**Title: Public Webinar on Final PFAS Reporting Rule under TSCA, January 2024**

**Description: On January 25, 2024, EPA held a webinar on the Agency’s October 2023 per- and polyfluoroalkyl substances (PFAS) reporting rule under Section 8(a)(7) of the Toxic Substances Control Act (TSCA). The webinar provided an overview of the TSCA Section 8(a)(7) rule’s requirements.**

**EPA-1:** It looks like participants are going up quite quickly right now. I’m just going to give it

a second and then I will let everyone in. All right, so while people are coming in, I just wanted to start

and say welcome. My name is Sarah Soliman. I work for the stakeholder engagement branch for

the Office of Chemical Safety and Pollution Prevention at EPA (Environmental Protection Agency). I’m

also the one that you guys have been emailing all of your questions to. So, great to have you all

here. Thank you for joining us for the Toxic Substances Control Act Section(a)(7) Rule: Reporting and

Recordkeeping Requirements for PFAS. In just a second, I am going to turn it over to our wonderful

people with Abt Associates who are going to do a little kind of how WebEx works, and then we will have

a presentation, and then we’ll be answering as many of your pre-selected questions as possible. With

that, thank you all so much. I’m going to turn it over to Katherine.

**Abt-1**: Thanks, Sarah. Thanks everyone for joining today.  Like Sarah said, I’m just going to

go over a few webinar software tips. First, there are two ways to connect with the audio today. You can

either listen through your computer speakers, or you can use the number that is posted at the

bottom of the slide to call in. All participant lines will be muted for the duration of the

webinar, regardless of the audio method that you choose. We’ll be using two panels for

today’s webinar. They are the participant panel and the question and answer (Q&A) panel.

Both of these can be found on the right-hand side of your screen. You may need to click the arrow

next to the desired panel to expand and see all the content. If for some reason one of them does

not appear, you can navigate to the bottom right of your screen and click on whichever one you are

missing. Throughout the duration of the webinar, you can enter questions into the Q&A panel.

When submitting questions, please select “all panelists” from the dropdown menu before you hit

send, as this will ensure that all of the speakers can see your question. These questions will be

moderated at the end of the webinar during the Q&A session, and the final materials, including

the recording and the slides will be posted to the EPA website. Then lastly, we also have

simultaneous interpretation available for this webinar in Mandarin, Japanese, and German. If you

would like to join one of these channels, you can click on the globe icon in the bottom left-hand

side of your screen and then select the language that you would like to listen to. You can adjust the

volume of the audio line, so between English and the other language, using the slider. That’s all I have,

and I’ll hand it back to Sarah.

**EPA-1**: Thank you, Katherine. We are about to get started. Just a reminder, yes,

we will be sharing everything afterwards. I also just want to give a huge thank you to our fabulous

interpreters who are helping us provide this webinar in a couple of different languages today. With that, I

am going to turn it over to Stephanie. Thank you so much.

**EPA-2**: Thanks, Sarah and Katherine. Let me make sure I can move this. Okay, great.

Good afternoon or good morning, everyone. My name is Stephanie Griffin. I’m in EPA’s Office of

Pollution Prevention and Toxics. I’m a team lead in the data collection branch. Our branch helped

develop that, the recently finalized rule under the Toxic Substances Control Act, or TSCA, the

Section 8(a)(7) rule requiring reporting and record keeping for per- and polyfluoroalkyl substances, or

PFAS (per- and polyfluorinated substances). I’m really happy to be here today to go over the rule

requirements and answer some questions that were submitted in advance of today’s webinar, and try to

answer any other questions from the audience that may come up later on.

For a quick overview of today’s presentation, I’ll be going into some background of this rule, as

well as information related to the scope of TSCA. I’ll then talk about the rule specific

requirements, including what substances are covered, who is covered, what will be reported, as well as

information related to CBI (confidential business information) claims,  the reporting deadline and record

keeping. We’ll use the rest of the hour for questions, starting with several that have been

submitted already. For those of you who did submit questions in advance, thank you. Many will be

answered on these slides during the rule overview. Many others I can answer after the

presentation. Please do, you know, pay attention. You might have your question answered as we go

through these slides. However, I do want to flag that EPA did receive hundreds of questions. Some are a

bit more nuanced or perhaps less applicable to a broader audience. I will not be able to get to all of

those during today. But please keep in mind that EPA is planning to use many of these questions to

create an FAQ (frequently asked questions) document and provide that as a resource in coming months.

Also, just wanted to flag today’s webinar will be going over the rule requirements. There’s not going to

be a demo of the future reporting tool today. With that, I’m  going to get started on some of the background of the rule.

