manufacturers that fall into one of the three impacted categories. And, more generally, we'll talk about who is subject to a TSCA fee requirement, the process for identifying TSCA fee payers, completing the required reporting in CDX, the opportunity to pay fees through a consortium, how EPA will calculate individual fee payments and invoice amounts, and next steps for EPA on implementation.

To those that submitted questions in advance, again, thank you. We'll try to cover those during the presentation on the appropriate topic slide or at the end. As time allows us, we'll take additional questions.

So, on to slide three, just a brief background on TSCA fees and risk evaluations and some history that will help bring some context to the topic that we'll be discussing. As many of you know, in 2016, the Toxic Substances Control Act, or TSCA as we refer to it, was comprehensively amended.

Among a number of things, the 2016 amendments provided EPA with expanded authority to collect fees to help (delay) a portion of the costs associated with overall cost to implementation efforts, including the cost of EPA-initiated risk evaluation.

TSCA required that EPA establish that new fee structure by rule and we finalized the TSCA fees rule in October of 2018. And under that rule, there are now fees for a variety of activities, including test rules and test orders under TSCA Section 4, new chemical notices and exemption applications under TSCA Section 5, manufacturer-requested risk evaluations under TSCA Section 6, and most relevant to today's discussion, EPA-initiated risk evaluations under TSCA Section 6 as well.

Slide four, just again some background on TSCA risk evaluations. In December of last year, EPA finalized high-priority designations for 20 existing chemicals, a designation that essentially initiated the risk evaluation process for each of those chemicals.

There are a number procedural steps and components to TSCA risk evaluations including a draft and final scoping document where EPA will identify the hazards, exposures and conditions of use that the agency expects to consider.

It involves an assessment of those hazards and exposures, characterization of any risk and the risk determination, which may lead to additional risk management action. TSCA mandates that risk evaluations be completed within three years with a possible six-month extension - a lengthy process.

So, on to slide five, just a bit on the risk evaluation fees and then we'll go into the details of this. The total fee for a risk evaluation activity is \$1.35 million. That is the total fee. It's shared amongst the identified responsible payers generally distributed on a per capita basis. Responsible fee payers are identified through the process that's defined in the TSCA (fees rule) that we'll talk more about and it's the process which we are in the midst of right now.

Entities who are identified on the final list of fee payers are on the hook for paying a portion of that risk evaluation fee. Entities that qualify as a smallbusiness concern - another phrase that's defined in the TSCA fees rule - receive an 80 percent discount off of their fee amount and there's an option for fee payers to pay that amount either individually or to form joint consortia of multiple payers.

And this is just the overall background. We'll talk more about each of these topics. I just wanted to bring some context to the discussion.

Move on to slide six then to talk about EPA's recent announcement, which is one of the main reasons for hosting this call today. Following release of preliminary list of manufacturers earlier this year, we heard – we heard from a number of stakeholders' concerns regarding practical challenges of complying with the self-identification requirements that are associated with the cost of fees rule. Those comments are in the docket for the preliminary list. If folks are interested, it's available on regulations.gov.

We indicated during our previous conference call that the agency was considering options to reduce this concern. And, in the interim, we extended the comment reporting period. Then, on March 25, EPA announced a plan to consider proposing exemptions to the TSCA fees rule for certain manufacturers that are subject to EPA-initiated risk evaluations. More specifically, manufacturers that import the high-priority chemical substance in an article, manufacturers that produce the chemical as a byproduct, manufacturers that produce or import the chemical substance as an impurity. EPA expects to begin this rulemaking process in the very short term with the goal of finalizing the rule by October 1, 2021.

On slide seven, along with the rulemaking announcements and as a bridge to the final revised rule, EPA issued a no-action assurance to these same three categories of manufacturers, subject to TSCA fee requirements for the ongoing EPA-initiated risk evaluations.

In effect, that no-action assurance means that EPA will not pursue enforcement action against the entities in the three categories of manufacturers for failure to self-identify as otherwise required in the rule. Obviously, this announcement and the no-action assurance have a significant impact to the ongoing process to identify fee payers and we want stakeholders to be aware of the action and the implications.

