

**Progress Implementing Changes to the New Chemicals Review Program under the Amended TSCA
Public Meeting Draft Agenda**

December 6, 2017, 9 a.m. – 5 p.m.
Horizon Ballroom, Ronald Reagan Building

- 9:00 a.m. Welcome
Nancy Beck, Ph.D., Deputy Assistant Administrator, Office of Chemical Safety and Pollution Prevention (OCSPP)
- 9:15 a.m. New Chemicals Decision-Making Framework and TSCA Orders and SNURs in the Context of New Chemicals Review
Jeff Morris, Ph.D., Director, Office of Pollution Prevention and Toxics (OPPT)
- 9:45 a.m. Questions on the Decision Framework
- 10:00 a.m. Points to Consider Document: Introduction - *David Tobias, Ph.D., Risk Assessment Division, OPPT*
- 10:20 a.m. Break (10 minutes)
- 10:30 a.m. Discussion of Points to Consider Document and Pilot Results (continued)
Pilot Panel
- *Greg Schweer, New Chemicals Management Branch Chief, OPPT (moderator)*
 - *Michael Hayes, Ph.D., Principal Researcher, Procter & Gamble*
 - *Marina Filler, Ph.D., Product Regulations Specialist, BASF Corporation*
 - *Elke Jensen, Ph.D., Risk Assessment Consultant & Product Toxicology Specialist, The Dow Chemical Company*
 - *Michael Walls, Vice President of Regulatory and Technical Affairs, American Chemistry Council*
- 11:00 a.m. Questions on the Points to Consider Document and Pilot
- 11:30 a.m. Public Comment
- 12:30 p.m. Lunch (1 hour)
- 1:30 p.m. Decision Guidelines Manual - *Maria J. Doa, Ph.D., Director, Chemical Control Division, OPPT*
- 1:45 p.m. Chemical Categories - *Tala R. Henry, Ph.D., Director, Risk Assessment Division, OPPT*
- 2:05 p.m. Sustainable Futures - *Tala R. Henry, Ph.D., Director, Risk Assessment Division, OPPT*
- 2:15 p.m. Questions on Afternoon Presentations and Discussion of Questions Submitted in Advance
Tanya Mottley, Acting Deputy Director of Programs, OPPT
- 3:00 p.m. Break (15 minutes)
- 3:15 p.m. Public Comment
- 4:45 p.m. Wrap Up - *Jeff Morris, Ph.D., Director, OPPT*

New Chemical Review under Amended TSCA

Jeff Morris

Office of Pollution Prevention and Toxics

US EPA

Public Meeting

December 6, 2017

Background



- New law requires EPA to make an affirmative finding on new chemicals or significant new uses of existing chemicals, before those chemicals can enter the market
- Chemicals under review at time of enactment were considered “resubmitted” and review period restarted; additional notices continued to come in, resulting in the need to re-review and “backlog”
- Backlog was eliminated in August 2017
- Current focus is to continue to improve processes to meet new requirements in law



Presents an unreasonable risk

- Section 5(f) order
- Section 6(a) proposed rule
- Restriction/prohibition of manufacturing, processing, distribution, or disposal

Not likely to present an unreasonable risk

- Commercialization can commence after the determination is made
- Section 5(g) – Statement in the FR

Information is insufficient to permit a reasoned evaluation of the risk.

- Section 5(e) – Regulation pending more information
- Section 5(e) order
- Testing generally required

Insufficient Information to permit a reasoned evaluation and may present unreasonable risk

- Section 5(e) – Regulation pending more information
- Section 5(e) order
- Testing generally required



Where the conditions of use identified in submissions raise risk concerns, if the submitters provide timely written amendments to their submissions addressing those concerns, in general EPA will consider the conditions of use in those amended submissions to be the intended conditions of use.



Where EPA has concerns with reasonably foreseen conditions of use, but not with the intended conditions of use as described in a submission (original or amended), EPA will assess whether those concerns can be addressed through significant new use rules (SNURs).

Decision Framework



As described in the risk evaluation rule, the identification of any reasonably foreseen conditions of use will be fact- or knowledge-specific: that is, it will be based on evidence, knowledge, or experience leading EPA to foresee conditions of use different from those described in the submission.

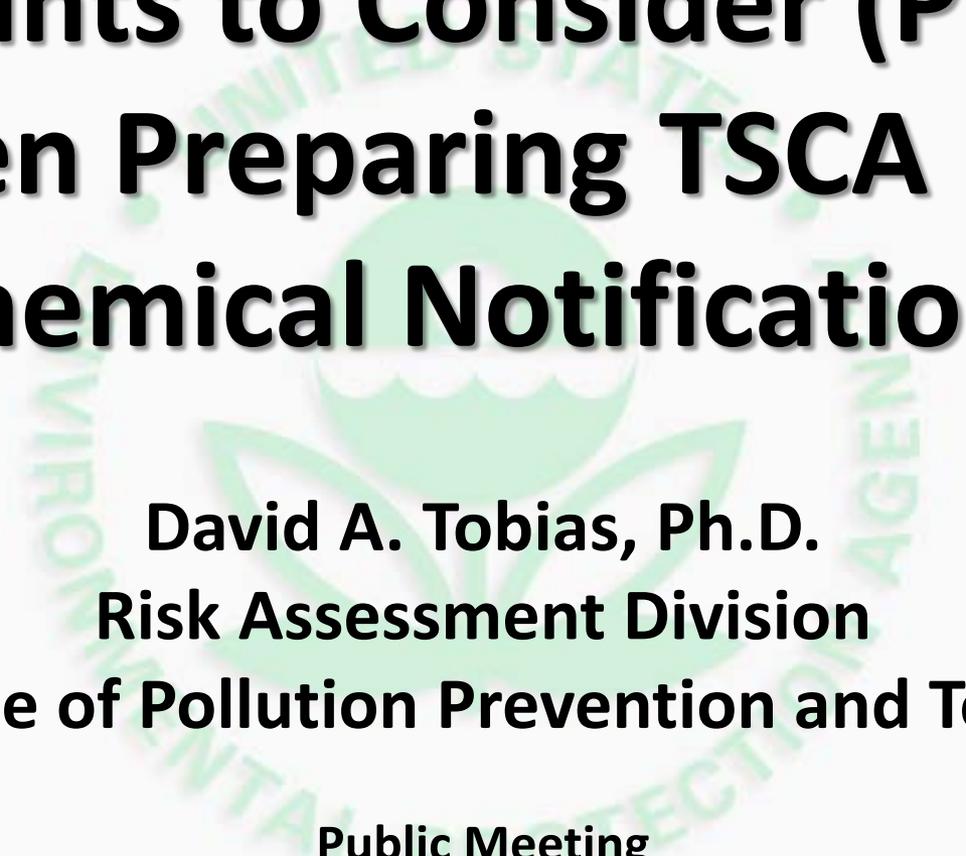
Decision Framework



Questions on the Decision Framework



Points to Consider (PtC) When Preparing TSCA New Chemical Notifications



**David A. Tobias, Ph.D.
Risk Assessment Division
Office of Pollution Prevention and Toxics**

**Public Meeting
December 6, 2017**

Outline of Draft PtC



- I. Purpose
- II. General Information Requirements
- III. New Chemical Process
- IV. Risk Calculations
- V. Focus meeting
- VI. Standard Review
- VII. Post-Submission
- VIII. Pilot and comments received

I. Purpose



- PtC provides concise guidance to improve PMN submissions – largely based on existing documentation, e.g., Sustainable Futures (SF)
 - PtC should reduce delays and back and forth with submitters
 - Two common problems in submissions
 - Provided information does not allow for refinement of risk assessment
 - Useful information that is in the submitter's possession is not provided at all → e.g., analog data
- Document sent out to industry participants for comment and as part of a pre-notice communication pilot

II. General Information Requirements



- Chemical identity
- Production, import and use
- There is not a base set of guideline testing (pchem, fate, ecotoxicity, human health) that must be provided

III.a. New Chemical Process



- Focus on information that can improve and expedite review
 - Consider a pre-notice consultation meeting
 - “Lower tier” than full PMN review
- Covers all sections of risk assessment including chemistry, hazard, worker/consumer/general population exposure, environmental fate and ecological exposure
- Includes descriptions of assumptions that are commonly made in the absence of information

III.b. New Chemical Process



- Know your chemical
 - Begin with p-chem followed by partitioning, absorption, metabolism, degradation...
 - Understand the chemical type for the submission and the relevant issues
 - Is the chemical likely to hydrolyze → the degradants will be important for ecotoxicity
 - Does your chemical fit in a new chemical category → Consider the described testing to determine potential data needs

III.c. New Chemical Process



- ▶ Examples of useful information
 - ▶ Particle size distribution
 - ▶ Strongly impacts worker exposure
 - ▶ Should target form of chemical that workers may be exposed to
 - ▶ In the absence of data, particles are assumed to be respirable
 - ▶ Descriptions of process information, particularly at submitter controlled sites
 - ▶ In the absence of data, EPA generic scenarios will be used to estimate worker exposures and releases → these estimates are intended to be conservative

III.d. New Chemical Process



- ▶ Human health hazard and ecotoxicity
 - ▶ Use physical chemistry to understand absorption and routes of exposure
 - ▶ Search for analogs and structural alerts
 - ▶ Know your chemical → understand metabolites and degradants
 - ▶ Is the data based on a guideline or related method
 - ▶ If not, EPA may ask for sufficient rationale for its use in the new chemical program
 - ▶ Non-guideline studies may be acceptable in certain situations

IV. Risk Calculations, V. Focus Meeting and VI. Standard Review



- ▶ Human health risk
 - ▶ Risk based on MOE for non-cancer (e.g., neurotoxicity) and slope factor for cancer
- ▶ Ecological risk
 - ▶ Acute aquatic risk – one day surface water concentration exceeds acute CoC
 - ▶ Chronic aquatic risk – twenty days or more of surface water exceedance above chronic CoC
- ▶ Focus meeting
 - ▶ Finalization of the initial risk assessment for the PMN
- ▶ Standard review
 - ▶ More in depth review of hazards and exposures for cases with complex concerns

VII. Post Submission Communication



- Please notify program manager of new submissions
 - Delays can occur due to large volume of communications across new chemical submissions
 - Please consider descriptive file names and separation of data into appropriate pieces when using CDX
- Consider use of binding option
- EPA may ask that you refine estimates of release and exposure based on
 - Control technology
 - Worker protections
 - Process descriptions
 - Use information

Additional Information



- Documentation was developed for the Sustainable Futures program
 - Contains description of most of the risk assessment process including models and tools
 - Gives insights on what types of engineering processes and releases will be calculated
 - EPA may request a rationale for changing release parameters away from the defaults typically entered into ChemSTEER™

Comments Received on PtC



- EPA received comments from industry participants to improve clarity and utility of PtC
- Some comments requested expanded scope, but this is meant to be a concise introduction → see references for more details

Comments Received on PtC



- Several comments on use of model vs submitted data on the new chemical substance or analog data
 - Risk assessment data hierarchy
 - High quality information on the PMN
 - High quality information on endpoint appropriate analog
 - Modeled data
- Why isn't submitted toxicity data used?
 - Possible flaws in study or insufficient description of test material or system
 - Submitted data doesn't address all of the needed endpoints
 - ➔ Data submitted for algae and daphnia but modeled data indicates highest hazard concern for fish

Comments Received on PtC



- EPA should provide a complete list of needed testing during pre-notice consultations
 - EPA is not in a position to provide a complete list at the pre-notice consultation stage
 - Testing recommendations for TSCA are commonly based on risk concerns via exposure pathways to identified populations (worker, consumer, general population, eco)
 - ➔ This requires all the steps of the risk assessment process, and these are not performed during the pre-notice consultation stage

Comments Received on PtC



- Requests for lists of worst case assumptions
 - Described in the Sustainable Futures material and defaults for the tools and models
 - ECOSARTM and EPISuiteTM have been programmed to provide conservative estimates
 - ChemSTEERTM allows for creation of conservative worker/release assessments
 - E-FASTTM can be run with SIC code options to evaluate low Stream-flow scenarios and the CEM model defaults to conservative consumer exposure assessments

Next Steps



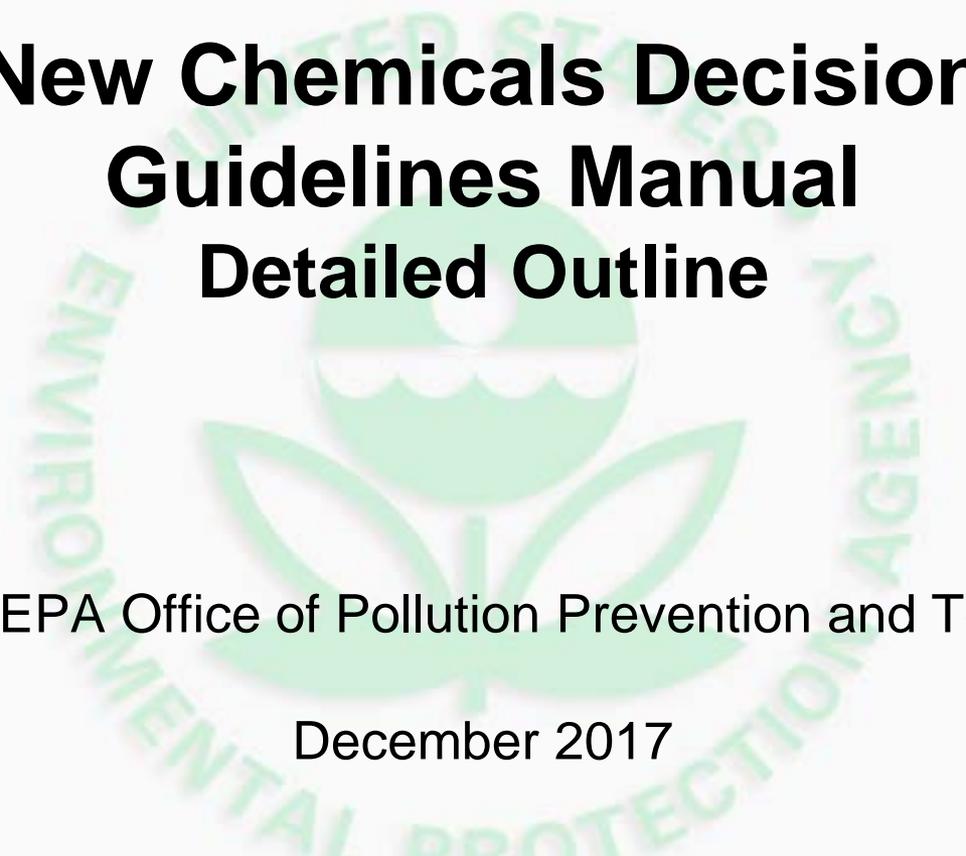
- EPA plans to seek further comments
- After meeting all pre-publication requirements, EPA will update draft PtC document and create an official version for use
- Once finalized, EPA encourages the use of the PtC document and pre-notice consultations to improve the efficiency of the new chemical program



New Chemicals Decision Guidelines Manual Detailed Outline

U.S. EPA Office of Pollution Prevention and Toxics

December 2017





Purpose of the Document

- Provide submitters and the broader public with information on how OPPT conducts its new chemicals assessments
- Help stakeholders determine what forms of regulation and restrictions might be imposed on the manufacture, processing, distribution, use, and/or disposal of a new chemical substance



Description of the Document

- Overview of
 - Review of new chemical submissions
 - Process OPPT follows
 - Policies and decision guidelines used in making decisions under TSCA section 5



Description of the Document

- Internal operational reference long in use to be a model
 - Based on the review of 55,000 new chemical submissions since 1979
- Will be updated to reflect amendments to TSCA under the Frank R. Lautenberg Chemical Safety for the 21st Century Act.