Many folks may know, the background of the rule came in December 2019, when the fiscal year

2020 National Defense Authorization Act, or NDAA, amended TSCA by adding Section 8(a)(7). This

Section 8(a)(7) stated that EPA shall promulgate a rule requiring each person who’s manufactured

a PFAS in any year since January 1st, 2011, to submit to EPA a report for each year since 2011,

information that is described in the statute. I’ll go through what that information is in the coming

slides. Following passage of the NDAA, EPA then started working on the rules proposal.

There were multiple public comment periods. EPA also convened a Small Business Advocacy

Review panel under the Regulatory Flexibility Act to hear directly from small entity representatives and

work with the panel members, including members from the Office of Management and Budget and the

Small Business Administration. After considering all of the public input and input from the Small Business

Panel, EPA then published a final rule on October 11th, 2023, and this rule is now codified at 40 CFR

(Code of Federal Regulations) Part 705. Given some of the questions EPA’s received so far, I want

to go over the relevant scope of TSCA authority first. The law defines chemical substance fairly

broadly to include both organics and inorganics, naturally occurring substances, polymers, and

substances of unknown or variable composition, complex reaction products, and biological

materials which collectively are UVCB substances.  However, the statute also explicitly carves out

certain substances from the scope, including for uses as pesticides, food, drugs, medical devices,

and cosmetics. To the extent a manufactured PFAS is specifically excluded from the definition of

chemical substance under TSCA due to those uses, that would not be covered by TSCA or this rule.

Now when considering TSCA chemical substances, I also want to note EPA has the authority to

require reporting and record keeping, as we’re doing here for chemical substances, including when

they’re applied to or part of an article or a mixture. EPA has the authority to regulate those constituent

or component chemical substances. The articles defined in TSCA rules, and its definition is here

on the slide. But essentially it is a manufactured item that’s formed to a specific shape or design,

and the end uses depend, at least in part, on that shape or design. It either does not have a

change in chemical composition during its end use, or if it does have that kind of change, those

chemical changes don’t have separate commercial  purposes. Also, fluids and particles are never

considered articles.

Now, common examples of articles could include items like a steering wheel

or some other automobile components, doorknobs, and potentially, depending on end use functions,

things like finished textiles or thermoformed plastics. For mixtures, there’s a definition under

TSCA Section 3(10). The law defines mixtures as any combination of two or more chemical substances

if it’s a combination that doesn’t occur in nature and is not the result of a chemical reaction. Of

course, a mixture may be the result of a chemical reaction if none of those individual substances

are new chemicals, and also if that could have been manufactured for commercial purposes

without a chemical reaction at that time. Now, because this rule requires reporting on the individual

PFAS that have been manufactured, for any article or mixture that contains at least two PFAS, the

manufacturer would report on each PFAS itself, rather than the article or mixture as a whole.

Next, we’ll move on to discussions of the requirements under this rule. First, going into the

scope of PFAS reportable under this rule. Now, for this rule, EPA is defining PFAS using a

structural definition. A chemical substance would be a PFAS if it concludes at least one of the

three substructures that are shown on this slide. I don’t need to read out to you right now. Excuse

me. My computer just froze a little bit. Any toxic chemical substance that meets that structural

definition and which was manufactured at any time since January 1st, 2011, would be reportable

under this rule. I’m emphasizing the toxic chemical substance again, because, again, some

substances may be excluded from the scope of TSCA, such as uses for pesticides, pharmaceuticals,

medical devices, munitions. We’ve received a fair number of questions on that scope so far. Also to

confirm, fluoropolymers are within the scope of  this rule if they meet the above criteria. There

are no polymer exemptions for this reporting rule.

Now, under this definition, EPA identified at least 1,462 PFAS from the so-called known TSCA

universe. These include PFAS listed as active on the February 2023 TSCA inventory, which means

that they’ve been reported as having been manufactured or processed in commerce at some point

since 2006. This total also includes PFAS that have been submitted to EPA’s New Chemicals Program

under the low-volume exemption claim, or LVEs, since that is separate from the inventory. EPA defined

TSCA for this rule using a structural definition. In other words, there’s not a discrete or exhaustive list of

covered substances. However, EPA is providing lists of examples of potentially reportable PFAS in order

to assist manufacturers both on EPA’s Toxic Chemicals dashboard, as well as the Substance Registry

Services, or SRS, tool. There are rule-specific lists of example substances, or even just structures or

moieties that meet the structural definition here. Now, for both of those lists, they’re not limited to just

that known TSCA universe. They do include essentially any additional structures or substances, even if

they’re not on the TSCA inventory and not in LVE.