There's a link in this slide to EPA's web site where you'll find some useful information including the March 25 announcement itself, a copy of the noaction assurance that was signed by the assistant administrator in EPA's Office of Enforcement and Compliance Assurance, and the associated request for a no action assurance that was signed by the assistant administrator in EPA's Office of Chemical Safety and Pollution Prevention.

On to slide eight. Just a bit about the implications of the announcement and the no action assurance. One of the more immediate implications of the announcement in the no action assurance is the change in expectations for reporting during different periods that closes on May 27.

For manufacturers who fall into one of the three categories, the next steps on reporting actions will depend on the circumstances, whether they were identified on a preliminary list already and whether they already self-identified. And we'll get into the specifics about that later in the presentation.

We've also posted new FAQ's on our web site. There's about a dozen that pertain specifically to the announcement and the no-action assurance that should hopefully help to answer some of the common questions and frequently-encountered scenarios. And finally, you'll see that inside the CDX system the response options have been modified to accommodate the changes indicated in the announcement of the no-action assurance.

With all that in mind, I'll shift back to some of the basics of the TSCA fees rule requirements and processes starting on slide nine with the entities subject to fees. For EPA-initiated risk evaluations, the fee requirements apply to manufacturers, manufacturers of the high-priority chemical.

A number of folks have asked how did EPA define manufacturer. The term "manufacturer" is defined in TSCA Section 3 to include those who manufacture, produce or import a chemical substance.

So, in other words, if you're producing a chemical or if you're importing a chemical, you're a manufacturer under TSCA. And if that chemical has been designated by EPA as a high-priority substance, then you're subject to the TSCA fee for that risk-evaluation activity.

The fee requirements did not apply to processors, downstream users, folks who do not otherwise produce or import the chemical. We continue to get some questions from folks, for example, U.S. companies who use the chemical in their process or who incorporate a chemical or components containing a chemical into a finished product. But again, those who do not actually produce or import the high-priority chemical itself are not subject to the TSCA fee requirements.

Moving to slide 10 on exemptions. Many of you have asked about exemptions in the past and those questions have surfaced again in light of the recent announcement regarding exemptions and the no-action assurance.

We just wanted to be clear. Again, there are – there are no exemptions in the current TSCA fees rule for specific groups of manufacturers or specific types of manufacturing activity. EPA indicated in the recent announcement our intention to propose exemptions via rulemaking for three categories of manufacturers.

And again, those are manufacturers who import the chemical substance in an article, who produce the chemical substance as a byproduct, and produce or import chemical substance as an impurity. And again, we – again, we issued a no-action assurance as a bridge to an expected final rule that will include these exemptions.

So, some of you have asked if EPA is considering a – or would consider additional exemptions such as an exemption for those who manufacture for purposes of research and development or those who manufacture below a certain production volume threshold or those who manufacture below a certain de minimis-type threshold.

The forthcoming rulemaking does present an opportunity to consider additional changes to the TSCA fee structure including additional exemptions beyond the three that were covered in the recent announcement and no-action assurance. And indeed, I think that Madison and folks in our chemical controls division expect to engage with stakeholders as we work to develop that proposed rule.

Issuance of the no-action assurance was a fairly extraordinary action. It was taken in light of extraordinary circumstances. We do not expect to further expand or modify that action. So, for these 20 ongoing EPA-initiated risk evaluation, those manufacturers remain subject to the TSCA fee requirement.

There's no exemptions currently in the TSCA fees rule for manufacturer with low-production volumes, for manufacturers below de minimis level, the non-isolated intermediates, for example, or for research and development purposes.

On slide 11, we thought it would be important again to point out that there are some statutory exclusions that folks should be aware of. Section 3 of TSCA, for example, excludes certain chemical manufacturing and importing activities from TSCA jurisdiction entirely.

Chemicals that are manufactured, processed or distributed (in commerce), produced solely as a food or food additive, a drug, cosmetic, tobacco, product, pesticide and even special nuclear materials are excluded from the definition of chemical substance under TSCA and, therefore, also not subject to TSCA fee requirements.