High Level Outline

- Introduction
- Pre-notice consultation
- TSCA section 5 applicability
- Conditions of use
- Estimating physical-chemical properties of chemicals
- Characterization of biotechnology submissions



High Level Outline

- Chemical categories
- Hazard assessment
- Environmental fate
- Chemical and biotechnology exposure assessments
- Exposure-based policy for chemicals
- Risk assessment



High Level Outline

- P2 framework
- Risk management
- Appendices
 - Appendix A Chemical Categories
 - Appendix B Exposure Assessment Tools and Models
 - Appendix C Sources of Information
 - Appendix D List of Acronyms



Comment on the Outline

- EPA is requesting comment on the detailed outline for the New Chemicals Decision Guidelines Manual
- Are there other sections that should be added?

Chemical Categories

Tala R. Henry, Ph.D.

Director

Risk Assessment Division

Office of Pollution Prevention and Toxics

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Chemical Categories¹



- **A chemical category** is a group of chemicals whose physicochemical and human health and/or ecotoxicological properties and/or environmental fate properties are likely to be similar or follow a regular pattern, usually as a result of structural similarity.
- The similarities may be based on the following:
 - a common functional group (e.g. aldehyde, epoxide, ester, specific metal ion);
 - common constituents or chemical classes, similar carbon range numbers;
 - an incremental and constant change across the category (e.g. a chain-length category);
 - the likelihood of common precursors and/or breakdown products, via physical or biological processes, which result in structurally similar chemicals (e.g. the metabolic pathway approach of examining related chemicals such as acid/ester/salt).
- As a result of these similarities, data gap filling in a chemical category can be carried out by applying one or more of the following procedures: read-across, trend analysis, and (external) (Q)SARs.

¹From: Guidance on Grouping of Chemicals, Second Edition, Series on Testing and Assessment No. 194; ENV/JM/MOMO(2014)4

EPA/OPPT's Use of Chemical Categories: Existing Chemicals



- Existing Chemicals – EPA and OECD High Production Volume Programs
 - Closely related chemicals are considered as a group, or category, for (hazard) assessment; Not every chemical needs to be tested for every endpoint
 - Facilitates estimation of hazard for untested chemicals/endpoints via “Read Across”
 - Efficient way to reduce animal testing and costs of assessment
 - OECD **Guidance on Grouping of Chemicals**, is based on the guidance originally developed by EPA for the HPV Challenge Program

	Chemical 1	Chemical 2	Chemical 3	Chemical 4	
Structure	xxxxxxxx	xxxxxxxx	xxxxxxxx	xxxxxxxx	
Property 1	● → ○	○	● → ○	○	SAR/Read-across
Property 2	● → ○	○	○ ← ●	●	Interpolation
Property 3	○ ← ●	●	● → ○	○	Extrapolation
Activity 1	● → ○	○	● → ○	○	SAR/Read-across
Activity 2	● → ○	○	○ ← ●	●	Interpolation
Activity 3	○ ← ●	●	● → ○	○	Extrapolation

● Existing data point ○ Missing data point

EPA/OPPT's Use of Chemical Categories: New Chemicals



- Substances which fall into New Chemical Categories are ***not necessarily the chemical substances of greatest concern*** to EPA.
 - Category Chemicals may not be made up of the most hazardous chemicals, but rather they include chemicals for which sufficient history has been accumulated so that hazard concerns and testing recommendations vary little from chemical to chemical within the category
- Grouping chemicals with shared chemical and toxicological properties into categories, enables both PMN submitters and EPA reviewers to benefit from accumulated data and past decisional precedents
 - Streamline/focus EPA's **hazard (fate) review**
 - Expedite identification and provide consistency for **testing recommendations**, when a chemical **“may present unreasonable risk”** [and under amended TSCA when **“insufficient information for reasoned evaluation”**]
- Categories are not intended to be a comprehensive list of all substances that may be subject to further action in the New Chemicals Program;
 - Currently 56 NCP Chemical Categories: 31 Eco Only; 17 Eco + Health; 8 Health Only
 - Continual updating/development as resources allow
 - Some new categories developed due to new TSCA

Chemical Categories: Same Principles, Different Purposes



	Existing Chemicals (OECD & EPA HPV Programs)	TSCA New Chemicals
Category is based on similar physicochemical properties, fate properties and/or health or eco hazards	✓	✓
Category Boundaries	Category Justification (Narrative): Pchem, Fate, Hazard Data/Trends to support Read-Across	Pchem properties or 'cut-offs'/bands to quickly designate chemical "in" or not
Specific Chemicals Identified/Listed	✓	✗ (many/most CBI)
Data-Sharing/Extrapolation	Read-Across; group assessment	"Best" Analog with data for endpoint; sometimes multiple analogs to cover various endpoints
Testing Recommendations	✗	✓

NCP Chemical Category: Definition/Development



- Candidate categories are proposed by EPA's New Chemicals Program reviewers, based on experience reviewing PMNs on similar substances
- At proposal, the database supporting the category is evaluated for quality and for general applicability to other potential members of the category
- New Chemical Category:
 - **Definition:** describes the molecular structure a new chemical must have to be included in the category
 - **Hazard Concerns:** hazard concerns for the category are identified based on literature or data for other PMNs
 - **Boundaries:** conditions such as molecular weight, equivalent weight, the log of the octanol/water partition coefficient (log P), or water solubility, that would determine inclusion in (or exclusion from) a category
 - **General Testing Strategy:** Identifies standard (e.g., OECD or OCSPP) hazard and fate tests to address concerns for the category

NCP Chemical Category: Use in Evaluation



- When a new substance is identified as being a member of a category, the chemical is evaluated in the context of the potential health or environmental concerns associated with that category
- Identification of a chemical as belonging in a NCP Chemical Category happens early, typically at SAT and hence, streamlines/focuses hazard assessment
- NCP Categories include Testing Strategies; hence, if testing is deemed necessary,
 - Identification of tests is expedited
 - Consistency in testing requests may be realized

Chemical Categories - New



- **4 Lung Effects Categories:** Polycationic Substances (Cationic Binding); General Surfactants; Waterproofing Agents; Insoluble Polymer Lung Overload
 - Need for definitive finding prompted search for more/quantitative data
 - Tiered testing strategy; includes in vitro (non-animal) testing approaches
 - Status: Working with submitters that 'suspended' PMN review to scope testing
- **Photo-Acid Generators (PAG) Category:**
 - 8(e) Data Submissions challenged previous assumptions
 - Tiered testing strategy; includes in vitro (non-animal) testing approaches
 - Status: Working with submitters that 'suspended' PMN review to scope testing
- **Tracer Chemicals:**
 - Received PMNs for over 100 structurally similar chemicals with same use
 - Strategically identified which chemicals to test and developed testing strategy
 - Status: strategic testing agreed; candidate for formal development of category
- **Perfluorinated Chemicals**
 - Approximately **400** chemicals in several structural categories (e.g., ethers, sulfonamides, sulfonic acids, phosphonic acids) compiled; Data (health tox, eco tox, fate) for **< half**
 - Next Steps: Data review; integrate with Agency-wide PFAS hazard characterization effort
 - Status: candidate for formal development of category

Chemical Categories - Future



- To date, new chemical category development has been based on:
 - Accrual of experience and desire to streamline reviews – first NCP Categories
 - Resource availability (NCP Categories updated periodically, as allowed)
 - Necessity – e.g., amendments to TSCA/definitive finding; new data challenging assumptions; large number of similar PMN submissions
- EPA is soliciting input/ideas on if/how to develop additional/update existing Chemical Categories; Docket:
EPA-HQ-OPPT-2017-0585 at <http://www.regulations.gov>

Sustainable Futures

Tala R. Henry, Ph.D.

Director

Risk Assessment Division

Office of Pollution Prevention and Toxics

**Progress Implementing Changes to the
New Chemicals Review Program under the Amended TSCA
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Sustainable Futures: Background



- New Chemical Reviews are mandated to be conducted in 90 days (absent extension)
- Most new chemical notices that EPA reviews lack test data needed to fully estimate potential risks
- Lacking experimental data, EPA has relied on screening methods to review and evaluate new chemicals under TSCA to help identify chemicals that could pose unreasonable risk
- Grew out of the Pollution Prevention Framework and Eastman Kodak Project XL and PPG Industries Project XL
 - Project XL (eXcellence and Leadership) was a voluntary program in which EPA offered regulatory flexibility to encourage companies, communities and others to develop/test cleaner, cheaper, smarter alternatives that could produce superior environmental results beyond those that would have been achieved under current regulations and policies.
- The methods, which EPA created, are the basis of the ***Sustainable Futures*** program and are available to the chemical industry and other stakeholders at no cost

Sustainable Futures: Goals



- To provide chemical developers the same risk-screening models that EPA uses to evaluate new chemicals before they enter the market
- To provide EPA's computer-based models and training in their use to help companies develop safer chemicals quickly and cost-effectively

<https://www.epa.gov/tsca-screening-tools>

- To provide companies that take the training and graduate from Sustainable Futures an expedited EPA premanufacture review

Sustainable Futures / P2 Framework Manual

**U.S. Environmental Protection Agency
Office of Chemical Safety and Pollution Prevention**

EPA-748-B12-001

2012



Sustainable Futures: Graduates



- BASF
- Cabot Corporation
- Cargill Incorporated
- Chevron Phillips Chemical Company
- Clariant Corporation
- Cytec Industries, Inc.
- Eastman Kodak, Inc.
- Givaudan Fragrances Corporation
- PPG Industries
- International Flavors and Fragrances, Inc.
- NALCO Champion, An Ecolab Company
- 3M

Sustainable Futures: Moving Forward



- Continue/Discontinue/Re-invent Program
- Increase/Decrease Training Workshops
 - EPA has conducted approximately 2-4 per year
 - Requires sponsors (industry, academia, other interested parties)
- Update on-line Sustainable Futures / P2 Framework Manual to reflect new TSCA
 - **Minimal technical changes;** Manual is largely step-by-step instruction/demonstration of the technical analysis EPA conducts using predictive models, which has not changed significantly under amended TSCA;
 - Reporting formats/transparency has increased
- Overlap with Points-to-Consider: PtC is 'short version' of SF/P2 Framework without chemical/specific examples or detailed information on predictive tools

Sustainable Futures: Moving Forward



Other Ideas/Input?

Docket EPA-HQ-OPPT-2017-0585 at
<http://www.regulations.gov>

Other Advance Questions

Tanya Hodge Mottley
Acting Deputy Director of Programs
U.S. EPA Office of Pollution Prevention and Toxics

December 6, 2017



Public Access to Information

- TSCA section 5(d) – each PMN “shall be made available, subject to section 14, for examination by interested persons”; status?
 - Sanitized PMNs and their attachments can be requested directly from the EPA Docket Center at: Phone: (202) 566-1744; Email: docket-customerservice@epa.gov
 - EPA is working to create electronic dockets for PMNs
 - Sanitized versions of signed consent orders are available in ChemView and using the PMN search tool



Public Access to Information

- “TSCA section 5(g) – “statement of Administrator findings” requirement for each “not likely” determination is inadequate in light of definition of “best available science”; status to release documents with actual basis for finding?
 - Requirements in section 26(h) with respect to best available science do not dictate specific content of the statement of Administrator findings under section 5(g); determination documents are available at:
<https://www.epa.gov/reviewing-new-chemicals-under-toxic-substances-control-act-tsca/chemicals-determined-not-likely>.
- Updates to EPA’s PMN status database/table for tracking PMN status are not occurring
 - EPA is still updating its final determinations on the web.
 - Previous terminology used for interim status created confusion; EPA is developing revised terminology for interim status and intends to resume updating that column once the effort is complete.



Confidential Business Information

- TSCA section 14 – EPA’s review of non-exempt CBI claims; status?
 - Per section 14(c)(3), EPA requires upfront substantiation of CBI claims
 - EPA is reviewing CBI claims as required under section 14(g)
 - On 1/19/17, FRN published giving submitters from 3/21 – 10/19/17 to substantiate all non-exempt CBI claims in submissions made from 6/22/16 – 3/21/17.
 - CBI claims in many submissions received during that timeframe have only recently been fully substantiated; we’re reviewing & making determinations.



Confidential Business Information

- How can the public track review results, ensure timeliness; how will EPA disclose decisions on CBI claims?
 - Disclosures required under TSCA Section 26(j) are subject to the disclosure restrictions in Section 14
 - EPA's confidentiality determinations, and the substantiations pertaining to those determinations, may themselves contain CBI
 - EPA is considering how best to publicly communicate various aspects of CBI review efforts, including the release determinations.



Unique Identifier

- TSCA section 14(g)(4) - requires that EPA, among other things, “assign a unique identifier to each specific chemical identity for which the Administrator approves a request for protection from disclosure....”; status?
 - Purpose of unique identifier is to provide a specific reference identifier that protects the confidentiality claim to the specific chemical identity for the claim duration, while providing a way for the public to identify other filings pertaining to that substance.
 - Per 5/8/17 FRN, EPA identified challenges re application of unique identifier requirements and requirement to protect specific chemical identity of valid CBI claims
 - 5/24/17 public meeting held to discuss issues; written comments accepted through 7/7/17
 - EPA is reviewing information collected and working to develop acceptable approach



Chemical Identity

- TSCA section 14(c)(4) – requires EPA develop guidance for generic names; status?
 - EPA has begun drafting guidance for generic names based on a review of statutory requirements, existing guidance, and current CBI review efforts for confidential chemical identities.
- TSCA section 8(b)(4)(C) – requires EPA “promulgate a rule that establishes a plan to review all claims to protect specific chemical identities of chemical substances on the confidential portion” of the TSCA Inventory; status?
 - EPA is engaged in the initial regulatory development processes to develop this required rule.



Risks to Exposed or Susceptible Subpopulations

- Evaluation of whether new chemicals “may present an unreasonable risk to a potentially exposed or susceptible subpopulation”
 - Relevant toxicity endpoints are compared to exposures that incorporate behavior patterns for subpopulations, as appropriate for the use and exposure scenarios for the chemical.
 - As an example, if a chemical has developmental concerns EPA will evaluate the drinking water exposures based on the higher amount of water consumed per body weight for young children if children are an exposed population.