Do keep in mind the broader scope of that list was aimed to just be as comprehensive as

possible in order to help manufacturers comply or better understand the structural definition. That

said, I am happy to announce that EPA has compiled a list of known toxic substances. This is, again,

from the inventory and LVEs, with the exception of substances with CBI claims and whose generic

names we can’t share PFAS. That file will be posted separately on this rule’s web page hopefully

tomorrow. I’ll give a bit more context of that resource at the end of this presentation. But I do

want to flag, of course, that manufacturers should not limit the scope of reporting to just that

list. Again, any chemical substance meeting this PFAS structural definition and was manufactured

for commercial purposes at some point between 2011 and 2022 should be reported.

Now moving on, going over the reporting entities here. Anyone who has manufactured,

including imported, a PFAS in any year between 2011 and 2022 is required to report under this rule.

Now, under TSCA, manufacturing does mean importing. Unless I say specifically otherwise going

forward, include importers whenever I say manufacturers. That means that anyone who has, not

manufactured, including imported a substance, so a processor, somebody who’s a distributor or

otherwise using or disposing of a PFAS does not need to report if they’re not also manufacturing

it. Unlike many TSCA rules, this rule does not have any reporter exemptions. Any manufacturer,

and that includes small businesses, article importers, as well as manufacturers of substances

like byproducts or R&D (research and development) chemicals need to report to the extent that they

have information.

Likewise, there’s no minimum reporting threshold or amount of PFAS that must be produced in

order to report. Any amount of PFAS known to be manufactured is reportable. Finally, I do want to flag

that some covered entities may include some waste management sites. So, keeping in mind that the

scope of manufacturing means imports, and it also includes coincidentally manufactured PFAS like

byproducts, some waste management sites may be required to report if they know or can reasonably

ascertain they’ve manufactured a covered PFAS during this time. However, EPA did identify a waste

management activity that is not covered by this rule and that is importing PFAS in municipal solid waste

streams for the purpose of disposal or destruction. This is as opposed to importing PFAS and wastes

that are not within municipal solid waste streams, or importing PFAS in those municipal solid waste

streams for something other than disposal or destruction, and such as recycling or processing.

Moving on to the data elements that are requested under this rule. As I mentioned before, the

type of information requested under this rule aligns with the information outlined in the law. These

topics include chemical identity, trade name, and molecular structure, the categories of use, the

quantity manufactured both in total and for each category of use, description of byproducts that

may result from the manufacturing, processing, using or disposal of each substance. All existing

information concerning the environmental and health effects of each substance, the number of

individuals exposed in their workplace and the duration of that exposure, and finally the manner

or method of disposal and any change in that manner or method. And as the law requires, this

information must be reported for each PFAS in each year since 2011 that it was manufactured.

Now, some PFAS manufacturers may notice that some of the data elements here may overlap

with some other EPA reporting programs or information requests. To address that and reduce any

duplicative reporting, this rule allows manufacturers to not re-report data if they’ve already submitted

information for a specific data element for that year. This is under either the TSCA Chemical Data

Reporting rule or CDR, the Toxics Release Inventory or TRI program, or the Greenhouse Gas Reporting

Program. Now, in the rule, EPA identified the specific data elements that may have been reported under

one of those other three rules. For instance, CDR also collects information on production

volumes and worker exposure. If a manufacturer had previously reported that information to EPA,

they would only need to then indicate that in the reporting tool rather than submit the information.

Manufacturers may have also previously submitted environmental and health effects information to

EPA under another program. Those also do not need to be resubmitted, provided that the manufacturer

tells EPA under this rule which program or office it was submitted to and in which year. Note that

the scope of all existing information regarding environmental and health effects is not limited to

the lookback period. In other words, any of that relevant health effects or environmental effects

information would need to be submitted even if it was developed prior to 2011. Now, unlike all the

other data elements, this existing information on environmental and health effects would not need

to be resubmitted for each year between 2011 and 2022.

Now, one thing I do want to flag is, on the subject of potential duplicative reporting, a

key difference with this rule and the other three that are listed here, this rule requires data for each year

since 2011 in which that substance was manufactured. That’s also without any sort of quantity or

activity exemptions. Manufacturers must ensure all information has been provided to EPA as required

under this rule. And even if a PFAS manufacturer has submitted some information to EPA under, say, the

TRI program, but that amount was not inclusive of all the covered activities that are relevant to this rule,

that manufacturer should not claim the data element the full requested scope of information for the

data element under this rule.

Now, in addition to that so-called longer or standard form, for PFAS manufacturers, there are

two streamlined or shorter reporting form options for specific types of manufacturers. The first

streamlined option is just for article importers. This form will only include the following data elements,

chemical identity, processing and use information, and production volume. The production volume is

of the entire article and not just the chemical itself. Article importers must also indicate

whether that PFAS is ever physically at the reporting site. I do want to flag that article

importers who use that streamlined form will not need to assert or substantiate CBI claims

for chemical identities. Moreover, EPA is not going to be making any CBI claim determinations

on chemical identities based on those forms. But I’ll go into some more details on CBI claims in

a few minutes.