For folks who believe that they may fall under one of these exclusions, I encourage you to read carefully the language in TSCA Section 3. A few questions have risen, for example, for have asked, "If I'm regulated by FDA, am I excluded from TSCA fees?"

It's important to note that the statutory exclusion on TSCA doesn't hinge on regulation by another federal agency or falling under the jurisdiction of another agency or statute per se, but rather on whether the substance meets certain definitions in the applicable laws. So, in the case of food and drugs, for example, it's whether or not the substance meets the definition of food and drug as defined in the Federal Food, Drug and Cosmetic Act.

Another statutory exclusion falls under Section 12 of TSCA, manufacture – manufacturing activities (including import) that are done solely for the purpose of export in the United States are generally excluded from TSCA requirements and that would also include the TSCA fees rule requirement.

Some of you have asked again whether a chemical substance that is manufactured solely for export and then is exported but subsequently reimported. Perhaps a common scenario might be a customer return, whether that import activity would be subject to the rule.

And again, if the substance is re-imported solely for purposes of export in accordance with the requirements in TSCA Section 12(a), that activity would generally be excluded from TSCA jurisdiction and, therefore, TSCA fee requirements.

For those with re-imported substances - if not re-imported solely for purposes of export - for example, if it may be sold or distributed domestically, then it would be subject to the TSCA fees requirement. Hopefully, that's useful for clarification.

Slide 12 talks a little bit about the process to identify fee payers, which again, is the process that we're in the midst of right now. For some fee events like new chemical submissions, for example, the entity responsible for paying the fee is readily apparent. In the new chemical case, it would be the submitter of the pre-manufacturing notice.

Contrast with assigning fees for EPA-initiated risk evaluation, EPA needs to undergo a process to identify manufacturers of the high-priority chemicals. This process is described in the cost of fees rule and it includes a number of steps including the publication of a preliminary list, a requirement for all manufacturers to self-identify, a period of public comment, an opportunity for correction of any errors on the preliminary list, and then publication of a final list. And, of course, we're in the midst of this process for the 20 EPA-initiated risk evaluation.

On slide 13, we'll talk a little bit about the preliminary list. In January, as you're well aware, EPA published the preliminary list of manufacturers associated with each of those 20 chemicals and opened a 60-day period for self-identification and public comment. Since then, we have extended the comment period to May 27 2020, essentially 120-day period to complete this activity.

EPA used publicly-available reporting data from EPA's chemical data reporting rule and the toxics release inventory to develop the list. Some of you have reached out to clarify why your company was identified on the preliminary list. Some have indicated that you are not producing or importing a high-priority chemical and perhaps wondered why you were on the list and whether or not you were subject to fees.

To clarify, EPA anticipated that the preliminary list might contain errors. And those who are incorrectly identified on the preliminary list should report in CDX as to the "no manufacture" response option to ensure that you're not identified on the final list. We'll talk more about reporting and the response options in the – in the next slide to come.

Some others have expressed concerns that the preliminary list might be under-inclusive. And as indicated in previous calls, we are aware that the preliminary list may be under-inclusive in some circumstances - for example, in light of reporting thresholds or exemptions in the chemical data reporting program or in the toxics release inventory program. Those reporting thresholds or exemptions do not apply to the TSCA fees reporting environment.

The TSCA fees rule requires all manufacturers to self-identify irrespective of whether or not they identify on the preliminary list. And EPA expects to use that information to develop what we believe will be a comprehensive and accurate final list of responsible fee payers.

Moving on to slide 14 - actually a good transition to self-identification and other certifications. It is a regulatory requirement in the TSCA fees rule that all manufacturers of high-priority chemicals self-identify at EPA irrespective

of whether or not they were included on a preliminary list. We're now in the middle of the comment reporting period for meeting that obligation.

The purpose of this reporting is to inform EPA development of the final list of responsible fee payers. It is intended to be a fairly straightforward exercise. There are just a handful of possible responses and no requirement to submit to EPA additional documentation or supporting information.

The three – the three general options for responding with CDX include self-identification as a manufacturer of high-priority chemical. There are two different options for certifying "no manufacturer" and "cessation" as the terms are described in the rule to avoid the obligation.