Alternative Animal Testing

- TSCA section 4(h) – requires EPA to explain the basis for any decision that requires the use of vertebrate animals
- Request that EPA consider adding functionality to query ChemView by the decision reached and whether the use of animals is required, as well as to sort the output by date
 - EPA will explore the possibility of adding ChemView functionality as requested

New Chemicals Decision-Making Framework: Working Approach to Making Determinations under Section 5 of TSCA

November 2017

Introduction. This document outlines EPA’s approach to making decisions on new chemical notices submitted to EPA under TSCA section 5, as amended by the Frank R. Lautenberg Chemical Safety for the 21st Century Act. The Lautenberg Act amendments to TSCA require that EPA make affirmative determinations on notices received under section 5. The document begins with EPA’s general decision framework for new chemicals, and then works through how EPA intends to approach each of the five types of new-chemical determinations required under the statute. As EPA continues to gain experience with new chemicals decision making under amended TSCA, it expects to evolve this working approach to making determinations under section 5.

Overall framework

- New chemicals determinations are made using a risk-based approach, taking into account both hazard and exposure.
- The determinations of “presents unreasonable risk”¹ and “not likely to present unreasonable risk”² are made based on sufficient information to conduct a reasoned evaluation.³ If the Environmental Protection Agency (EPA) does not have sufficient information to conduct a reasoned evaluation, EPA may make a determination of “insufficient information”⁴ or “insufficient information and may present unreasonable risk.”⁵
- EPA may also make a finding of “substantial production and substantial or significant release or exposure.”⁶
- In its reasoned evaluation to determine whether a substance presents or is not likely to present unreasonable risk, EPA considers the potential adverse impact (e.g., severity or reversibility of effect) of the substance and/or its degradation

¹ See Toxic Substances Control Act (“TSCA”) § 5(a)(3)(A), 15 U.S.C. § 2604(a)(3)(A).

² See TSCA § 5(a)(3)(C), 15 U.S.C. § 2604(a)(3)(C).

³ Reaching an understanding of what constitutes a *reasoned evaluation* is central to making sound and transparent determinations. A reasoned risk-based evaluation will generally include adequate information to characterize both hazard and exposure, with an ability to shape those characterizations into a quantitative or robust qualitative characterization of risk. While under section 5 both “presents” and “not likely” determinations must be made through a reasoned evaluation, the wording of “presents unreasonable risk” is less equivocal than “not likely to present unreasonable risk.” This suggests that the level of uncertainty in a reasoned evaluation to inform a “not likely” determination could be greater than that in an evaluation to inform a “presents” determination.

⁴ See TSCA § 5(a)(3)(B)(i), 15 U.S.C. § 2604(a)(3)(B)(i).

⁵ See TSCA § 5(a)(3)(B)(ii)(I), 15 U.S.C. § 2604(a)(3)(B)(ii)(I).

⁶ See TSCA § 5(a)(3)(B)(ii)(II), 15 U.S.C. § 2604(a)(3)(B)(ii)(II).

“New Chemicals Decision-Making Framework: Working Approach to Making Determinations under Section 5 of TSCA,” page 1

products, and the nature of the potential exposures (e.g., duration, magnitude, population, etc.) under the conditions of use, including workplace practices and exposure controls. The evaluation also considers EPA's confidence in the data used in the risk estimate. For instance, if EPA's evaluation indicates a cancer risk based on a particular tumor type seen that is linked to a mechanism of action most relevant or predominant in an animal species (e.g., mediated via PPAR-alpha), how much confidence does EPA have—i.e., what is the likelihood—that the animal data indicate potential risk to humans? The concepts of reasonableness and likelihood are interrelated, and therefore need to be considered together in making a determination.

- In general, EPA considers the intended conditions of use to be the circumstances around manufacture, processing, distribution in commerce, use, or disposal as stated in the submission, original or amended. Such circumstances include engineering controls and other worker protections described in the submission.
- Where the conditions of use identified in submissions raise risk concerns, if the submitters provide timely written amendments to their submissions addressing those concerns, in general EPA will consider the conditions of use in those amended submissions to be the intended conditions of use.⁷
- Where EPA has concerns with reasonably foreseen conditions of use, but not with the intended conditions of use as described in a submission (original or amended), EPA will assess whether those concerns can be addressed through significant new use rules (SNURs). The expectation is that SNURs will generally be effective vehicles to address such concerns and that, as a general matter, EPA will address such concerns through SNURs.
- As described in the risk evaluation rule, the identification of any reasonably foreseen conditions of use will be fact- or knowledge-specific: that is, it will be based on evidence, knowledge, or experience leading EPA to foresee conditions of use different from those described in the submission.⁸

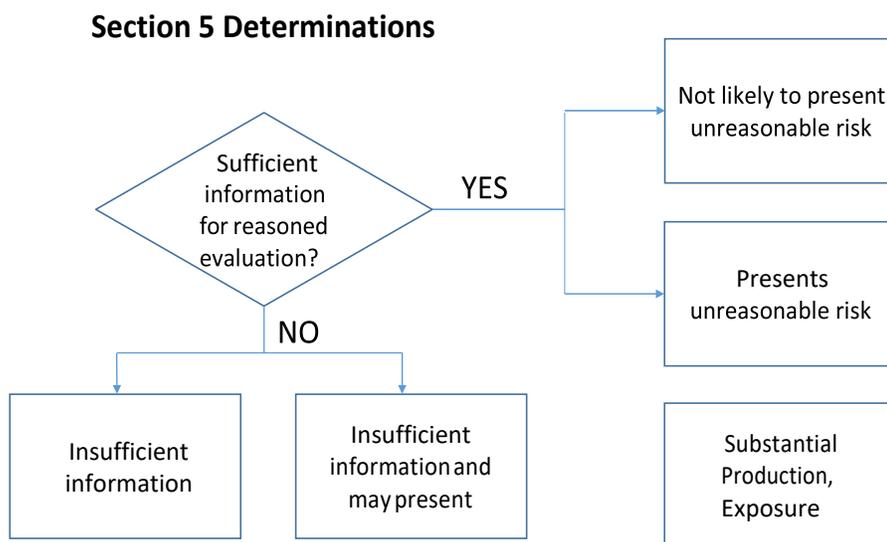
⁷ In general, “timely” means early enough in the review process to allow EPA to re-assess risks and make a determination within the applicable review period. In some cases, however, both EPA and the submitter may agree to suspend the review period to allow for a re-assessment.

⁸ An example of such knowledge would be information that an analog to the PMN substance (1) has known conditions of use not described in the PMN; and (2) EPA has experience, knowledge or information suggesting it is reasonably possible that the submitter or some other entity could use the PMN substance for the known conditions of use of the analog. Or, for example, EPA may determine that releases to water for the intended use will not exceed the concentration of concern (CoC), but larger releases could result in a CoC exceedance. In this case, it is reasonably foreseen that the CoC could be exceeded. The principle is that EPA should try to minimize speculation when identifying reasonably foreseen conditions of use.

- The purpose of testing in a section 5 order is to reduce uncertainty in making risk determinations. Specifically, it is generally to reduce uncertainty associated with assessments that gave rise to a finding of “may present unreasonable risk” or to an “insufficient information” determination. In addition, consistent with the statute, any request for testing by EPA will be structured to reduce and replace animal testing to the extent practicable and scientifically justified.

Determination-Specific Decision Frameworks

In the following discussions, EPA lays out general principles for making section 5 determinations and some of the factors considered. These discussions are not intended to be interpretations of what is required by TSCA or the range of discretion afforded by TSCA; nor are they a recitation of the elements of a specific determination. In addition, specific cases may present circumstances that are not addressed in these discussions or that warrant different approaches from those set out here.



Presents Unreasonable Risk

- As a result of the review process, EPA concludes that there is sufficient information to conduct a reasoned evaluation. That is, data on the chemical

substance or on analogs are adequate to characterize, with an acceptable degree of certainty, the hazard of the substance and its exposure potential.

- Health or environmental risks under the conditions of use are above risk benchmarks⁹; and
- Risk-related factors—such as severity of endpoint, reversibility of effect, or exposure-related considerations—lead EPA to determine that the risks are unreasonable under the conditions of use.
- EPA’s concerns regarding the conditions of use have not been adequately addressed through amendment of the pre-manufacture notice (PMN) made during the review period in conjunction with the issuance of a SNUR, or issuance of a SNUR without amendment of the PMN.

Not Likely to Present Unreasonable Risk

- As a result of the review process, EPA concludes that there is sufficient information to conduct a reasoned evaluation. That is, data are adequate to characterize, with an acceptable degree of certainty, the hazard of the substance and its exposure potential.
- Health and environmental risks for the conditions of use are below our benchmarks; or
- Health and environmental risks are above the appropriate benchmarks, but other risk-related factors—such as severity of endpoint, reversibility of effect, or exposure-related considerations (duration, magnitude, population, etc.)—lead EPA to determine that the risks are not likely to be unreasonable.¹⁰
- If EPA had concerns regarding the conditions of use, such concerns were adequately addressed through amendment of the PMN made during the review period in conjunction with the issuance of a SNUR, or issuance of a SNUR without amendment of the PMN.

⁹ Benchmarks here means estimated risks above which EPA generally has had concern. For example, a 1×10^{-6} cancer risk estimate has often been considered a “benchmark” above which EPA has concerns for exposure to the general population.

¹⁰ As stated in the risk evaluation final rule, in determining whether there are unreasonable risks, relevant factors include, but are not limited to: the effects of the chemical substance on health and human exposure to such substance under the conditions of use (including cancer and non-cancer risks); the effects of the chemical substance on the environment and environmental exposure under the conditions of use; the population exposed (including any susceptible populations); the severity of hazard (the nature of the hazard, the irreversibility of hazard); and uncertainties in the assessment.

Insufficient Information to Permit a Reasoned Evaluation

- As a result of the review, EPA determines that there is insufficient information to conduct a reasoned evaluation. That is, data (including for the chemical substance, for an analogous substance, from a predictive model, or a structural alert) are inadequate to characterize, with an acceptable degree of certainty, the hazard of the substance, and/or its exposure potential.
- The available information, such as on an analog or a structural alert, is not adequate to determine if there may be potential health or environmental concerns for the substance.
- EPA's concerns regarding the conditions of use have not been adequately addressed through amendment of the PMN made during the review period in conjunction with the issuance of a SNUR, or issuance of a SNUR without amendment of the PMN.

Insufficient Information to Permit a Reasoned Evaluation and May Present Unreasonable Risk

- As a result of the review, EPA determines that there is insufficient information to conduct a reasoned evaluation. That is, data are inadequate to characterize, with an acceptable degree of certainty, the hazard of the substance, and/or its exposure potential.
- However, there is some indication, such as by information on an analog or a structural alert, of potential health or environmental concerns for the substance.
- EPA's concerns regarding the conditions of use have not been adequately addressed through amendment of the PMN made during the review period in conjunction with the issuance of a SNUR, or issuance of a SNUR without amendment of the PMN.

Reasonably Anticipated to be Produced in Substantial Quantities and May Enter the Environment in Substantial Quantities or May be Significant or Substantial Human Exposure

- As a result of the review, and guided by EPA's established criteria, EPA determines that the substance is anticipated to be both produced in substantial quantities *and* be a significant/substantial source of environmental or human exposure or release.
- The statutory consideration of "reasonably be anticipated" should be considered equivalent to "reasonably foreseen" in terms of EPA having the evidence, knowledge, or experience to suggest that this finding is appropriate.

Overview of Comments Received on the Draft "Points to Consider" Document

Comment Number	Topic	Comment
1	Aquatic Haz/Tox	Section III. D. iii. What values are represented? LC50 or COCs?
2	Aquatic Haz/Tox	Section III. D. iii. Not clear why EPA will derive both acute and chronic COCs irrespective of hazard concern. Should be clarified; in general a substance of low concern based on measured or modeled data should not require a COC determination.
3	Aquatic Haz/Tox	Section III. D. iii. In general we have noticed more chronic testing being added to consent orders even for substances that are not acutely toxic; understanding the basis for that thinking would provide useful guidance to submitters.
4	Aquatic Haz/Tox	Section III. D. iii. It would be useful to include some explanation why this might be the case, and how this squares with a preference for measured data. Otherwise you might have testing in all 3 relevant species that is unnecessary; some additional guidance would be helpful.
5	Aquatic Haz/Tox	Section III.F.iii. What does EPA do for polymers? Needs to be addressed (in lieu of ECOSAR)
6	Aquatic Haz/Tox	Section III.F.iii. Need more information on this. EPA needs to provide guidance on how to address poorly soluble products as part of guidance doc't. Needs to addressed in Preconsult meeting.
7	Aquatic Haz/Tox	Section III.D.iii. Substances for which adequate chronic tox data are not available: What are the values in the table representing? Are they LC50 values or COCs?
8	Aquatic Haz/Tox	Section III.D.iii. We believe it would be more consistent and transparent to align the toxicity cutoffs with GHS (See below). This would simplify our hazard evaluations and hazard communication with our multiple stakeholders (regulators, our associates and our customers). (ref GHS? referencing table iii.)
9	Aquatic Haz/Tox	Section III.D.iii. Potential to align on BCF and log Kow with GHS as well
10	Aquatic Haz/Tox	Section III.D.iii. The document states that "Even if there are submitted ecotoxicity test data, EPA will generally use Ecological Structure Activity Relationships" If a submitter has already generated experimental data (for all 3 relevant species), the reliance on QSAR model results is confusing and could result in an overly conservative estimation vs. real data. This seems to be a waste of time and resources and could result in an inaccurate risk assessment.
11	Aquatic Haz/Tox	Section III.D.iii. The document states EPA should derive acute and chronic concentrations of concern (COC) irrespective of hazard concern. We believe a substance which is classified as "low concern" based on either modeling or data should not require a COC determination.
12	Aquatic Haz/Tox	Section III.D.iii. The document states that EPA recommends that a submitter provide both acute and long-term (chronic) aquatic data We have noticed chronic testing (chronic daphnia and early life stage fish testing) being added to recent consent orders even for substances that are not acutely toxic. Requiring chronic toxicity experimental data for products that are practically non-toxic seems like a waste of resources and unnecessarily uses additional animals.
13	Aquatic Haz/Tox	Section III.D.1.iii. Will EPA accept FET in place of fish?
14	Aquatic Haz/Tox	Section III.D.1.iii. Clarify if concern levels derived from hazard data alone? (ie. EC/LCx, NOEC only).