The other streamlined reporting form is for R&D substances manufactured in small

quantities, specifically less than ten kilograms a year. This form’s information is limited to the

chemical identity, production volume, and again, an indicator for whether it’s physically at site.

Both of these streamlined reporting forms have the option to submit additional information

to EPA. Now, regardless of the type of form a PFAS manufacturer uses, the reporting standard is

the same. All potentially covered manufacturers, under other Section 8 reporting rules or existing

information rules, must report information to the extent it’s known or reasonably ascertainable.

Now, just to ensure we’re all on the same page, let me just go through some of the definitions

real quick. Known or reasonably ascertainable refers to the information that’s in a person’s possession

or control, plus all information that a reasonable person, similarly situated would be expected to

possess, control, or know. Further possession or control here refers to the submitter

or any subsidiary partnership with the submitter where they’re a general partner, parent company,

or any other company or partnership that is owned or controlled by the parent company, associated

with R&D, test marketing or commercial marketing of that chemical. This includes files that are

maintained by the submitter’s employees who are associated with those types of R&D or marketing

activities, or otherwise, would be reasonably likely to have that kind of data. This also

includes files maintained by other agents of the submitter. Now, what this essentially means is

that companies must consider what information is in their possession or control or information that

someone in a similar position as them would be expected to have or know. For instance, this could

mean staff in different parts of a company may have different types of information, like related

to sales, or R&D, or production line. It does not limit the company’s scope to just supervisory

or managerial employees. This could include information that has been provided to them through

existing customer surveys that were conducted, sales reports, SDSs (safety data sheets), and

information obtained externally through technical publications or conferences. Additionally,

the reasonably ascertainable factor of this standard also means that a company may reach

out to some, either downstream customers for some of that processing and use information

or to their supplier. But in many cases, this is generally not an exhaustive search or

survey, assuming this is depending on a particular circumstance. The application of this standard is

case-specific. The amount of information that is known or reasonably ascertainable by someone

will look different to different companies, or even across different industries. But importantly, this means

that manufacturers do not need to test products or implement new monitoring requirements just to

comply with this rule. Now, finally, any manufacturer, and this is particularly true for article importers,

who don’t know and cannot reasonably ascertain that they have manufactured a PFAS, do not need to

report. However, EPA strongly encourages those entities to document your due diligence steps taken,

although this is not a requirement.

Now, moving on to the CBI requirements. This slide describes the broadly applicable CBI

claim requirements for manufacturers under both the 2016 Lautenberg Act that amended TSCA,

as well as last year’s CBI procedural final rule. Both the law and implementing regulations require

CBI claim submitters to substantiate their claims at the time of submission, unless specifically

exempt from substantiation and to certify those claims. Now, there are limits on what may be

claimed as CBI, such as information that is typically provided publicly. There are further

limits on CBI claims for health and safety data, which is relevant because health and safety data

are part of the larger umbrella of all existing information concerning health and environmental

effects. Specifically, a chemical’s identity is always considered part of a health and safety

study, and the extent of CBI protections for health and safety studies are generally

limited to process related information and PII (personal identifiable information) or other

sensitive personally identifying information.

Now there are some rule specific requirements, related to CBI claims for PFAS manufacturers

here. First, all manufacturers who claim the specific chemical identity as confidential must submit a

generic chemical name or description that includes ‘fluor’ in that generic name. Essentially, we need to

be able to indicate that this is a PFAS substance. This is consistent with EPA’s guidance on TSCA generic

chemical names, which is available online. Secondly, and I mentioned this briefly before, but article

importers are not required to assert or substantiate CBI claims for chemical identity when using that

streamlined reporting form. EPA is not going to make any CBI determinations for chemical identity based

on just those forms.

Finally, there are joint submission requirements here. EPA is requiring joint submissions to be

initiated by manufacturers who do not know the specific chemical identity but have a supplier, contract

manufacturer or another third party who does. This does not apply to article importers. The article

importer forms will not be allowed to initiate a joint submission. This is similar to CDR requirements, in

which a joint submission allows the manufacturer to start and complete a reporting form to the extent

that they know, and then use the reporting tool to send that joint submission to a secondary submitter

to independently provide the specific chemical identity directly to EPA so the secondary submitter will

not be sending that information to the primary submitter. If they do, then it’s no longer going to be a

joint submission.