And there's another option to certify the small business concerns as – again, that's defined in the rule to reduce the obligation. All those responses must be reported in EPA's central data exchange, CDX system. And that system is set up to facilitate the responses consistent with the requirements in the rule.

A few of you have asked about a form for providing the required information. And to be clear, there is – there is no separate form to complete. Again, all responses are required in the rule to be made electronically within CDX system.

Some companies may manufacture multiple high-priority chemicals and have asked whether they need to report multiple times in CDX. And the answer to that is yes. A company must self-identify with respect to each high-priority chemical that they've manufactured.

Others have asked about companies with multiple sites, multiple facilities or perhaps multiple subsidiary companies that all manufacture a high-priority chemical. If a company has multiple facilities, sites, or subsidiary companies that manufacture the chemical, they need only self-identify one time and pay one portion of the cost of risk evaluation fee. And the authorized official of the parent company can self-identify on behalf of those multiple entities.

Another issue that we've heard from some of you and that we addressed on the previous call and I wanted to raise it again here is the scenario where multiple facilities owned by a single company were identified on a preliminary list.

And in that case, the parent company should identify once and indicate within CDX – it's called the additional information field and it's a free text box – that they are self-identifying on behalf of the individual facilities listed in the preliminary list. Doing this will ensure and help EPA to ensure that the parent company – as opposed to each individual facility or each individual subsidiary – is identified just once for the final list. We'd also encourage the parent company to submit just a very brief comment in the docket, regulations.gov, stating the same.

Slide 15 is an actual screenshot from CDX of the different response options for self-identification, certification of no manufacturer and certification of cessation. As mentioned earlier, the response options were modified following the announcement and no-action assurance to accommodate those who fall into one of the three impacted categories. And you'll see the new response language on this slide regarding the articles imports, byproducts and impurities under the "no manufacture" header.

We already talked a bit about who needs to self-identify as a manufacturer subject to fee requirements. And moving on to slide 16, we provide some clarification as to who can certify to avoid the obligation and under what circumstances.

The certification of "no manufacturer" primarily allows mistakenly-identified companies to correct errors on the preliminary list and avoid the fee obligation. To qualify for that certification, you must certify as to not manufacturing the high-priority chemical within five years proceeding publication of the preliminary list. There are a number of you who asked some very specific questions about timing and, hopefully, the actual language in CDX provides that clarity.

The "no-manufacture" response, again, was recently modified to accommodate responses for manufacturers who might fall on the three categories impacted by the announcement of no-action assurance. [That

response] would be applicable to those who were identified on a preliminary list or who had already self-identified. I'll talk a little bit more about specifics for reporting by those who are impacted by the announcement and "no-action assurance.

The certification of cessation generally allows avoidance of fee obligations for manufacturers who did manufacture in the previous five years, but have ceased manufacturing prior to the cutoff date in the rule - which is the date prior to initiation of the prioritization process for the particular chemical undergoing risk evaluation and for all of the 20 chemicals at issue today that date is March 20, 2019. And additionally, that the company will not manufacture five years into the future from the date of the certification.

Some of you have inquired about whether there will be an opportunity or process for changing a reporting response at a later date, for example, if the company wishes to certify now as to cessation, but later within the five-year future period wishes to begin manufacturing again. While companies are able to amend their responses during this open comment period, EPA will not be allowing changes post May 27, 2020 when the reporting period ends. The reporting responses will directly inform the final list of fee payers and individual invoice amounts. And it would be impractical for EPA to continuously modify the list of fee payers and the invoiced amount to accommodate late changes to the self-identification or other certifications as part of this process.

On slide 17, I mentioned earlier that reporting for the three categories of manufacturers that are impacted by the announcement and the no-action assurance would depend on the specific circumstances. And slide 17 breaks down those different scenarios.

If a manufacturer who is not – who falls into one of the three categories was not on the preliminary list and has not yet self-identified, there is no further action expected of that manufacturer.

If that same manufacturer who fell into one of the three categories was on the preliminary list, but has not yet self-identified, they can respond with the new language in CDX as to "no manufacture."

And if the entity had already self-identified in CDX, again, they're able to amend their response to "no manufacture" which now includes this new language on the three categories.