15	Aquatic Haz/Tox	Section III.D.1.iii. ECOSAR: Does the EPA have guidance on how to conduct these measurements for polymers, UVCBs, difficult to test substances?
16	Aquatic Haz/Tox	Section III.D.1.iii. EPISUITE: Does the EPA have guidance on how to conduct these measurements for polymers, UVCBs, difficult to test substances?
17	Aquatic Haz/Tox	Section III.D.1.iii. Please clarify how an acute fish study would be conducted at 10x the solubility limit? Fish only?
18	Aquatic Haz/Tox	Section III.D.1.iii. EPA recommends submitters provide the following information on the new chemical substance: Again, reference to the chemical categories document and exposure based testing policy would help make it clear what is expected
19	Aquatic Haz/Tox	Section III.D.1.iii. Are AFs 5 and 10, as mentioned above? Does EPA still follow Nabholz et al 1993?
20	Aquatic Haz/Tox	Section III.D.1.iii. Re justification of analogs: What is considered acceptable justification? A comparison of phys chem data alone, or more?
21	Aquatic Haz/Tox	In situations where EPA runs ECOSAR even when there are submitted ecotax data, in what situations will they use the ECOSAR data despite the actual test data?
22	Chemistry	Section III. C. A separate subsection on measured v. estimated data might be useful to reinforce the Agency's apparent preference for measured data. The subsequent discussion of ECOSAR raises a question about whether there is such a preference (page 17). It would be important for EPA to address what aspect of measured data might be considered unacceptable – it may not be able to be resolved in a pre-submission context, but describing the issue better would provide useful guidance.
23	Chemistry	Section III. C. Suggest footnoting to the flag or an example of its use on the Inventory.
24	Chemistry	Section III.F.ii. What kind of information? Concentration of new substance? What else? Where is this placed on the PMN form?
25	Chemistry	Can the EPA provide any guidance for larger polymers? Chemicals which do not dissolve fully in water?
26	Chemistry	EPA needs to provide information on polymers. The use of modelling is most appropriate for discreet chemicals, and not polymers.
27	Chemistry	Does EPA only model the portion where Mn<1000? Industry needs guidance on this.
28	Chemistry	Section III.A. Will EPA be prepared to discuss topics like poorly soluble chemicals, polymers, if respirable particles are an issue, etc.
29	Chemistry	Section III.F.ii. Need information on how EPA addresses polymers
30	Chemistry	Section III.C. RE: Concentration of dissociated (ionized)... Assume you refer to pKa? Will a measurement or modeled prediction (e.g., ACD Labs) suffice for pKa?
31	Chemistry	Section III.C. RE: measured values for p-chem properties, etc.: Suggest providing context that this information is used to predict environmental fate of the PMN substance.
32	Chemistry	Section III.C. Will EPA provide guidance for how to measure properties for polymers, UVCBs? For example, water solubility, log P.

33	Chemistry	Section II.A. Footnote 4: Suggest bolding text to place more emphasis on the importance of the chemical categories document. Make it clear that testing recommended by chemical categories document. Also suggest including reference to "TSCA Section 5(e) Exposure-Based Policy: Testing" and placing emphasis on the guidance therein.
34	Data	Section II.B. On page 20 EPA expresses concern about gross overestimates. These references might be rationalized to be guidance for avoiding either over- or under-estimates?
35	Engineering	Section III. E. i. Footnote 36: Are all these up-to-date? (Generic Scenarios)
36	Engineering	Section III. E. i. 1. Not sure how this squares with the earlier discussion (first bullet, subsection B, page 4) on underestimates of the PV values.
37	Engineering	Section III. E. i. 1. It is not clear how PPE supplied in a submission is accounted for in exposure assessments. Are they always run worst-case? May be helpful to clarify.
38	Engineering	Section III. E. ii. At the appropriate place it might be helpful to also reference the Sustainable Futures training materials on polymers and discrete organics, which are a helpful resources and provide good rule of thumb guidance on relevant substances.
39	Engineering	Section III. E. ii. Would be helpful to include in section III guidance to submitters on providing more information on the basis for suggested engineering and exposure controls, not just the values – that is, to provide substantiating information on the recommended approaches.
40	Engineering	Section III.E. The submitter may commit to PE limitations, but EPA may still find concerns under foreseeable uses. It would be helpful to expand on how EPA applies foreseeable use issues when reviewing a chemical which would meet PE as submitted
41	Engineering	Section III.F. EPA needs to understand the manufacturing process, and the impact of potential changes to the manufacturing process, prior to identifying these changes as a concern. Our experience has been that EPA has identified concerns when the potential change is not possible, or does not manufacture the same chemical.
42	Engineering	Section III.G.i.1. Historically, submitters would not submit name/model # as EPA could mandate that only that model would be used. Model # needs to be considered an example of the potential model which is used, and not make it a requirement to only use that model. PPE manufacturers change model #'s, improvements occur. It should not be a SNUN because the PPE changed model numbers.
43	Engineering	Section III.E.i.1 How is PPE information supplied in a PMN submission accounted for in the exposure assessments? Are they always run with worst case (no PPE) assumptions?
44	Engineering	We've seen cases when information on engineering controls was provided to the agency, however, the agency still used a worst-case scenario, with comments that this information was not substantiated. We'd like to get a clarification from the agency on this subject. Would it be possible to provide an example of what EPA finds an acceptable, substantiated information with respect to engineering controls?
45	Engineering	Are all the EPA Generic Scenario Documents available to the public? On a few occasions, we have come across a GS document that we were unable to locate. (Example: September 2001 GS on the Manufacture and Use of Printing Inks).

46	Engineering	Will the agency be recommending a method(s) for the aerosolized droplet size? (There seems to be a lack of guidance/methods for this type of test)
47	Environmental Release and Disposal Information	Section III.G.i.2. Many times, the processors/users of the new chemical do not want to divulge process information on how it will be used. This can include operating conditions, all unit operations, etc. They have a concern that divulging this information could make suppliers into competitors.
48	Environmental Release and Disposal Information	Section III.G.i.2. Also, how to ensure that PMN's which are support documents provide sufficient information on the process? It is out of the control of the manufacturer of the chemical.
49	Environmental Release and Disposal Information	Section III.G.i.2. This is a very difficult concept. It would be necessary to count fittings within each facility where the material is used, and then get information on their LDAR program. This is not realistic.
50	Environmental Release and Disposal Information	Section III.G.i.2. What type of supporting information? This is very difficult data to generate, especially since the material has yet to be commercialized in the US
51	Environmental Release and Disposal Information	Section III.G.i.2. For imported products, the majority of the exposure and environmental release data is from processors/users. As mentioned above, these companies typically do not want to divulge information on their process which may impact their market. Need to improve their education.
52	Environmental Release and Disposal Information	Section III.G.i.2. Would be very difficult to convince a processor/user to provide this information.
53	Environmental Release and Disposal Information	Section III.G.iv.1. What field is used for this information? is this distance to residential for the manu/process/use, or from NPDES discharge/landfill?
54	Environmental Release and Disposal Information	Section III.G.iv.1. Difficult information to generate, and most likely specific for each POTW based upon treatment method.
55	Environmental Release and Disposal Information	Section III.E.i.2. It would be good to include general guidance on WWT/POTW removal of polymers in this section. This information can come from the IAD for polymers (See below). (ref to table on POTW removal, different types of polymers)
56	Environmental Release and Disposal Information	Section III.E. i. 2. RE: Control technology efficiency (e.g., the incineration efficiency for a similar product formulation containing a similar chemical to the chemical substance is between 99.1-99.5%; be sure to provide the supporting information): What level of documentation needed? Are supplier specifications on equipment acceptable or are actual measurements required? These operations are typically regulated and monitored at the state or local level.
57	Fate	Section III. D. iii. There is potential to align BCF and log Kow with GHS as well.
58	Fate	Section III.F.ii. Please list test methods (p-chem and partitioning)
59	Fate	Section III.F.ii. As this is difficult for EPA, it is also difficult to impossible for a submitter. It is possible to learn who the third party is, but the performance and monitoring data would be problematic to obtain. What type of performance data is requested? (re: waste treatment facility performance info)

60	Fate	Section III.D.1.ii. Does this statement regarding the acceptance of non-GLP test data also apply to other non-animal studies?
61	Fate	Section III.D.1.ii. Typo - Due to (top of page 14)
62	Fate	Section III.D.1.ii. Substances not suitable for modeling: Will the EPA provide guidance on how to measure or estimating properties for polymers, UVCBs, and difficult to test substances? Ie, water solubility
63	Fate	Section III.D.1.ii. Are estimates acceptable, or is measured data needed for incineration efficiency? Is this controlled by local ordinances?
64	Fate	Section III.D.1.ii. Will expert judgment be acceptable based on data or information regarding water solubility, pKa (charge), biodegradability?
65	General	Section III. C. EPA might consider a separate subsection, or a list in an appendix, of the various points at which worst-case scenarios might be applied. This would help reinforce that the power of those scenarios is that they may compound conservative results and that additional information can help clarify.
66	General	How does a submitter ensure that information provided by the submitter to EPA at some point in the process is getting shared with other relevant decision-makers? Can EPA describe how the information provided to the Agency is compiled into a single file?
67	General	Section II.A. Footnote 4: Are these all up-to-date?
68	General	Section III.A. It would be helpful if EPA can, in the context of a pre-submission consultation, identify any missing information considered necessary for the review. The consultation is also an important opportunity to understand where there are potential areas of concern from the Agency's perspective (e.g., hazard and exposure), testing strategies that might be expected for a complete Agency review, and whether the substance falls in a category of concern. This is particularly important for so that submitters can ensure they've addressed those areas as much as possible. This guidance document certainly helps. The reasonably foreseen uses is an example of where discussion/feedback from the Agency would be helpful in the pre-submission process.
128	General	Section III. A. One risk is that the Points to Consider document simply becomes a useful checklist, and that the pre-submission dialogue becomes less valuable to EPA or the submitter.
127	General	Section III. A. Can this be made shorter and more certain? Even a response/confirmation of request within one week would be better than an uncertain 2-4 period. Moreover, a 2-4 week period may not provide much incentive for a submitter to avail themselves of the pre-consultation meeting if they are trying to meet potential customer demand.
69	General	Section III. A. Would be helpful to address how these discussions/meetings reflect confidentiality considerations? Are all these discussions considered confidential by definition?
70	General	Section III. D. It would be helpful to have upfront in the summary, and perhaps in a separate subsection, some guidance on access to all relevant reports like CRSS, SAT and engineering reports, analog choices, etc. This might also be covered in post-submission communications between the Agency and submitters.

71	General	Section I.2. PAGE 2 This is also a good place to note that submitters should address category and structural alerts and may need to bring additional information forward. - "Specific details" and "additional information"
72	General	Timeline to get a chemical to market can be critical. Customers may show an interest to a chemical, but will continue their application development and select a different product if that chemical will not be available in a timely fashion. The development of the information which is recommended in the attached will take, at a minimum, an extra year to develop. This will have a significant impact on the ability of US companies to bring new chemicals to market. We may need to submit PMN's earlier, without having definitive information on exactly how the customer will be using the chemical. We may also need to submit PMNs on multiple chemicals instead of the best option, as this may reduce the timeline to market.
73	General	Section III.E. It would be interesting to understand how EPA conducts an open literature search, especially in context of foreseeable uses
74	General	Section III.F.iii. Need to know location on submission, and type of data requested (e.g., SF form, or other assessments)
75	General	Appreciate transparency willingness to reach out to stakeholders; borrows from SF and is a valuable guidance document; reinforces importance of doing your homework.
76	General	It would be beneficial if the draft document referenced the EPA Interpretive Assistance Documents (SF Training Materials) for both Polymers and Discrete Organics. These guidance docs are a great resource and help to provide "rules of thumb" when assessing new substances
77	General	Our understanding is that the agency breaks up a submission into various pieces and only hands out specific info to those reviewing their area of expertise. Often we lose time going back and forth with the agency, providing information to individuals that had initially been included in the original submission. This valuable info can drastically change the outcome of a reviewer's decision if they default to worst case. How does a company ensure that all the information they provide to the agency in a PMN gets to all the necessary individuals reviewing a submission the first time?
78	General	Somewhat related to the previous bullet. With a large amount of data submitted, it is more likely that a key piece of information may not make it into the hands of the right reviewer, negatively impacting the assessment.
79	General	Is it possible for companies to provide too much information?
80	General	Would there be value in providing generic examples of what a "good" PMN submission would look like with all the key information the agency would need to make decision?
81	General	Would there be value in providing a list of EPA default "worst-case" assumptions for various key endpoints when conducting the risk assessment?
82	General	Since TSCA reform, has there been any regulatory relief with a combined TME and PMN with a full P2 assessment for a graduate of Sustainable Futures?
83	General	Section 1 Purpose and Background Overview of NCR Process diagram - suggest depicting communication points between EPA and PMN submitter

84	General	Can a submitter request in the PMN cover letter (at the time of PMN submission) that if an engineering and/or exposure report is generated during the 90-day PMN review, submitter would like to receive a copy of the report after it's sanitized by EPA? Would EPA consider in-advance request for engineering/exposure report?
85	General	The document indicates on pages ##11 and 17 regarding review of "...other information, such as a review by another international agency..." Does this mean that we can submit a review done by Canada for an NSN for the same substance for consideration? Also, If REACh data is available, and we are not a registrant, can we summarize the data for the PMN substance (or a surrogate chemical) and indicate that the data is part of a consortium; therefore, we don't have access to the full reports?
86	General	When PMN is similar to previous PMN substances can submission be streamlined by assigning same review team.
87	General	Prenotice submission process: Helpful to review submission packages for missing information, testing strategies, category concerns, etc,
88	General	Should automatically provide submitter with engineering, risk assessment and other reports including Focus group notes within 5 working days of finalization. This will facilitate discussions.
89	Human Health Haz/Tox	Section III. D. iii. Suggest aligning the human health toxicity cutoffs with GHS, which would also simplify hazard evaluations and communications by submitters to multiple audiences.
90	Human Health Haz/Tox	Section III.D.i. How are the human health score of (low = 1, moderate = 2, or high = 3) derived? A table similar to the ecotox hazard/toxicity section (iii) with LD50 or NOAEL/LOAEL values would be helpful identifying key studies endpoints submitters should look for. Leveraging GHS classification criteria would be preferable
91	Human Health Haz/Tox	Section III.D.1. There is a good explanation of how a score is determined in the Env. Fate and effects section. A similar description would be helpful in this section.
92	Human Health Haz/Tox	Section III.D.1. RE: Human Health Score: Do these health score values have quantitative criteria as they do for the environmental scores?
93	Human Health Haz/Tox	Section III.D.1. RE: T Score - thresholds? Or refer to page 13
94	Human Health Haz/Tox	Section III.D.1.i. RE: Footnote 15: Suggest referencing TSCA chem cat doc and exposure based policy testing;
95	Human Health Haz/Tox	Analogs: Would like more information on selection process. Recognize CBI is a challenge.
96	Human Health Hazard/Tox	Section III. C. With respect to analogs, we often cannot determine whether the Agency is using the proposed analogs or using different ones. There are particular issues with respect to analogs on the Confidential Inventory, of course, but it is difficult to have a productive dialogue on analogs if submitters do not understand the basis. Further clarification would also help on the use of analogs when measured data is provided.