Also, like past TSCA rules, EPA will begin the process of moving any PFAS identity that

is currently listed as CBI on the inventory to the public inventory. If there are any manufacturers, again,

not including article importers, who report that specific identity but do not sufficiently assert or

substantiate confidentiality. This process would include a public notification period to allow other

reporters of that PFAS an opportunity to appeal a future declassification. Now, EPA intends to provide as

much non-CBI data submitted as publicly as possible, but the law does allow for states, tribes and their

political subdivisions to request access to TSCA CBI in writing. Now, a state, tribe or subdivision needs

to demonstrate its ability to continue protecting that information as confidential. If that entity

is granted access under the statutory conditions, EPA would then have an agreement in place with

them that lays out how the requester was going to continue that protection. Moving on to the

discussion of how this information is submitted to EPA. EPA is currently developing and testing a

reporting tool that is specifically designed for this rule.

Now, like a lot of other reporting applications, this will be on the Central Data Exchange, or CDX,

platform. Any existing information on environmental and health effects must be submitted using OECD

(Organisation for Economic Co-operation and Development) harmonized templates (OHT), wherever

that’s possible. Those would include all the underlying data or the relevant studies as well, and that

information would be uploaded as attachments in the harmonized template if that’s relevant to that

endpoint. As I mentioned before, reporters can indicate in the reporting application using a checkbox

whether they have already submitted that same information to EPA for that year under another

CDX application.

Now, looking ahead to when the information is submitted. EPA is providing a

one-year information collection period that began on the effective date of this rule, which was

November 13th. After that one-year period, the reporting period will begin, and the application

will be open. Now, most manufacturers will have six months once the reporting tool is open to

submit the data to EPA, which overall is an 18-month period to report. That reporting deadline

is May 8th of 2025. However, EPA is providing extra time for some of the small manufacturers.

Now, if you qualify as a small manufacturer under TSCA Section 8 and are also reporting under this

rule exclusively as an article importer, you have another six months to report once the tool opens,

so that reporting deadline will be November 10th, 2025. Again, you have to be reporting exclusively

as an article importer. No entity would have both of those deadlines relevant.

Finally, the record keeping requirements. There is a 5-year record keeping period that will start

at the end of the data submission period. Now, I do want to turn to a few of the most commonly

asked pre-submitted questions. There are a few questions on the next slides, and then I’ll

answer a bit more verbally.

EPA received several questions of this variation regarding whether a particular substance is

covered by this rule. There are kind of two varieties this question has taken on. The first is whether a

substance such as a polymer meets the structural definition of PFAS. The second is whether a substance

or use is covered by TSCA. For the first question on whether a particular substance is considered PFAS

under the structural definition, I would first refer you to one of the lists of examples of

substances meeting that definition. If you can’t find that particular substance, again, especially for a

class II substance, please reach out to EPA and we can confirm. As to the second question regarding

whether a substance is covered by TSCA or, say, the Federal Food, Drug, and Cosmetics Act (FFDCA),

please be aware that this is a product-specific answer. There are some jurisdictional questions

under the FFDCA that are fact specific. Those decisions often require input from both EPA

and FDA (Food and Drug Administration). Companies may consider contacting FDA if there are questions

about whether a product is appropriately considered a food, a food additive, drug, cosmetic, or device

under the FFDCA Section 201. I should flag, as I noted before, that if a company’s manufactured the

same PFAS for both TSCA-covered and non-TSCA-covered uses, that is still reportable for the TSCA-

covered uses.

Now, another common question we received is regarding the scope of reporting entities.

Another with many variations on this question regarding, if someone purchases PFAS from a domestic

supplier and then incorporates that into a product sold, do they need to report? The answer to that is

no. But that’s assuming they’re not also producing or manufacturing any PFAS during their operations.

Again, only manufacturers, including importers of PFAS, need to report. If you only process or

use or dispose of a PFAS, including because you purchased anything domestically and did not

produce any new substances, you do not need to report.

Another common question is, if there isn’t yet a test method for a particular PFAS, how do I

know whether I’ve manufactured it and need to report? Now, for these types of questions, I do want to

refer manufacturers to the reporting standard of known or reasonably ascertainable information. If a

manufacturer does not know and can’t reasonably ascertain whether they’ve manufactured a reportable

substance, you don’t need to report.

And particularly, testing is not a requirement just for compliance with this rule. However,

if you do know you have manufactured a covered PFAS, you just don’t know which ones specifically, you

still need to report. In those cases, the reporter would submit a generic name or description of the

substance and would provide as much structural information as possible.

Finally, a related question, but from the perspective of

article importers, if an article importer does not know whether their imports contained reportable

PFAS and they can’t reach or don’t hear back from their overseas supplier, what should they do? Do

they need to report? So, as in the above question, this falls back to the scope of known or

reasonably ascertainable information. EPA does not expect that universe of data to look

the same for everyone under this rule. If you have done your due diligence, if you have looked

to what is reasonably ascertainable for somebody in your position, and you do not know that you

have a covered PFAS that has been manufactured, you don’t need to report. But, again, I would

recommend you document those efforts.