Importantly, entities who are not identified on the final list will not be responsible for paying a portion of the TSCA risk evaluation fee.

On slide 18, there's also an opportunity for certain manufacturers to reduce their fee obligations. And specifically, those who are able to certify as a small business concern in CDX will receive an approximate 80 percent reduction in the fee obligation.

"Small business concern" is defined in the TSCA Fees Rule at (40 CFR 700.43). It's a definition that was modeled on the Small Business Administration's own small business standard. And, in short, the definition assigns an employee-based threshold in association with the manufacturer's NAICS code.

And to qualify for small business discount, the company's total number of employees, including the employees of all parent companies and subsidiaries within the corporate chain, must not exceed the size threshold for the applicable NAICS code. If there is no appropriate NAICS code that would apply to a particular manufacturer entity, the default threshold for employees is 500.

As with other certifications we discussed previously, there is requirement to submit supporting documentation as part of making this payment. The company will simply attest the accuracy of what they report to EPA as part of the CDX reporting process. I encourage folks who have – might have additional questions on small business concerns to take a look at EPA's web site which is listed on this slide for some additional useful information.

On to slide 19, the final list of responsible payers. After considering responses from manufacturers as part of this process and any other public input that we receive prior to May 27, EPA will develop the final list of responsible fee payers.

Entities identified on the final list will be responsible for paying a portion of the risk evaluation fee for the chemical. EPA will publish those lists no later than concurrent with publication of the final risk evaluation scoping document or by approximately June 2020.

Some of you asked – have asked about an opportunity to amend their certification response after the end of the comment period or to otherwise dispute a listing on the final list. And again, the rule does not contemplate another opportunity for update to the final list after publication and there's a few reasons for that.

One, the opportunity to make corrections and our expectation of stakeholders to do so is now, during this current comment and reporting period. It was one of the purposes of requiring [in the rule] that EPA first issue a preliminary list, mandating self-identification and other reporting, and opening up for public comments. And secondly, from a practical standpoint, the final list, again, determines who's responsible for the fee and provides the basis for EPA's allocations of fee amounts.

On slide 20, I just wanted to touch a few notes regarding the mechanics of completing reporting in CDX. There's a link to CDX on the TSCA fees web site under the category of reporting and paying fees. And for those who may not be familiar with CDX or CDX reporting, the CDX web site itself provides a number of very useful resources including instructions on how to register a new account and helpful frequently asked questions. There's also a CDX helpdesk that can walk you through the registration process. And for more detailed information on CDX in general, there's a CDX user guide.

But specific to TSCA fees for EPA-initiated risk evaluation, we now have a number of new resources on the TSCA fees web site, again, under the "Reporting and Paying Fee" section. There's a new step-by-step instruction

guide for completing self-identification and other certifications, essentially a compilation of screenshots and instructions to guide users through the process and to be able to see the screens that you'll encounter in the – in the system itself.

In addition, there is a step-by-step instruction guide for amending an initial response. And similar to the other guides, this will help instruct you as you navigate the process of amending your responses, should that become necessary.

There is a "risk evaluation rule CDX user guide" on the – specific to the reporting function for EPA risk evaluation. That user guide is available both in CDX while you're – while you're completing the reporting and it's also available on EPA's TSCA fees web site.

And lastly, there is a new frequent questions page as I've mentioned three times now. It contains a dozen or so FAQs regarding the recent announcement and the no-action assurance and expectations for reporting. We'll also be adding some more common questions on reporting and other topics in the very near future and we will continue to supplement that web site as the need arises.

On slide 21, just a note about payment. The TSCA fees rule provides authority for companies to pay either individually or through a consortium of pay fee payers. The rule requires that EPA be notified of formation of a consortium, the names of its members and the principal sponsor within 60 days of publication of the final scope of the risk evaluation, which we are expecting to be around August 2020.

Formation of a consortium is not a requirement, but it is something, again, that EPA welcomes as it creates efficiencies for members of the consortia and for the agency as well. It also allows consortia members to determine an equitable allocation of fee responsibility amongst its members, which is a topic that has surfaced a number of times.