97	Human Health Hazard/Tox	Section III. C. Suggest that a separate subsection on analogs be considered, particularly to provide guidance on the type of information that will be useful in assessing submitter-recommended analogs.
98	Human Health Hazard/Tox	Section I.2. page 2 It would be helpful to provide an example or two under each of these subparagraphs. For example, the lack of a full study may cause subsequent delays, and the lack of documentation that a submitter-recommended analog behaves in a particular way may similarly push EPA to rely on its choice of analog.
99	Human Health Hazard/Tox	Section II. C. Might be helpful to explain why EPA wants full study reports. This seems to be one area where there is a back-and-forth between the Agency and submitters and an area where delays might occur if the Agency has to get the full study.
100	Human Health Hazard/Tox	Section III. C. Would also be helpful to address in this section the value of other information that might be available, e.g., Robust Study Summaries from the EU. While there may be questions about the quality of the summary, it would help note the existence of potentially relevant information. It would be helpful to be specific about addressing even the effects not considered relevant for human or environmental exposures.
101	Human Health Hazard/Tox	Section III. D. i. The environmental fate section provides important detailed guidance on how EPA conducts its review, and a similar level of detail for human health would be helpful, especially for acute and chronic health hazards. A human health chart on points of departure would be useful.
102	Human Health Hazard/Tox	Section III. D. i. How are the human health scores derived? A table similar to the ecotox hazard/toxicity section with LD50 and NOAEL/LOAEL values would be helpful for identifying key study endpoints submitters should look for. Might be also helpful to align with GHS classification criteria.
103	Human Health Hazard/Tox	Section III. D. i. The potential for toxicity in relation to a PBT score is confusing. Apparently acute hazards do not play a role but how the Agency arrives at a qualitative score of 2 for the listed endpoints is not specified.
104	Human Health Hazard/Tox	Section III. D. i. Here and on page 17 regarding the submission of other information. Can a submission in another jurisdiction (e.g., a NSC in Canada) for the same substance be included? If EU REACH data is available, but the SIEF agreements prevent submission of the full study, can the Robust Study Summary or an explanation be provided?
105	Human Health Hazard/Tox	Section III. D. i. Suggest using the term as it appears in section 26(i) of TSCA. "scientific evidence"
106	Human Health Hazard/Tox	Section III.A. Will EPA provide information on potential analogues which they have information on?
107	Human Health Hazard/Tox	Section III.F.i. The reference defining structural alerts should be here.
108	Human Health Hazard/Tox	Section III.F.i. Need to define what information from a review by another international agency should be included. Also, need to indicate where in the PMN application this type of information should be placed.
109	Human Health Hazard/Tox	Section III.F.i. EPA should provide an example document to demonstrate how to do this justification (e.g., Analog ID)

110	Human Health Hazard/Tox	Section III.E. If the chemical has the potential for lung effects but the PMN use does not include a spray application, will EPA request particle size information? What is the best approach for data generation to ensure EPA does not assume worst case (respirable particles)? Can EPA provide further guidance on when there is a concern on respirability?
111	Human Health Hazard/Tox	Section III.D.i. Potential for toxicity in relation to PBT score is confusing. The document states that acute hazards do not play a role here but does not specify how the agency arrives at a qualitative score of a 2 for the listed human health end points, which would result in further engineering and exposure review.
112	Human Health Hazard/Tox	Section II.C. A full report or standard literature citation: Clarify that this is something such as a HERA report or an integrated safety assessment. Does this also apply to company technical reports?
113	Human Health Hazard/Tox	Expand guidance on how it evaluated human health hazards/tox. Similar to Fate and Aquatic tox. Charts and thresholds would be helpful.
114	Regulatory	Section III.F.i. Does this mean that EPA want to know the global inventory status for each PMN substance, or the submissions for inclusion to an international inventory which has been submitted by the submitter?
115	Regulatory	Section III.G.i.2. This is very difficult information to obtain. Not all NPDES require removal efficiencies, and they may not be willing to divulge this information, nor their WWTP technologies.
116	Regulatory	Section 1 Purpose and Background First para - does LVE also include TME?
117	Release to Water	Section III.E. ii. 1.RE: POTW removal: Will the EPA consider experimental data from simulated WWTP studies showing >90% removal? What data is needed to get above 90-95%?
118	Standard Review	Section VI. Might be helpful to include in an appendix a summary of the timing from submission to decision. The website has a narrative description but I recall at one point there being a "flow-chart" with estimated time frames.
119	Uses	Can additional guidance on how EPA determines foreseeable uses be provided? These uses will drive the non-order SNUR process and some basic understanding of how EPA is reaching those decisions would be helpful
120	Uses	Section III.F.i. Again, how to address foreseeable uses for particle size?
121	Uses	Section III.A. Will EPA provide information on foreseeable uses?
122	Uses	Would it be possible to obtain better definition on how EPA interprets foreseeable uses? We've seen it expanded into changes to manufacturing procedures, and varying monomer ratios for polymers. Is there any guidance on what EPA looks at, where they find this information, and how it impacts the evaluation?
123	Uses	Clarity needs to be provided for how EPA will interpret foreseeable uses for changes in manufacturing processes for chemicals which are imported. It has not been required to submit manufacturing process data for imported products. This needs to be clarified in the guidance document if this will required going forward. It is impractical to determine a change to a manufacturing process as a foreseeable use if there is no information on the current process.

124	Uses	Section 1 Purpose and Background First para - footnote 2 - suggest including as text not footnote, given its importance (reasonably foreseen, intended uses)
125	Uses	Section II.B. Recommend emphasizing importance of Use Information for a risk-based review
126	Uses	Can EPA provide some basic guidance on how they determine foreseeable uses?
127	General	EPA should use a tiered assessment framework that is risk-based, not hazard-based
128	General	All chemicals present hazards but a safe set of use conditions can generally be defined.
129	General	EPA must make an effort to help incorporate alternative and mechanistic approaches and not be satisfied with only mentioning these approaches.
130	Chemistry	Section II A. EPA should consider updating the Chemical Categories document with new categories (e.g., lung effects)
131	Chemistry	Section III C. CRSS - re: absence of particle size distribution, assume respirable: There are industry data and accepted practices on certain spray applications such as consumer spray cleaners that indicate such sprays generate non-respirable. Agency should consider this.
132	PreNotice Meetings	Section IIIA. Para 1 - WRT Prenotice meetings - Submitters want to use the prenotice meetings to identify potential areas of concern, so they can be addressed prior to submission. Otherwise it is just a checklist.
133	Human Haz/Tox	Section III Di For relevant routes of exposure there are accepted methods that allow for extrapolation between routes.
134	Human Haz/Tox	Section III Di RE: consideration of metabolic pathways, species sensitivities and mechanisms - would like more details. Would AOPs be helpful? MOA data on analogs sufficient?
135	Human Haz/Tox	Section III Di Re: selection of analogs - provide sufficient justification. Recognize CBI concerns.
136	Human Haz/Tox	Section III Di Re accept information submitted/reviewed by other agencies but want more guidance on how it could be submitted
137	Human Haz/Tox	Section III Di states that we "require information on short-term and long-term exposure" Notes that the data should be generated according to the type/length of application
138	Human Haz/Tox	Section III Di - agree that absorption is important. EPA should use proven tools and models like they do for REACH
139	Fate	Section Di EPA should continue accepting tools other than MITI as long as the model is well defined and valid, the output is documents, results are interpreted correctly - same for other endpoints
140	Aquatic Haz/Tox	Section III Dii Why will the agency use ECODSAR even if data are submitted - hopefully just to fill data gaps? Please clarify
141	Environmental Release and Disposal Information	The current framework is that hazard profile of a new chemical determines the need for exposure and risk assessment. Similar criteria should be established to use exposure potential to determine the requirement for hazard information. E.g., no exposure potential should justify less hazard information required. This is consistent with our general comment that the assessment should be risk-based other than hazard-based.
142	Aquatic Haz/Tox	WRT Difficult to test: We appreciate EPA being open to discussing testing protocols, but EPA should commit the resources to ensure that this happens on a timely scale. Otherwise, innovation and new product development are slowed or stopped.

143	Aquatic Haz/Tox	Section IIID Provide justification for consideration of the analog for the endpoint(s) identified." EPA should provide guidance on the degree of justification that is being requested and what will or will not be acceptable.
144	Engineering	Section III D. The link to EPA Generic scenarios does not work: https://www.epa.gov/tsca-screening-tools/using-predictive-methods-assess-exposure-and-fate-under-tsca#fate
145	Engineering	Section III.E. Environmental Releases/Exposure Assessments (page 20) - EPA should consider the use of higher tier exposure tools, such as those developed for EU REACH assessments, including, but not limited to the ECETOC TRA, ART (Advanced reach tool), EUSES, ConsExpo, and others.
146	Engineering	Section III.E.i.2. Environmental Release and Disposal Information (page 25) - EPA should provide a link to guidance for the "Leak Detection and Repair program" such as (but not necessarily) https://www.epa.gov/sites/production/files/2014-02/documents/ldarguide.pdf
147	Exposure	Section III.E.ii. Non-Occupational General Population, Consumer and Environmental Exposures (page 26) - "...non-occupational and environmental exposure assessments are generally performed if there are hazard concerns..." All chemicals have hazards. Should this be exposure concerns? Or potential risk?
148	Risk	Section IV. Risk Calculations (page 30) - this is the first section of the draft guidance document which does not utilize a capital letter (e.g. "A") for the first level subsection. Instead, it moves directly to lower case Roman numerals (e.g. "i").
149	Risk	Section IV.i. Human Health Risk Assessment (page 30) - we agree that a MOE approach is an appropriate way to evaluate risk, but EPA should be open to probabilistic approaches of assessing risk and implementing risk management measures.
150	Risk	Section IV.i. Human Health Risk Assessment (page 30) - EPA states that if "...test data on a new chemical substance indicates it elicited dermal sensitization, EPA generally identifies the new chemical substance as a potential respiratory sensitizer as well..." - We disagree with this approach since the two mechanisms for sensitization differ. It is one thing to use dermal sensitization as a flag for additional evaluation, but it is another thing (and too far) to use it as an identifier.
151	Risk	Section IV.i. Human Health Risk Assessment (page 30) - "...if there are potential inhalation exposures to workers from a suspected respiratory sensitizer, EPA may qualitatively identify respiratory sensitization as a potential risk for workers." - EPA should explain how these qualitative risks will be assessed and managed, since they are generally not amendable to a MoE approach. Similarly for carcinogenicity, in the absence of a quantitative risk assessment.

Keyword	Comment Numbers
Foreseeable Future	57, 60, 63, 65, 66, 68, 73, 93
Polymer	2, 18, 26, 34, 39, 40, 59, 60, 61, 65, 75, 80, 124
Sustainable Future	8, 124
PMN	3, 6, 8, 17, 21, 25, 47, 53, 55, 64, 67, 71, 72, 77, 84
COC	11, 15, 115, 118 1, 2, 18, 22, 26, 34, 39, 40, 50, 56, 57, 59, 60, 62, 63, 67, 81, 92, 97, 99, 103, 105, 109, 110, 119, 120, 124,
Guidance	125



DRAFT

Points to Consider

When Preparing TSCA

New Chemical Notifications

Office of Pollution Prevention and Toxics

November 6, 2017

This document provides EPA scientific approaches, best practices, and other general guidance that are not binding on either EPA or any outside parties. The document discusses existing statutory and regulatory requirements, but does not create new requirements.

This document is a draft published for comment. Do not rely on this draft document for guidance regarding submissions under Section 5 of TSCA.

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I. PURPOSE AND BACKGROUND

The purpose of this document is to provide concise information from the United States Environmental Protection Agency (“EPA”) to assist submitters in preparing a Premanufacture Notice (“PMN”), Significant New Use Notice (SNUN)¹, or exemption notice (*e.g.*, Low Volume Exemption or LVE) (hereinafter collectively referred to as “notifications”) that (1) meets the requirements of TSCA Section 5 and applicable regulations and (2) facilitates EPA’s review of Section 5 notices by ensuring that the information received accurately and completely reflects the intended² manufacture, processing, distribution in commerce, use, and disposal of the new chemical substances subject to the Section 5 notice. The information contained in this document can be found, along with more details, in EPA’s Instruction Manual for Reporting Under the Toxic Substances Control Act §5 New Chemicals Program at <https://www.epa.gov/reviewing-new-chemicals-under-toxic-substances-control-act-tsca/instruction-manual-reporting-under>.

New Chemical notification is a requirement under section 5 of the Toxic Substances Control Act (“TSCA”) and corresponding regulations which notifies EPA of a company’s intent to manufacture (which under TSCA includes import) a new chemical substance.³ PMNs must include data specified in 40 CFR Part 720 and on the PMN form (*i.e.*, EPA Form 7710-25 (Rev. 6-09)), available at: https://www.epa.gov/sites/production/files/2015-10/documents/final_pm_n_print_form070709.pdf, regarding chemical identity, impurities, synonyms/trade names, byproducts, production volume (“PV”), uses, and site information including identity, process descriptions, worker exposure information, information on release to the environment, including the quantity and media of release and control technology used. 40 CFR § 720.50 requires submission of test data in the possession or control of the submitter, parent company, or affiliates, which are related to the effects on human health or the environment. Other data concerning the human health and environmental effects of the new chemical substance that are known to, or reasonably ascertainable by, the submitter must also be described by the submitter as part of the PMN. SNUN requirements are specified in 40 CFR § 721.25, and requirements for premanufacture notification exemptions are specified in 40 CFR part 723.

Under section 5(a)(3) of TSCA, EPA determines that either (1) the new chemical substance or significant new use presents an unreasonable risk of injury to human health or the environment (§5(a)(3)(A)), (2) the information on the new chemical substance is insufficient to make a

¹ While the discussion regarding data to be submitted and EPA’s review and analysis applies equally to review of PMNs, SNUNs and exemption applications, for simplicity’s sake this discussion will refer to PMNs.

² While EPA welcomes any information that submitters can provide on the conditions of use associated with reasonably foreseen uses, in most cases this information may be limited. Therefore, the Points to Consider document focuses on information that may inform EPA’s evaluation of intended uses (*i.e.*, those identified in the notification and any amendments). As stated in EPA’s *Procedures for Chemical Risk Evaluation Under the Amended Toxic Substances Control Act*, the identification of ‘reasonably foreseen’ conditions of use will necessarily be a case-by-case determination, and will be highly fact-specific. See: Federal Register (2017), Vol. 82, pp. 7562-7580.

³ SNUNs are submitted pursuant to a Significant New Use Rule (SNUR) promulgated under TSCA § 5(a)(2) by companies that manufacture or process for the Significant New Use described in the SNUR.

reasoned evaluation of the health and environmental effects (§5(a)(3)(B)(i)), (3) the new chemical substance may present an unreasonable risk of injury to health or the environment (§5(a)(B)(ii)(I), (4) the new chemical substance is or will be produced in substantial quantities, and such substance either enters or may reasonably be anticipated to enter the environment in substantial quantities or there is or may be significant or substantial human exposure to the substance (§5(a)(B)(ii)(II), or (5) the new chemical substance is not likely to present an unreasonable risk of injury to human health or the environment (§5(a)(3)(C)). EPA either grants or denies exemption notifications according to 40 CFR 720.38, 40 CFR part 723 and section 5(h)(4) of TSCA. These determinations are the result of EPA's evaluation process, referred herein as the New Chemical Review process. This evaluation process is described in detail in EPA's Sustainable Futures/P2 Framework Manual, available at:

<https://www.epa.gov/sustainable-futures/sustainable-futures-p2-framework-manual>.