Now, I do have several other pre-submitted questions to answer, but first wanted to

ensure that people were aware of some of these resources. If you signed up for this webinar, I’m

assuming you’re familiar with the web page for this rule on EPA’s site. But it’s here again as a

reminder for where people may find reporting instructions and the small entity compliance

guidance, there. EPA is also planning to post the spreadsheet, as I mentioned before, of the

known toxic chemical substances from the active inventory and LVEs that meet the scope of PFAS.

There’s a very helpful Readme tab to review there. But for the benefit of folks here, please be aware

that there are two sheets in that file. One for the chemicals whose specific identities are known,

those are listed by CAS number, or in a few cases, just the LVE numbers if they don’t have a CAS

number. There’s also a tab for chemicals that do have CBI claims, and EPA is only able to share the

generic name and the TSCA session number or LVE number. The CBI claims list is not comprehensive

since there are some PFAS that have been reported to EPA previously that did not have their generic

names include ‘fluor’ in them and so we’re not able to reveal their identities as being a PFAS at

this time.

EPA is also going to be consolidating many of the questions we’ve received so far,

either through reaching out to Sarah, or directly to myself, or through the TSCA hotline. That will

be turned into an FAQ document. That would also be posted on this website when it’s available.

Unfortunately, I don’t have a timeline on that availability yet, but would aim for it in the

summer, early summer. This slide also has the TSCA hotline, phone, and email contact information.

Finally, there are user guides available for registering for and using CDX. Now, if there are

any PFAS manufacturers that don’t yet have a CDX account, I strongly recommend creating one now.

You’ll find it helpful to have access to it by the time the reporting period actually begins. This

slide contains a link to where that user guide can be found. With that, I’m going to now turn to some

additional questions that were submitted to EPA ahead of today, but which weren’t able to be added

to some of the slides. I’m hopeful we can save a little time at the end for any new questions that

have come up in the chat that haven’t already been answered. Just give me one second.

Again, there are several questions. Many questions. Some of them I know I have answered

already, but here are some that – we received a couple of variations on these themes. “If I purchase

multiple PFAS from a U.S. manufacturer importer, and then I combine them into a mixture that is later

sold in the U.S., do I report that PFAS as a – do I report the PFAS as a manufacturer of the mixture,

or does the original manufacturer of each PFAS report or do we both report?” This is a great

question because you need to break down who is the manufacturer of the individual substances.

  As I said before, under this rule, manufacturers need to report by PFAS and not for a mixture or

for an article. You report by PFAS manufactured. If there are multiple constituent PFAS,

each one of those reports is reported separately by its manufacturer. If you have purchased it just

from a domestic source, then you are not the manufacturer of that PFAS. If you are somebody

who imported that, you would be the manufacturer and you would report on that import. However,

do be sure to account for any coincidental production if you do produce new PFAS as

byproducts or impurities during your operations.

I have some questions from potential article importers. One person wrote in as an agricultural

machinery manufacturer overseas. They are an article importer, and a portion of their

machinery volume is imported into the U.S. and then directly exported into Canada. Would they

need to report the total import production volume, so combining the volumes that are ultimately in

Canada and the U.S., or just the import production volume that stays in the U.S.?

The answer is both. Once it is at the point of import, that is the point of manufacturing and that must

be reported. Also note that the rule requires the reporting of the volume of PFAS if it is exported

as well. That would be a separate data element if  it was somebody who needs to report on that amount

of PFAS.

Third question. “Is PFAS applicable to parts manufacturers or is it only applicable to

substance and mixture manufacturers?” I think this is a good question because it breaks down some of

the confusion between more traditional chemical manufacturers and those who are also manufacturers

but are considered article importers. This rule, to confirm, is applicable to all PFAS manufacturers,

including importers. Now, where can I find the definition of an importer

for the purposes of this rule? For folks who are familiar with this rule at 40 CFR Part 705, you’ll

notice that the definitions also include most definitions under another part of Section 8 rules.

40 CFR Part 704 does define importer, and you’ll be able to see whether or not that is applicable

to you. How to determine if we are required to report? For example, there is a company that

is a manufacturer of gloves. Some of the gloves have water resistant coating on the gloves.

I would say first, you would consider whether you have possibly manufactured or imported any

reportable PFAS. In doing this, you would consult your existing knowledge, your company’s records,

and consider reaching out to your suppliers, if that is reasonable. Again, if there is no known or

reasonably ascertainable information that supports that you have manufactured a covered PFAS, then

reporting is not needed.