Some of you asked to know how they would know if a consortium has been formed for a particular chemical, where to learn more about it, how to join,

questions of that nature. Just to note, EPA has not yet been notified that there are any consortia formed. But the deadline for that is off into the future at this point. And again, EPA does not manage the consortium. But upon notification that a consortium has been informed, EPA would intend to work with the consortium managers to determine whether EPA can be of assistance with communicating about the existence of a consortium and perhaps publication of additional information and link on our web site.

On slide 22, calculation of fee payment. For those that are not part of a consortium, the total fee for EPA-initiated risk evaluations is shared amongst the identified manufacturers on a per capita basis, with discounts for small businesses.

There's a formula for allocating the fee amongst payers that is specified in the TSCA fees rule. And again, it doesn't consider factors like production volume or market share.

Folks have asked if EPA would consider assigning fee amounts based on what they consider to be more equitable factors such as production volume or market share and the answer is "no" at this point. But, as I mentioned on the previous slide, this could be something considered within the context of a fee payment consortium. It's also something that could be considered as EPA works to update the rule in the year ahead.

The individual amounts that each entity will be responsible for will vary depending on the total number of fee payers that are identified on those final lists and the number of small versus non-small businesses.

And I have here a – on this slide a hypothetical for illustration purposes. Assume that, for example, if there are 100 manufacturers that are identified on the final list, the base fee for each of those manufacturers would be \$13,500 or 1% of the total fee amount, \$1.35 million divided by that total number of manufacturers.

Also assume that 10 are small business concerns, then they would receive an approximate 80 percent discount off of that base fee, so the fee for each of those 10 small business manufacturers would be \$2,700.

And then, for the remaining 90 non-small business concerns, their base fee would be adjusted upwards to ensure that EPA is able to collect the remainder of the fee. So, for each of those non-small manufacturers, the per capita share would be the total remainder of the fee, 1.323 million divided by 90 which turns out to be \$14,700 each.

Hopefully, that helped explain a little bit about our process for calculating fees. There's been a number of questions, understandably. People are interested to know how much will be on the hook to pay for. And again, that really depends on the number of manufacturers who identified on those final lists.

In addition, the rule itself and our web site provides some additional description of how fees will be assessed in these sort of complex multiple payer scenarios, including where there is a mix of small and non-small businesses and individual payers and consortia.

Moving on to slide 23 on invoicing. EPA expects to begin sending invoices through CDX shortly after the close of opportunity to form a consortium, and again, we expect that to be around August 2020. This is the earliest possible date that we can begin invoicing because those fee amounts again are dependent on the number and the membership of consortia.

Fee payments are due 120 days from the publication date of the final scope of each of those risk evaluations or, again, and this is an estimate, by around — we expect the final fee payments to be due around October 2020. Like the reporting requirements associated with the TSCA fees rule, payments are also to be made within CDX system.

Slide 24, just a few high-level notes on next steps. The timeframe for self-identification and certification as we talked about – we just wanted to remind everyone on the call that that comment reporting period closes on May 27, 2020. We've received a number of inquiries about whether that deadline will be extended further and we do not expect any further extensions at this time.

With respect to the rule updates and the amendments indicated in our March announcement, again, we expect to initiate that process in the very near future. We expect to engage stakeholders as we – as we develop that rule prior to issuance of the proposal. So, be on the lookout for additional opportunities to engage on that.

And then, finally, publication of the final list, the next milestone after the close of the comment reporting period. Again, we expect and are, indeed, required to publish final list concurrent – no later than concurrent with the publication on the final risk evaluation scoping document which we expect to be around June 2020.

So, with that, we have just about 10 minutes left in the call. I wanted to thank all those who submitted questions in advance. It certainly helps us in preparing for these types of calls. I know that there were some more complicated hypothetical scenarios and questions that we plan to respond to folks directly on, and also supplement our frequent questions webpage. With that, I'll turn it back over to our operator and get to some questions.

Operator:

Thank you. As a reminder, to ask a question, you will need to press "star," "1" on your telephone. To withdraw your question, press the "pound" key. Again, that's "star," "1" to ask a question. Please stand by while we compile the Q&A roster.