The regulations require certain information from submitters when they complete and file notifications with the Agency (see, *e.g.*, 40 CFR Part 720 and Part 723). In the absence of that information, EPA typically makes conservative assumptions, which oftentimes lead to the practice of delayed reviews and frequent suspensions because submitters choose to work with the Agency to provide and/or develop additional information. This document is intended to reduce the frequency of this practice. EPA has identified two basic scenarios that often lead to delays in reviewing notifications in the New Chemical Review process:

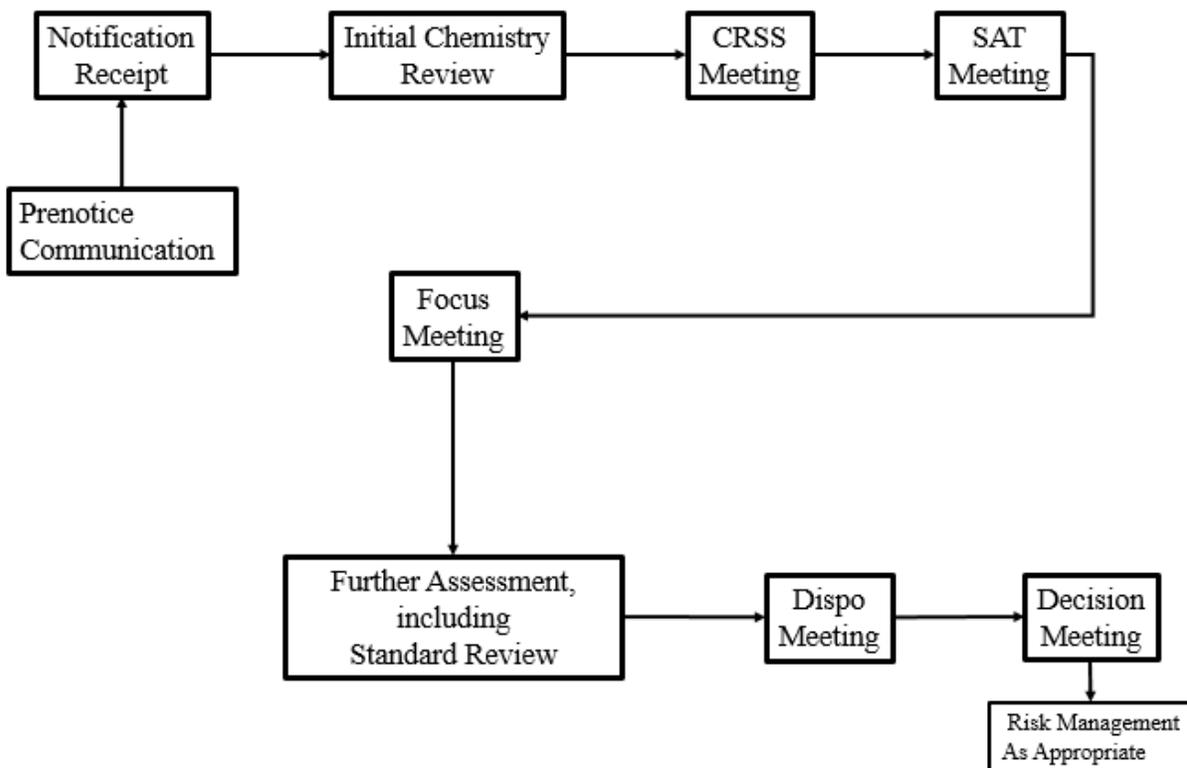
- (1) The provided information lacks specific details, which precludes EPA from using the information in lieu of generally conservative assumptions, and
- (2) Additional information, which would aid EPA with refining its assumptions, are not provided by the submitter in the original notice, are not in the possession or control of the submitter, or are not generated until after the initiation or completion of the New Chemical Review process.

Notifications that lack detail typically result in follow-up or additional interaction with submitters, which in turn, adds time to the New Chemical Review process. If the submitter provides additional information, EPA will generally conduct additional analyses and/or re-evaluate the notification in light of the additional information. In an effort to ensure that notifications are not delayed, EPA encourages submitters to review and to consult this document while preparing their notifications, so they understand the utility of submitting complete information with the original submission.

The information provided in this document provides an overview of the New Chemical Review process and how EPA evaluates notifications. The format is to begin with a description of information required to be submitted to EPA electronically via the Internet using EPA's Central Data Exchange (CDX)) on EPA Form 7710-25 (Rev. 6-09) (see:

https://www.epa.gov/sites/production/files/2015-10/documents/final_pmnn_print_form070709.pdf), then to describe each step of the New

Chemical Review process, as shown in the following diagram, and finally, to provide recommendations on types of information and/or specificity of information that will facilitate a more refined evaluation of new chemical substances.

Overview of the New Chemical Review Process^a

^a Abbreviations: CRSS = Chemistry Review and Search Strategy; SAT = Structure-Activity Team; Dispo Meeting = Disposition Meeting

II. GENERAL INFORMATION REQUIREMENTS FOR NOTIFICATIONS

The information in this section is required to be entered on EPA Form 7710-25 (Rev. 6-09). If there is not a section on the form to enter the information, it must be provided to EPA as an attachment. Note: Citations to the Code of Federal Regulations (CFR) are made where specific types of information are required; however, these only serve as examples. Submitters should read the relevant regulatory provisions to ensure submissions comply with all of the information requirements, prior to submitting a notification to the New Chemical Review process.

A. Chemical Identity and Physical-Chemical Property Information

The New Chemical Review process requires an accurate depiction of the chemical identity and molecular structure (or representative structure(s)) and description of physical-chemical properties of the chemical substance. The presence of functional groups and basic physical-chemical properties of a chemical substance are used by EPA to determine what hazards and exposure pathways may be expected and relevant for the chemical substance. This information is also used to determine if a chemical substance belongs in one of EPA's established TSCA New

Chemicals Program Chemical Categories.⁴ Guidance to follow to avoid submitting an incomplete PMN can be found at: <https://www.epa.gov/reviewing-new-chemicals-under-toxic-substances-control-act-tsca/guidance-avoiding-incomplete>.

*Submitters are required to provide the following information on EPA Form 7710-25 (Rev. 6-09).*⁵

- A correct Chemical Abstracts (“CA”) Index name. *See, e.g.*, 40 CFR 720.45(a)(1)(i).
- Consistent chemical identity information throughout the notification. For example, submitters are required to make sure that the chemical identity on page 4 of EPA Form 7710-25 (Rev. 5-95) matches the manufacturing diagram.
- Information on polymers on page 5 of EPA Form 7710-25 (Rev. 5-95). *See, e.g.*, 40 CFR § 720.45(a)(2).
- As much structurally descriptive information as possible for chemical substances of unknown or variable compositions, complex reaction products and biological materials (“UVCBs”).
- A generic name that is only as generic as necessary to protect the confidential chemical identity of the new chemical substance. The name should reveal the specific chemical identity to the maximum extent possible. *See*, TSCA Section 14(c)(1)(C), 40 C.F.R. § 720.85(a)(2)(ii), and <https://www.epa.gov/sites/production/files/2015-08/documents/genericnames.pdf>.

B. Domestic Production, Import, and Use Information

*Submitters are required to provide the following information on EPA Form 7710-25 (Rev. 5-95).*⁶

- An estimate of the expected maximum 12-month PV to be manufactured (includes both domestic production and import) during any 12-month period during the first three years of production. Submitters are required to avoid underestimating, as this may influence future activity depending on the results of the risk evaluation. *See, e.g.*, 40 CFR § 720.45(e).
- The expected percentage of total chemical substance PV for the first three years of production for each category of use. For example, 50% of the PV will be used for coatings and 50% of the PV will be used for inks. *See, e.g.*, 40 CFR § 720.45(e).
- Appropriate product and/or article use categories and functional use categories for the chemical substance⁷. *See, e.g.*, 40 CFR § 720.45(f).

⁴ EPA’s established TSCA New Chemical Program Chemical Categories can be found at: https://www.epa.gov/sites/production/files/2014-10/documents/ncp_chemical_categories_august_2010_version_0.pdf.

⁵ See generally, 40 CFR § 720.45 “Information that must be included in the notice form”

⁶ *Id.*

⁷ The OECD Working Party on Exposure Assessment (TFEA) has developed guidance documents for reporting releases, use of exposure models, reporting monitoring information, and reporting exposure information (<http://www.oecd.org/env/ehs/risk-assessment/oecdactivitiesonexposureassessment.htm>). Definitions of use codes, emission scenario documents, and additional guidance will be posted to this website over time.

- Specific percent of total PV of the chemical substance used for all uses described in the notification. *See, e.g.*, 40 CFR § 720.45(f).
- Specific concentrations (weight fraction) used in all consumer applications. *See, e.g.*, 40 CFR § 720.45(f).
- The identity of all sites controlled by the submitter where the chemical substance will be manufactured, processed, or used. *See, e.g.*, 40 CFR § 720.45(g)(1).
- Accurate estimates (in ranges) of the number of manufacturing, processing and use sites. *See, e.g.*, 40 CFR § 720.45(g)(2).
- A process description of each manufacture, processing, and use operation controlled by the submitter, including a diagram of the major unit operations and chemical conversions, the identity and entry point of all feedstocks, and the points of release of the chemical substance. *See, e.g.*, 40 CFR § 720.45(g)(2). Accurate representation of the process aids EPA in determining potential release and exposure points and improves the accuracy and overall quality of the engineering assessment.
- Worker exposure information at all sites controlled by the submitter, including worker activities, physical form of the chemical substance to which workers may be exposed, the number of workers, and the duration of activities. *See, e.g.*, 40 CFR § 720.45(g)(3).
- Information on release of the new chemical substance to the environment, including the quantity and media of release and type of control technology used. *See, e.g.*, 40 CFR § 720.45(g)(4).
- A description of each type of processing and use operation involving the chemical substance for sites not controlled by the submitter, including identification of the estimated number of processing or use sites, situations in which worker exposure to the chemical substance will occur, the number of workers exposed and the duration of exposure, and controls which limit worker exposure. *See, e.g.*, 40 CFR § 720.45(h).

C. Test Data

*Submitters are required to provide the following data in their possession or control on the chemical substance:*⁸

- All test data in the submitter’s possession or control which are related to the effects on health or the environment of any manufacture, processing, distribution in commerce, use, or disposal of the new chemical substance or any mixture or article containing the new chemical substance, or any combination of such activities. This includes test data concerning the new chemical substance in a pure, technical grade, or formulated form. *See, e.g.*, 40 CFR § 720.50(a)(1).
- A full report or standard literature citation for the following types of test data (*See, e.g.*, 40 CFR § 720.50(a)(2):
 - Health effects data.
 - Ecological effects data.
 - Physical and chemical properties data.

⁸ See generally, 40 CFR § 720.50 “Submission of test data and other data concerning the health and environmental effects of a substance”

- Environmental fate characteristics.
- Monitoring data and other test data related to human exposure to or environmental release of the chemical substance.
- Completed full study reports. *See, e.g.,* 40 CFR § 720.50(a)(3)(i).

In addition to providing the required test data, submitters may consider providing full study reports, if available, of any other test data the submitter considers to be important for EPA to consider, e.g., test data on analogs. Providing full studies streamlines the review process and allows EPA assessors to determine study quality, completeness and suitability and to evaluate study outcomes.

III. THE NEW CHEMICAL REVIEW PROCESS AND THE IDENTIFICATION OF ADDITIONAL INFORMATION THAT CAN EXPEDITE AND REFINE THE REVIEW

A. Pre-Notice Consultation

Pre-notice Consultation meetings are recommended by EPA. These meetings should only cover topics related to the preparation of a notification and the completeness of a notification to enter the New Chemical Review process. These meetings are not intended to obtain EPA decisions on the content and likely outcome from the New Chemical Review process. For example, EPA will not make a determination at a Pre-notice Consultation meeting on whether there may or may not be potential risks to human health and/or environmental receptors, nor will EPA make a risk management finding (*e.g.*, not likely, may present, or will present).

Prior to requesting a Pre-notice Consultation, submitters should review the Points to Consider document. Many of the questions that EPA receives during Pre-notice Consultation meetings are addressed in this document, and submitters may determine after reading this document that a Pre-notice Consultation meeting is not necessary. In the event that submitters still have questions about their notifications, Pre-notice Consultations generally consist of the following steps:

- Initial Request for a Pre-notice Consultation meeting
 - EPA encourages submitters to submit a written request to EPA’s Chemical Control Division. The request will ideally include the following types of information:
 - Identity of the chemical substance,
 - Type of submission (*e.g.*, PMN, SNUN, or an exemption),
 - Description of proposed and reasonably foreseeable uses,
 - A list of issues the submitter wishes to raise for EPA’s consideration, and
 - Summary of any previous discussions involving EPA staff on the issues
- Timing for EPA’s response and determination on the necessity of a Pre-notice Consultation meeting
 - EPA generally responds to Pre-Notice Consultations within two to four weeks of receipt.
 - Following receipt, EPA will discuss with the requester whether a written response or meeting/teleconference is preferred.
- Conduct of the Pre-notice Consultation meeting
 - The meeting may take place by telephone or in person, depending on the submitters’ location and availability.
 - EPA will take notes during the meeting and will record who attended.
 - The meeting length should generally be from one to no more than two hours in length, although many Pre-notice Consultation meetings are completed in less than an hour.

- EPA will respond to the submitter’s questions about EPA’s initial written responses on the submitter’s issues and will clarify those responses to the extent possible during the meeting.
- Summary of the Meeting
 - Upon request, within 10 working days of the Pre-notice Consultation meeting, EPA will provide a set of minutes to the submitter that describes the matters that were discussed, any commitments made by EPA or the submitter, and any conclusions reached at the meeting.

B. Initial Chemistry Review

Following receipt of a notification, the Initial Chemistry Review is conducted. EPA reviews the notification for completeness—that is, to ensure that required information in specific sections of EPA Form 7710-25 (Rev. 5-95) is provided.

C. Chemical Review and Search Strategy (“CRSS”) Meeting

Hazard and exposure assessments are informed by the physical-chemical properties of a chemical substance. The CRSS meeting of the New Chemical Review process includes an examination of the following:

- TSCA Inventory status;
- chemical identity;
- structure/chemical nomenclature;
- structural analogs;
- synthesis (including byproducts and impurities);
- use as provided in the notification, identified in an open literature search, or as identified by EPA for similar chemical substances, including whether the use is regulated by TSCA;
- physical-chemical properties (*e.g.*, physical state, molecular weight, melting and boiling point, vapor pressure, solubility, octanol water partition coefficient, pH); and
- pollution prevention aspects,⁹ using information provided in the notification.

Decisions at the CRSS meeting include notice completeness, validity, eligibility for exemption or exclusion, and candidacy for exposure-based review (*i.e.*, PV greater than 100,000 kg/year).

The hierarchy of data sources EPA uses to determine physical-chemical property data is as follows, with the most reliable source listed first:

- Measured values from submitters or primary references.