“What is the best way to collect the data for reporting? Do you suggest the

manufacturers work with third party consultants for guidance?” There is unfortunately not a

clear black and white answer for this that is universally true, because different strategies for

data collection work with different manufacturers or companies, or even in different industries. I

also really want to note that hiring consultants is not necessarily required to comply with this

rule, although that really depends on a company’s particular circumstances and what is reasonable

for their positions. EPA does understand and has estimated some people may do so. But do note

that, like the fact that testing is not required, hiring consultants may not necessarily

be required here just to comply.

  We had several questions or requests asking for examples of PFAS containing articles,

and I know I gave a few very quick ones earlier in the slides. But there were many variations

of – doesn’t or can an article include packaging, or a container holding another substance? To the

first question about examples of PFAS containing articles, there is no comprehensive list. In fact,

that may be part of the reason why we need this rule in the first place, because there is such

a data gap there and where PFAS can be found. It also really depends on two things. First, whether

a specific item actually meets that definition of article. I have had that definition on the slides

earlier on. But just keep that in mind, an item does need to meet that definition first. Secondly,

not everything that is an article may contain PFAS. There are some examples of articles that

might contain PFAS. It’s not universally true, but some of them that might may be things like textiles,

wires, electrical equipment or components, cookware, transportation equipment.

But I would encourage folks, if you’re looking for additional references, to actually check out

the economic analysis that EPA produced for this rule. That’s available in this rules docket. I’m

not sure if any of my colleagues at EPA who are on this call can maybe drop a link to that and  make that

accessible. But the economic analysis and one of the appendices actually contains a  helpful crosswalk

between the U.S. Trade Bureau’s Harmonized Tariff System codes and then examples of PFAS uses in

articles. There may be many other sources and different companies or industries, many have trade

groups that also have resources that are available to help identify potential PFAS.

Another question we received is if a manufacturer discovers a covered PFAS in their

chemical inventory, but the ultimate disposition, or the ultimate use of that was unknown,

should they report that listed PFAS or omit it? You would definitely report that PFAS, if you knew that

you had a PFAS that had been manufactured. You would report all the requested information, including

some of that downstream use or disposal information, to the extent you know or reasonably ascertain. If

you don’t know and cannot reasonably ascertain some of those data elements, you would simply report

KLRA – not known or reasonably ascertainable.

“Will there be a way to identify substances manufactured as R&D? This is as opposed to the

substances that would not qualify for that streamlined R&D manufactured form. Will there be a

checkbox or will there be other ways to flag that?” The answer to that is that as I mentioned, the

reporting tool application is still under development. But from what I know right now is that would be a

workflow you would identify at the start of reporting. EPA intends to have that selected initially,

and the user would then be directed to the correct questions or data elements for that type of form.

“Now, will chemical structures be required to be uploaded in a certain format?” I should flag

first that chemical structures should be reported again if known or reasonably ascertainable,

but it’s not needed if it is a class I substance on the TSCA inventory. If it’s a substance that’s

not yet on the inventory, or it’s class II, say it’s a polymer, or another variable composition,  and EPA, we

don’t already have that information. That would have to be provided if it’s known.  I believe that this

would be set up like PMN (pre-manufacture notice) submissions in that it would be simply an

attachment. When reporting the manufacture of a byproduct or impurity,  will there be a place to

indicate that this is a byproduct or impurity? Now, to be clear, any manufactured PFAS is reportable,

regardless of its production, as a byproduct or an impurity. Whether that PFAS was manufactured

intentionally or perhaps as a byproduct is not necessarily going to be marked differently on the form.

But under the law, there is a specific reporting section just for byproducts that

have been produced during the manufacturing, processing, use or disposal of a covered PFAS.

It’s possible you have another reportable PFAS that is a byproduct of one reportable PFAS.

But there’s no such similar section just for PFAS impurities.

Another question we received a few times was if health and environmental effects information,

for instance, test data was previously submitted to EPA, but not in IUCLID (International Uniform

Chemical Information Database) format or not under the OECD-harmonized template. Must that data be

reformatted to IUCLID and then resubmitted? The answer is no. If there is previously submitted

environmental or health effects data, it does not need to be resubmitted just to comply with that

OHT format. I need to stipulate that this assumes that the manufacturer will be able to provide the

information regarding the details of which program or under which rule the information was previously

submitted and in which year. For instance, a manufacturer may indicate they had submitted

information under TSCA Section 8(e) or a notice of substantial risk in 2010. This also does not

alleviate the requirement to ensure all existing health and environmental effects information is

submitted. That does again include that underlying monitoring or any other reports information.