Our first question comes from an anonymous line. Please state your first and last name. Your line is open. Please state your first and last name. Your line is open.

(Kathleen Roberts): Hi. This is (Kathleen Roberts). I have a question about import and import brokers and commercial companies that use them. I think under CDR there's sort of an understanding that between the two entities someone must report under CDR. Is that expected to be the same circumstance for the fees?

(Ryan Schmit): Hi, (Kathleen). And thanks for the question. This is – this is one I know that you had submitted a number of weeks ago and we're due to get you a response which we are working on in writing.

But essentially, yes, we've defined importer fairly consistently across regulatory programs under TSCA. It includes a variety of individuals who are associated with the import transaction. So, to the extent that a person such as an agent or a broker meets the definition of importer, that entity would be responsible for complying with the TSCA fees rule. Of course, if multiple entities meet that definition of importer, they are free to come to a separate agreement on who will actually conduct the reporting and how the fees will be shared.

(Kathleen Roberts): Thanks, (Ryan).

(Ryan Schmit): Thanks Kathleen, and we'll get you a response in writing on that.

(Kathleen Roberts): Perfect. Appreciate it.

Operator: Your next question comes from the line of (Karina Due). Your line is open. (Karina), your line is open. Again, (Karina), your line is open. Our next question comes from the line of (Joseph Spolsky). Your line is open.

(Joseph Spolsky): Yes. Hello. I just have a quick question regarding imports. So, if a company is importing a product, a liquid product that is not an article and it contains one of the 20 high-priority chemicals as a preservative, would the company importing that mixture which contains the high-priority chemical as a preservative be responsible for the fees, for the risk evaluation?

(Ryan Schmit): Thank you for the question. So, again, there is – there are no exemptions in the TSCA fees rule with the – with the caveat being the recent announcement that we have with respect to imports of articles and production and import of byproducts and impurities.

With respect to a chemical substance - a high-priority chemical substance - that's coming in a mixture, something that did not meet the definition of an article, the import activity would be considered manufacturer under TSCA and that entity who's importing would be on the hook for meeting the requirements of the TSCA fees rule.

(Joseph Spolsky): OK. Thanks.

Operator: Again, to ask a question, press "star," "1" on your telephone. And you have a

question from (Brent Tracey). Your line is open.

(Brent Tracey): Hi. My question is on the subsidiary and parent company reporting. Is it

required that the parent company reports especially if the subsidiary was

specifically identified through CDR reporting for the preliminary list?

(Bryan Schmit): So, it's a – it's a good question. I think the scenario that we – that I spoke to

earlier in the presentation was one where there were perhaps multiple subsidiary companies under a parent company umbrella who were each

manufacturing a high-priority chemical.

And we've said that that company needs only report once. There's no requirement that the parent company has to do the reporting if the parent company has one subsidiary, for example, that is a manufacturer under TSCA and the subsidiary company wants to undertake the reporting and the fee payment obligation on its own. There's nothing prohibiting that subsidiary

from doing so.

We were just making some accommodations for companies that had perhaps multiple facilities or multiple sites that they need to only self-identify and pay one portion of the fee – self-identify once and pay one portion of the fee.

Does that help?

(Brent Tracey): Yes. Thank you.

Operator: Our next question comes from the line of (Catherine Hogan). Your line is

open.

(Catherine Hogan): Thank you, but my question was asked and answered.

Operator: OK. Thank you. And next question is from (Kate Gale). Your line is open.

(Kat Gale): Hey, (Ryan). It's (Kat) from the American Chemistry Council. Can you hear

me?

(Ryan Schmit): Yes, I can.

(Kat Gale): Hi, (Ryan). So, I have two questions. One, are you guys going to be

uploading the transcript to the web site for this call as you did for the last call?

(Ryan Schmit): Yes. And we'll try to do that as quickly as possible and others on the line can

correct me if I'm wrong, but I think that's the case.

(Kat Gale): Great. Thank you. And then, my other...

Julia Ortiz: That is the case.

(Kate Gail): Great. Thank you. And then, my main question is you had said – the question

was brought up during the presentation about companies having to identify

each individual high-priority substance within the CDX submission.