⁹ For more information, see: New Chemicals and Pollution Prevention Efforts, Reviewing New Chemicals under the Toxic Substances Control Act, available at: <https://www.epa.gov/reviewing-new-chemicals-under-toxic-substances-control-act-tsca/new-chemicals-and-pollution>

- Estimated values based on chemical analogs.¹⁰
- Estimated values generated using computer models.¹¹
- Estimated values based on common chemical structure or type.

EPA often receives notifications where the following types of relevant information have not been generated, prior to submitting the notification:

- Measured values for the chemical substance including at least the basic physical-chemical properties (e.g., water solubility, vapor pressure, melting point, and octanol/water partition coefficient).
 - In the absence of data, EPA will generally utilize chemical analogs and/or computer models to estimate these properties.¹²
- Particle size distribution or droplet size analysis data if the chemical substance is manufactured or processed as a particulate or used in aerosolized spray applications. EPA will often have particular concerns for respirable particles/droplets less than 10 µm (micrometers) that have the potential to enter the deep lung. The particle size distribution analysis should be based on the form of the substance to which the workers may be exposed, e.g., post-transport.
 - In the absence of data, EPA will generally assume the chemical substance is respirable.
- The concentration of the dissociated (ionized) and undissociated (neutral) forms of an acid, base, or organic salt in water. The degree of ionization or dissociation may have a substantial impact on the resulting risk assessment.
 - In the absence of data, EPA will generally assess a worst-case scenario—for toxicity, fate, and exposure.

Consideration of whether the chemical substance qualifies for the polymer exemption. A formal commitment, by the submitter, to adhere to the conditions of the polymer exemption (see 40 CFR § 723.250) could allow the chemical substance to be included on the TSCA Inventory with a regulatory flag, once the company has sent the Notice of Commencement (“NOC”). This would expedite the review process, if EPA’s finding on the notification is “not likely to present an unreasonable risk.”

D. Structure Activity Team (“SAT”) Meeting

¹⁰ For more information, see: EPA (2012) 3. *Getting Started by Identifying Existing Data*, Sustainable Futures / P2 Framework Manual, EPA-748-B12-001, available at: <https://www.epa.gov/sites/production/files/2015-05/documents/03.pdf>

¹¹ For more information, see: EPA (2012) 5. *Estimating Physical / Chemical and Environmental Fate Properties with EPI Suite™*, Sustainable Futures / P2 Framework Manual, EPA-748-B12-001, available at: <https://www.epa.gov/sites/production/files/2015-05/documents/05.pdf>

¹² The predictive methods that EPA has developed to screen chemical substances include expert systems, *in silico* methods, analog analysis and read across, among other approaches. EPA also has access to additional information that cannot be made public because it is protected as “confidential business information” (“CBI”) under TSCA.

At the SAT meeting, an interdisciplinary team of chemists, biologists, toxicologists, and information specialists evaluate test data on the new chemical substance (when available), data on analogs, and structure activity relationships (SARs) to formulate initial characterizations on Human Health Hazard/Toxicity, Environmental Fate, and Aquatic (Environmental) Hazard/Toxicity. Below is a summary of the New Chemical Review processes employed to identify and summarize the available data for each of these assessment components prior to the SAT meeting. The discussion begins with how EPA performs its evaluation for each of these components, followed by types of information submitters may provide to facilitate EPA’s review of the new chemical substance.

i. Human Health Hazard/Toxicity

EPA evaluates hazard endpoints both qualitatively (*e.g.*, irritation, respiratory sensitization, mutagenicity), as well as quantitatively (*e.g.*, points of departure from experimental studies), when data are available. The purpose of the human health hazard/toxicity evaluation is to preliminarily characterize or identify the following in preparation for the SAT meeting:

- Absorption by the relevant exposure routes.
 - In the absence of submitted experimental absorption data, the SAT uses absorption data from analogs, or physical-chemical properties [*e.g.*, vapor pressure, water solubility, molecular weight, and log K_{ow}] to provide a qualitative estimate of absorption [*e.g.*, nil, poor, moderate, or good].
 - When no data are available—for the chemical substance or an analog—EPA may assume, based on the properties of the new chemical substance, that absorption could be 100% by any/all routes.
- Potential hazards associated with the new chemical substance based on data provided with the notification.
- Confirm selection of analogs¹³ for informing the identification of potential hazard(s).
- Hazard key words for the new chemical substance (*e.g.*, irritation, sensitization, or lung overload). The SAT also reviews safety data sheets provided by the submitter for their characterization of hazard key words.
- Relevant routes of exposure (*e.g.*, dermal, inhalation, fish ingestion, and/or drinking water).
- The human health score (low = 1, moderate = 2, or high = 3); a hazard value greater than 1 will initiate the engineering and exposure assessments (note, an ecotoxicity hazard score greater than 1 will also initiate these assessments), The human health score is typically based on qualitative considerations such as hazard

¹³ Information on selection of analogs is available from the following resources:

EPA (2012) 9. *Analog Identification Methodology (AIM)*, Sustainable Futures / P2 Framework Manual, EPA-748-B12-001, <https://www.epa.gov/sites/production/files/2015-05/documents/09.pdf> and <http://www.oecd.org/chemicalsafety/risk-assessment/groupingofchemicalschemicalcategoriesandread-across.htm>

- endpoints¹⁴. For example, endpoints such as developmental/reproductive toxicity or carcinogenicity may lead to scores of 2 or 3.
- Potential for toxicity (“T”) for the overall persistent (“P”), bioaccumulative (“B”), and toxicity (“PBT”) score. The “T” score is numeric, but is determined qualitatively; a score of 2 is needed for P, B, and T to designate the new chemical substance as a PBT [*i.e.*, P2B2T2 = PBT]).
 - The T score (in the overall PBT score) is based on developmental/reproductive and/or chronic hazards to the general population, and/or to chronic hazards to aquatic organisms (see Section III(C)(iii)); it is not designated for acute toxicity (*i.e.*, mammalian or aquatic organisms) and is not typically used for hazards identified by the dermal or inhalation routes of exposure, as these types of toxicity and exposure routes are not typically associated with P and B chemicals.

When making the above determinations, EPA reviews new chemical substances in the following manner:^{15, 16, 17, 18}

- Review structure, physical-chemical properties, and structural alerts.
 - Consider molecular shape and size, fundamental physical-chemical properties, presence and position of reactive functional groups, charge density, minimum cross-sectional diameter of molecules, octanol/water partition coefficients, potential for absorption, metabolic pathways, species sensitivity, and mechanisms of toxicity.
 - Consider potential metabolites or degradates.

¹⁴ Information on structural alerts is available here:

¹⁵ For more information, see: EPA (2012) 8. *Non-Cancer Human Health Hazard Screening Protocol*, Sustainable Futures / P2 Framework Manual, EPA-748-B12-001, available at: <https://www.epa.gov/sites/production/files/2015-05/documents/08.pdf>

¹⁶ For more information, see: EPA (2012) 9. *Analog Identification Methodology (AIM)*, Sustainable Futures / P2 Framework Manual, EPA-748-B12-001, available at: <https://www.epa.gov/sites/production/files/2015-05/documents/09.pdf>

¹⁷ For more information, see: EPA (2012) 10. *Predicting Carcinogenicity Potential Using OncoLogic™*, Sustainable Futures / P2 Framework Manual, EPA-748-B12-001, available at: <https://www.epa.gov/sites/production/files/2015-05/documents/10.pdf>

¹⁸ For more on exposure-based testing, see: <https://www.epa.gov/reviewing-new-chemicals-under-toxic-substances-control-act-tsca/exposure-based-policy-under-section>

- Determine if chemical (or metabolite or degradate) fits within a TSCA New Chemicals Program Chemical Category¹⁹, or if the structure contains structural alerts for toxicity²⁰.
- Identify hazards associated with the category and/or structural alerts.
- Review submitted data.
 - Identify hazards associated with or addressed by the submitted data.
 - Determine if the data are suitable for the identification of a point of departure (e.g., no observed adverse effect level [NOAEL], lowest observed adverse effect level [LOAEL], or benchmark dose lower bound [BMDL]) for quantitative risk estimation, or if they can be used for qualitative risk estimation (e.g., sensitization data).
- If there is a Sustainable Futures submission, or other information, such as a review by another international agency, review hazard information for data on the submitted chemical, an analog, or models.
 - Identify hazards associated with or addressed by the submitted data.
 - Determine if the data are suitable for the identification of a point of departure (e.g., NOAEL, LOAEL, or BMDL) for quantitative risk estimation, or if they can be used for qualitative risk estimation.
- Check for analogs. This step is often necessary even if toxicity data are submitted because: submitted data may not address a hazard concern identified based on chemical structure (e.g., category²¹ or structural alert) or the submitted data are for a route of exposure other than those relevant for the new chemical substance.
 - Analogs suggested by submitter,
 - Analogs identified during CRSS,
 - Search for analogs using AIM,²² ChemIDplus Advanced,²³ OECD QSAR Toolbox,²⁴ etc.
- Determine (based on data) or estimate (based on physical-chemical properties) absorption by route of exposure (i.e., inhalation, dermal, and/or oral).
- Considering totality of available data:
 - Determine hazards associated with the chemical substance.

¹⁹ For more information, see: EPA (2010) TSCA New Chemicals Program (NCP) Chemical Categories, Office of Pollution Prevention and Toxics, U.S. Environmental Protection Agency, Washington, D.C., 157 pp., available at: https://www.epa.gov/sites/production/files/2014-10/documents/ncp_chemical_categories_august_2010_version_0.pdf

²⁰Information on structural alerts is available here: <http://www.oecd.org/chemicalsafety/risk-assessment/guidancedocumentsandreportsrelatedtoqsars.htm>

²¹ EPA (2010) *supra* note 16.

²² The Analog Identification Methodology (AIM) Tool is publicly available software, that is available for download at the following: <https://www.epa.gov/tsca-screening-tools/analog-identification-methodology-aim-tool>

²³ ChemIDplus Advanced is an online TOXNET Database maintained by the U.S. National Library of Medicine, available at the following: <https://chem.nlm.nih.gov/chemidplus/>

²⁴ The OECD QSAR Toolbox is publicly available software, that is available for download at the following: <http://www.oecd.org/chemicalsafety/risk-assessment/oecd-qsar-toolbox.htm>

- Provide hazard summary.
- Identify points of departure suitable for use in risk assessment and the basis for their selection.

Considerations:

- The following types of information are useful to the New Chemical Review process. If the submitter concludes that any or all of this information is not applicable or relevant to the new chemical substance, providing an explanation or rationale for why such toxicity information is not relevant for the intended use of the chemical substance could inform and expedite EPA's evaluation. If the information is developed, submission would be required by TSCA § 5 and 40 CFR Part 720.
 - Information related to potential human health hazards from short-term exposures.
 - Information related to potential human health hazards from long-term exposures.
 - For experimental data, identify what is considered to be the NOAEL, LOAEL, no observed adverse effect concentration ("NOAEC"), or lowest observed adverse effect concentration ("LOAEC") and explain the rationale (endpoint/measure) for identifying these benchmarks.
- Submitters should consider whether the new chemical substance has been submitted to/reviewed by another international agency (*e.g.*, Health or Environment and Climate Change Canada, European Chemicals Agency, National Industrial Chemicals Notification and Assessment Scheme, *etc.*). If so, it could be useful to provide those submissions and/or supporting information with the PMN.
- Submitters should consider whether the structure of the new chemical substance has any structural alerts²⁵ (*e.g.*, mutagenicity, oncogenicity, sensitization, and/or reproductive/developmental toxicity). Many of these "alerts" are well recognized/established and required as part of classification and labelling in other jurisdictions, hence providing this information can inform EPA's review.
- For any new chemical substance that may potentially be respirable (either as particulates, liquids, mists, or aerosols), submitters should consider whether the particle size/droplet size information may aid the assessment of respirability.
- Given the language in amended TSCA pertaining to alternative test methods (TSCA Section 4(h)(2)(A)), submitters should consider whether *in silico*, *in vitro*, or other non-vertebrate test information are appropriate for evaluating their chemical substance. This should include appropriate documentation of the method used to generate the data and a clear description of results and what they mean for hazard/risk analysis.
- Submitters should consider whether there are acceptable analog(s) for any toxicity endpoint to support the New Chemical Review process. Analog data may be useful to provide multiple lines of scientific evidence for a determination of hazard concerns, when for example, the hazard concern is identified for a route of exposure (*e.g.*, inhalation) other than the route of exposure (*e.g.*, dermal) for which data are available for the new chemical substance. Particularly useful are:

²⁵ Guidance documents on the identification and use of structural alerts can be found at:
<http://www.oecd.org/chemicalsafety/risk-assessment/guidancedocumentsandreportsrelatedtoqsars.htm>

- Justification for consideration of the analog for the endpoint(s) identified (e.g., similarity of structure, physical chemistry, toxicological data, as applicable)²⁶.
- Chemical name and CAS numbers of all analogs.
- Clear structural representation of the analog substance(s). It is best to provide a visual representation of the molecular structure along with that of the chemical substance. If EPA cannot determine the molecular structure or composition of the analog, it will not be considered.
- Full studies on the analogs, if available, to better ensure efficient consideration by EPA.

ii. Environmental Fate

Environmental fate data provide significant insight into other components of the New Chemicals Review process such as potential environmental partitioning to various media (air, soil, water, sediment) and potential degradation rates (persistence) in each of those media. Basic fate properties also allow EPA to focus the chemical substance assessment on relevant routes of exposure for workers, consumers, the general population, and environmental receptors. The purpose of the Environmental Fate evaluation is to preliminarily characterize the following in preparation for the SAT meeting:

- Environmental partitioning.
- Potential for persistence (“P”) and bioaccumulation (“B”), use the following general criteria²⁷ (note, if a new chemical substance is designated as P2B2 or greater, all routes of release and exposure are assessed, regardless of the human health or ecotoxicity hazard score).^{28, 29}

Persistence ^a	Low Persistence (P1)	Persistent (P2)	Very persistent (P3)
Water, soil, sediment	< 60 days	≥ 60 days	> 180 days
Air	≤ 2 days	> 2 days	

²⁶ Information on selection of analogs is available from the following resources:

EPA (2012) 9. *Analog Identification Methodology (AIM)*, Sustainable Futures / P2 Framework Manual, EPA-748-B12-001, <https://www.epa.gov/sites/production/files/2015-05/documents/09.pdf> and <http://www.oecd.org/chemicalsafety/risk-assessment/groupingofchemicalschemicalcategoriesandread-across.htm>

²⁷ EPA (1999) *Category for Persistent, Bioaccumulative, and Toxic New Substances, Policy Statement*, Federal Register, Vol. 64, No. 213, pp. 60194-60204.

²⁸ For more information, see: EPA (2012) 7. *Estimating Persistence, Bioaccumulation, and Toxicity Using the PBT Profiler*, Sustainable Futures / P2 Framework Manual, EPA-748-B12-001, available at: <https://www.epa.gov/sites/production/files/2015-05/documents/07.pdf>

²⁹ Note, EPA also uses information on physical-chemical properties (e.g., logK_{ow}), chemical groups (e.g., metals, nanomaterials, perfluorinated compounds, UVCB), etc., to inform the P and B call.