“Are SDSs considered health and safety studies?” Yes, SDSs are part of that very large umbrella,

that is all existing environmental and health effects data. It’s very possible somebody has an SDS, but

that is not the only such data for a given PFAS. But that would certainly be submitted as part

of that larger category. Related to health and safety studies, there were questions regarding CBI claims

under health and safety studies.

The question is if a health and safety study was submitted before 2016, and that is so before

the Lautenberg Act was passed and TSCA was amended. If it was submitted before 2016 and had CBI

claims, must it be resubmitted in IUCLID format in order to reassert and re-substantiate the CBI claims?

Do keep in mind that the OECD or the IUCLID template requirement is not the same as a CBI related

requirement for this rule. As I said before, there were previous submissions of the environmental and

health effects information. Manufacturers don’t need to resubmit that here. They don’t need

to resubmit just for CBI compliance, but they would need to ensure that they have reasserted

and re-substantiated those CBI claims.

Question on the rule requiring all manufacturers of PFAS, including PFAS containing articles must

report this information for any year since 2011. Say a company imported PFAS in some of those years,

but not all. Does the company need to report information for each of those years? Yes. The

requirements are very clear, as it was written in the law, that this information would be reported

for each year that a PFAS was manufactured between 2011 and 2022. While I don’t have much

information to share right now regarding the reporting tool, I  can say that EPA is definitely working on

ways to minimize burden on things like reporting multiple years for the same chemical as much as

possible.

We did get a couple of questions related to the difference between this TSCA 8(a)(7) rule and

some other reporting rules, such as the TRI rule, that classifies PFAS as chemicals of special concern.

The questions were essentially asking, what are the differences? There are many differences.

For starters, there are different statutory authorities under which these rules are promulgated. There are

also very different purposes for reporting. This rule is notable in that it is a one-time retroactive

reporting rule. While it is limited to just manufacturers, so not processors, there are also no exemptions.

That is not the same case. In TRI, that is an annual ongoing reporting for specific types of facilities. It is

not limited to just chemical manufacturing facilities, but there are certain exemptions, such as

for articles that are not applicable to this TSCA rule. It’s also focused on the multimedia

releases and other wastes generated at facilities, whereas this is looking more at where the

manufacturing occurs.

I do want to be mindful of the time. Were there additional questions that came up in the chat

that I might be able to answer now and weren’t already addressed here?

Sarah or Katherine, feel free to chime in.

**EPA-1:** I had to find my mute button. So,

we’ve got a couple of minutes left, so I will read up a couple of other questions. “What are the

exemptions for PFAS reporting other than not reasonably ascertainable?”

**EPA-2:** That’s a good question. There are no exemptions. As I mentioned before, there

are some municipal solid waste importing activities that may not be covered here. The

not known or reasonably ascertainable is the reporting standard. It’s not an exemption because

what may be known to one company is not known to the other. But thanks for asking.

**EPA-1:** All right. “Do you have a good definition of manufacture, or can you point

to a good written definition?”

**EPA-2**: Yes, TSCA does define manufacturer. This rule also defines it. You can find this

definition and it includes a larger discussion or a larger

definition of manufacturing for commercial purposes at 40 CFR 705. EPA has also included

that in a lot of these guidance materials. You can find it and more plain language discussions of

it in the reporting instructions for instance.

**EPA-1**: Okay. “If the PFAS are used in a manufacturing

process but not found in the final article, is the manufacturer obliged to report?”

**EPA-2:** I don’t know from the information that was posed there, just because somebody

used a PFAS does not necessarily mean they manufactured one. It really depends on whether they

produced it or they imported it. Again, they should note, or manufacturers should be aware of not

limiting themselves to substances – or excuse me, not overlooking substances that may have been

inadvertently or coincidentally produced like a byproduct, for instance.

**EPA-1**: All right, let me grab one more, because I know we’re running out of time, but

“are packaging considered as imported articles?”

**EPA-2:** Yes. It is, assuming that the packaging material meets that definition of article. If

somebody knows or can reasonably ascertain that there is a PFAS in packaging material that they

imported, for instance, they would have to report. But again, it goes to what is known or reasonably

ascertainable. They don’t need to be testing plastic wrap, for instance, if that is what they have.

**EPA-1**: Well, we are at the end of our time today. There were, at one point, close to 3,000

of you on here.  Thank you all so much for coming. I know there’s still a lot of questions, but we’ll have

the Q&A from this and it’ll be part of our documentation. Also, everyone should have my email. Please,

if you have any additional questions, I’m happy to take those. Just FYI (for your information), I’m not the

one that can answer them, but I can take them and make sure they get to the right people.

I just want to thank all of you for coming. Also, just a special thank you to all of our fabulous interpreters

today that allowed us to offer this in different languages. We appreciate you. And with that, I hope

everyone has a great day or night and thank you so much. Take care.