We had a question that was can companies identify multiple high-priority

substances in one submission or do they have – can they just submit one with

multiple high-priority substances listed? Does that make sense?

(Ryan Schmit): Yes. So, it's – the way that our CDX system is design and I believe we also

have CDX experts on the phone if they wanted to weigh in or if I misstate

this, but the way I understand CDX to be set up is that, as you go through the

reporting process, you actually select the specific chemical that your company

would be manufacturing.

There's a drop-down list of the 20 different high-priority chemicals that are

undergoing risk evaluation. And you select one of those chemicals and

proceed with the reporting process from there. So, you would just need to

repeat that process for each chemical that the company was manufacturing.

(Kat Gale): Great. Thank you. And thank you, guys, for hosting this webinar.

(Ryan Schmit): Thank you for the question.

Operator: Our next question comes from the line of (Mark Nervais). Your line is open.

(Martha Marrapese): That would be me, (Martha Marrapese). Hello, (Ryan). I'm with (Wiley, Rein). I have a question about your comment that the deadline of May 27 is staying firm at least at this point.

You know, we have it on good information that there are companies who are furloughing workers who may be responsible for this reporting. And so, I'm wondering is this reporting requirement going to be covered under EPA's separate policy for enforcement discretion that the – that Susan Bodine issued recently?

(Phil Milton): Good afternoon. This is (Phil Milton) with the Office of Enforcement and Compliance Assurance. At this point, we're not considering this to be covered by that memo.

(Martha Marepiece): All right. Thank you, (Phil). I'm hoping that that will be reconsidered if this deadline stays firm. But the only other question I have for (Ryan) really quickly is can you repeat what you said about non-intermediates and R&D status chemicals, if possible? Thanks.

(Ryan Schmit): Sure. And thanks for – thanks for chiming in, (Phil). So, with respect to exemptions, I just want to be clear that there were no exemptions to the TSCA fee requirements for EPA-initiated risk evaluations that were part of the final rule that was finalized in 2018. We've taken steps now with the recent announcement to indicate our intention to propose certain exemptions, three specific ones – import of high-priority chemical in an article, by-products and impurities.

We did not take any similar action with respect to other exemptions that people may be more familiar with in other TSCA regulatory programs. So, for example, we're aware that in the new chemicals context or CDR or TRI there may be certain exemptions, for example, for folks who manufacture a chemical for R&D purposes or who manufacture a chemical as a non-isolated intermediate.

And because there are no exemptions in the TSCA fees rule, those folks – those manufacturers would be on the hook to comply with the various TSCA fees requirements.

(Martha Marrapese): OK. Thank you. And thank you, again, for hosting this webinar. It's been really helpful.

(Ryan Schmit): Thanks, (Martha).

Operator: Again, to ask a question, press "star," "1" on your telephone. Our next question comes from the line of (Ashley Pike). Your line is open.

(Ashley Pike): Hi. This is (Ashley). I have a question regarding reporting threshold. I just want to make sure I'm understanding the process correctly. Is there a difference with the threshold for the self-identification as compared to the reporting?

(Ryan Schmit): No. So, if I'm understanding the question right, again, this is – this is kind of back on the topic of exemptions. And one thing that I had mentioned is that there is no production volume threshold below which manufacturers would be excused from TSCA fee requirements and no type of de minimis threshold.

So, folks who are manufacturing chemicals at low production volume amounts or in ways that they consider to be de minimis are nonetheless subject to TSCA fee requirements except to the extent that they may qualify for one of the three areas impacted by the recent announcement and no-action assurance.

(Ashley Pike): OK. Thank you very much.

Operator: There's no further question at this time. Presenters, please continue.

(Ryan Schmit): Great. I think that you said there are no further questions. And again, I really appreciate folks' time today to call in and to learn more about this topic and to all those who submitted questions in advance. I want to reiterate that we're here to help and, to the extent you have additional questions at any time after this call, feel free to reach out to us. And, with that, thanks again to everyone. Stay safe and healthy. Thank you.

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Operator:

This concludes today's conference call. Thank you for all joining. You may now disconnect. Presenters, please stay online for the post-conference.

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