Bioaccumulation^a	Low bioaccumulation (B1)	Bioaccumulative (B2)	Very bioaccumulative (B3)
Fish BCF or BAF	< 1,000	≥ 1,000	≥ 5,000

^a Note, qualitative estimates based on modeling and/or physical-chemical properties are also used to inform the P and B score.

- Relevant routes of exposure.

When making the foregoing characterizations, EPA reviews new chemical substances in the following manner:

- Review submitted data.
 - Data from studies performed according to validated test guidelines and under Good Laboratory Practice (GLP) standards or non-guideline non-GLP studies which are sufficiently documented to allow EPA to reconstruct and re-evaluate the experimental methods and data are normally considered to be the most appropriate for use in fate assessments.
- Identify suitable analogs.
 - EPA also evaluates analogs with measured data from previous new chemical substance submissions and databases of publicly available literature. If analog information is available for an appropriate chemical or group of chemicals, then this information is used instead of modeled estimates (see below).
- Use modeling to estimate fate parameters.
 - Due to the absence of submitted or analog data, EPA often relies on modeling of the fate properties for new chemical substances using EPISuiteTM.³⁰
 - Each of the various models within EPISuiteTM, like all models, has a domain of applicability; that is, the models are only useful/accurate for certain chemical groups. Applicability domains include cut-offs, often based on molecular weight and chemical composition/moieties that inform the reliability of the model for various chemicals, (*e.g.*, chemical substances with a molecular weight greater than 1,000 Daltons and inorganic and organometallic chemicals are generally outside the domain of EPISuiteTM).
 - EPA assesses biodegradation rate information conservatively based on the outputs of the MITI models within the BIOWIN model of EPISuiteTM. The MITI model is built on measured information from ready biodegradation testing. EPA considers this the most relevant model in EPISuiteTM for informing persistence and sewage treatment plant removal rates.
 - EPISuiteTM does not generate direct photolysis rates, but it does calculate indirect photolysis rates. These are used to estimate atmospheric half-lives and contribute to the persistence call.
 - The rate estimates for biodegradation, persistence, and indirect photolysis are used for designating the P score.

³⁰ EPISuiteTM is publicly available software, that is available for download at the following: <https://www.epa.gov/tsc-screening-tools/epi-suitetm-estimation-program-interface>

- Transport and partitioning parameters are assessed using EPISuite™.
- Where applicable, EPA uses the BCFBAF model from EPISuite™ to inform the B score. A conservative approach is used to evaluate the outputs of the BCF regression model and the Arnot-Gobas model within BCFBAF (*i.e.*, the higher output of the two models is commonly used to inform the B score). The BCF regression model does not incorporate metabolism for a particular chemical structure and this may result in a higher estimated BCF value than the Arnot-Gobas model, which does include a metabolism rate QSAR. For the Arnot-Gobas model to outweigh the BCF regression model and reduce a B score, the structural components of the new chemical substance need to be well represented in the metabolism QSAR.
- Use physical-chemical properties to estimate fate parameters.
 - If the new chemical substance is not suitable for modeling, then the fate determinations are estimated based on the physical-chemical properties.

Considerations:

- The following types of information are useful to the New Chemical Review process. If the submitter concludes that any or all of this information is not applicable or relevant to the new chemical substance, providing an explanation or rationale for why such fate information is not relevant for the intended use of the chemical substance could inform EPA's evaluation. If the information is developed, submission would be required by TSCA § 5 and 40 CFR Part 720. Guidelines can be found for most of the parameters below within the OECD 100 and 300 series of tests or the OPPTS 830/835 testing series.
 - Basic physical-chemical information on partitioning parameters, particularly Henry's law or air-water partitioning coefficient (K_{AW}), soil organic carbon-water partitioning coefficient (K_{OC}), distribution coefficient (K_d), and octanol-water partitioning coefficient (K_{OW}). These basic data can be useful to EPA in conducting fate modeling and estimating other fate processes.
 - Information on chemical transformation during manufacturing, processing and/or use to help identify the form of the chemical substance that is released from a given industrial process to the environment.
 - For example, the form of the chemical substance that workers are exposed to may not be the same form that downstream general population or environmental receptors are exposed to.
 - Information on degradation and bioaccumulation. All relevant environmental degradation pathways are considered including both aerobic and anaerobic biodegradation and abiotic degradation (*e.g.*, hydrolysis, and photolysis).
 - Information related to behavior during waste water treatment processes and waste water treatment removal efficiencies.
 - Waste water treatment efficiency is determined by estimated rates of degradation process that occur in treatment facilities, particularly biodegradation and hydrolysis, and partitioning process, volatilization to the air and sorption to biosolids, that lead to removal of a chemical from the wastewater. Hence, standard guideline test data on degradation and

partitioning processes (e.g., laboratory, bench-scale tests) improve the determination of waste water treatment removal.

- If the waste water treatment is performed by a third party, performance and monitoring data on the water treatment facility in advance would be useful to EPA’s analysis. However, the review period does not allow for EPA to routinely search and access such data.
- Information related to incineration removal efficiency. Measured data for the chemical or an analog is preferred, but estimates without monitoring may also be informative if the basis is well described. If other ordinances (local or state) will impact incineration facilities that will receive waste this may be described in the submission.
- Information on migration through soil. Providing information on physical chemical properties (e.g., water solubility) and degradation (e.g., biodegradation) may also inform understanding of soil migration and impacts to groundwater.
- For experimental studies, provide all methodological and analytical details (full study reports are preferred) such as levels of residuals/starting materials in the chemical substance to help interpret the results of fate studies.
- Information to address the bioaccumulation potential of the chemical including *in vitro* fish metabolism studies and *in vivo* testing for fish bioconcentration factor of the chemical.
- The EPA accepts outputs from tools/models besides EPISuite, however the tool/model must be publicly available and a detailed rationale for how the other model is better suited for the chemical and the endpoint of concern must be provided.

iii. Aquatic (Environmental) Hazard/Toxicity

EPA will identify endpoints/organisms of interest based on the environmental fate profile and expected environmental release pathways for a new chemical substance. If, for example, a chemical substance is expected to be present in the water column, toxicity to three organisms (*i.e.*, algae, aquatic invertebrates, and fish) will be assessed. The purpose of the Aquatic (Environmental) Hazard/Toxicity evaluation is to preliminarily characterize the following in preparation for the SAT meeting:

- Identify potential aquatic hazard concerns, using the following acute and chronic toxicity endpoint values (LC₅₀, EC₅₀, ChV) to identify concern levels:³¹

	Low Concern	Moderate Concern	High Concern
Acute	≥ 100 mg/L	1 to < 100 mg/L	< 1 mg/L
Chronic	≥ 10 mg/L	0.1 to < 10 mg/L	< 0.1 mg/L

³¹ For more information, see: EPA (2012) 13. *Quantitative Risk Assessment Calculations*, Sustainable Futures / P2 Framework Manual, EPA-748-B12-001, at 13.2 *Performing an Aquatic Risk Assessment for SF Submissions*, available at: <https://www.epa.gov/sites/production/files/2015-05/documents/13.pdf>

- Identify the ecotoxicity hazard score (low = 1, moderate = 2, or high = 3). An ecotoxicity hazard score greater than 1 will initiate the engineering and exposure assessments.
- Derive acute and chronic concentrations of concern (“COC”) *e.g.*, acute COC for fish = $LC_{50} \div 5$, chronic COC for fish = $ChV \div 10$, where 5 and 10 are assessment factors and ChVs are chronic values that are effective concentrations at 10% (*i.e.*, EC_{10}) extrapolated from the no observed effect concentration (“NOEC”) or the lowest observed effect concentration (“LOEC”); ChVs may also be derived from the geometric mean of the NOEC and LOEC.³²
- For the overall PBT score, determine whether the new chemical substance meets the “T” criteria for aquatic organisms (*i.e.*, a chronic hazard concern level of moderate or high) (see Section III(C)(i) for a discussion of the “T” criteria for human health hazard).

When making the above determinations, EPA reviews new chemical substances in the following manner:³³

- Review structure, physical-chemical properties, and structural alerts.
 - Consider molecular shape and size, fundamental physical-chemical properties (including octanol/water partition coefficients, water solubility, and melting point), presence and position of reactive functional groups, potential for absorption, charge density, minimum cross-sectional diameter of molecules, and mechanisms of toxicity.
 - Consider potential metabolites or degradates (for example, hydrolysis products).
 - Determine if chemical (or degradate) fits within a chemical category, or if the structure contains structural alerts for ecotoxicity (*e.g.*, phenols or esters).
 - Identify hazards associated with the category and/or structural alerts.
- Review submitted ecotoxicity data.
 - Identify hazards associated with or addressed by the submitted data.
 - Determine if the data are suitable (*e.g.*, followed an established test guideline; methodological documentation allows for critical review; measured chemical concentration) for hazard and risk assessment purposes.
- If there is a Sustainable Futures submission,³⁴ or other information, such as a review by another international agency, review hazard information for data on the submitted chemical, an analog or models.
 - Identify hazards associated with or addressed by the submitted data.

³² For more information, see: Boethling, R.S. and Nabholz, J.V. (1997) *Chapter 10 – Environmental Assessment of Polymers under the U.S. Toxic Substances Control Act*, In: *Ecological Assessment Polymers: Strategies for Product Stewardship and Regulatory Programs* (Eds. Hamilton, J.D. and Sutcliffe, R.), ISBN: 978-0-471-28782-7, John Wiley & Sons, 345 pp., at pp. 187-234.

³³ For more information, see: EPA (2012) 6. *Estimating Aquatic Toxicity Using ECOSAR*, Sustainable Futures / P2 Framework Manual, EPA-748-B12-001, available at: <https://www.epa.gov/sites/production/files/2015-05/documents/06.pdf>

³⁴ For more information, see: EPA (2012) 14. *Completing a Sustainable Futures PMN Submission*, Sustainable Futures / P2 Framework Manual, EPA-748-B12-001, available at: <https://www.epa.gov/sites/production/files/2015-05/documents/14.pdf>

- Determine if the data are suitable for hazard and risk assessment purposes.
- Search for analogs using AIM³⁵, ChemID Plus Advanced, QSAR Toolbox³⁶, *etc.* Note that this step may be necessary even if there is submitted data, if the submitted data do not address a hazard concern based on chemical structure (*e.g.*, category or structural alert).
- Even when ecotoxicity test data are submitted, EPA may need to use Ecological Structure Activity Relationships (ECOSAR) Predictive Model (<https://www.epa.gov/tsca-screening-tools/ecological-structure-activity-relationships-ecosar-predictive-model>) to estimate the toxicity to the three typical ecologically relevant organisms (*i.e.*, algae, aquatic invertebrates, and fish) particularly if the submitted ecotoxicity data does not address all three groups. ECOSAR is typically used for discrete organic chemicals.
- Since ECOSAR is primarily based on log K_{ow}, environmental toxicity estimates could be further refined, if a measured log K_{ow} value is provided in the notification. In the absence of a measured log K_{ow} value, EPA may use the log K_{ow} value estimated using EPISuite™.
- As a general rule, EPA will consider that an organic new chemical substance has a low hazard if the log K_{ow} is greater than 8.
- Measured water solubility values assist with informing the ecological hazard characterization. In the absence of measured water solubility data, EPA may use the water solubility value estimated using EPISuite™.
- EPA may consider environmental aquatic hazard to be low for a specific toxicity endpoint value (96-h fish LC₅₀), if that value is greater than ten times the measured water solubility value or the measured water solubility value is less than 1 microgram/liter (< 1 part per billion).
- Derive the COC, for the new chemical substance, by dividing the lowest acute and/or chronic toxicity value by an assessment factor (taking into account lab-to-field/inter-species variability).
- COCs are then used in conjunction with the exposure assessment, that is, compared with estimated surface water concentrations, as discussed in Section V to estimate potential risks.

Considerations:

- The following types of information are useful to the New Chemical Review Process. If the submitter concludes that any or all of this information is not applicable or relevant to the new chemical substance, providing an explanation or rationale for why such ecotoxicity information is not relevant for the intended use of the chemical substance could inform EPA's evaluation. Once the information is developed, submission would be required by TSCA § 5 and 40 CFR Part 720.

³⁵ Information on analog identification is available here: EPA (2012) 9. *Analog Identification Methodology (AIM)*, Sustainable Futures / P2 Framework Manual, EPA-748-B12-001, <https://www.epa.gov/sites/production/files/2015-05/documents/09.pdf>

³⁶ The OECD QSAR Toolbox is publicly available software, that is available for download at the following: <http://www.oecd.org/chemicalsafety/risk-assessment/oecd-qsar-toolbox.htm>

- Information related to environmental hazards for both short-term (acute) and long-term (chronic) exposures.
- If chemical substances are difficult-to-test, submitting testing protocols and engaging in pre-testing technical discussion with EPA prior to toxicity test initiation is highly recommended.
- Information on % amine-nitrogen content for all relevant chemical substances (e.g., polycationic polymers).³⁷
- Submitters should consider whether there are acceptable analog(s) for any toxicity endpoint to support the New Chemical Review process. Analog data may be useful to provide multiple lines of scientific evidence for determination of hazard concerns, even if data are available for the chemical substance.
 - Provide justification for consideration of the analog for the endpoint(s) identified.
 - Provide chemical name and CAS numbers of all analogs.
 - Provide clear structural representation of the analog substance(s). It is best to provide a visual representation of the molecular structure along with that of the chemical substance. If EPA cannot determine the molecular structure or composition of the analog, it will not be considered.
 - Provide full studies on the analogs to better ensure consideration by EPA.

E. Environmental Releases/Exposure Assessments

If, at SAT, it is determined that exposure and release profiles are needed for the new chemical substance, chemical engineers and exposure assessors develop the identified types of exposure and release profiles, which may include the following:

- Engineering assessment.
 - Process information and worker exposures.
 - Environmental release and disposal.
- General population exposures.
- Consumer exposures.
- Environmental exposure to non-human receptors.

i. Engineering Assessment

The engineering assessments begin with EPA importing physical-chemical property information into the modeling software, ChemSTEER.³⁸ This information is determined from earlier steps in the New Chemical Review process. The ChemSTEER model is, basically, a mass balance/material flow model and only requires PV and four basic physical-chemical properties

³⁷ For more information, see: Boethling, R.S. and Nabholz, J.V. (1997) *supra* note 327.

³⁸ The Chemical Screening Tool for Exposures and Environmental Releases (ChemSTEER) is publicly available software, that is available for download at the following: <https://www.epa.gov/tsca-screening-tools/chemsteer-chemical-screening-tool-exposures-and-environmental-releases>

(*i.e.*, vapor pressure, molecular weight, density, and water solubility).^{39,40} The notification and supporting attachments from EPA Form 7710-25 (Rev. 5-95) are examined for additional information to use in order to create the occupational exposure and environmental release assessment based on how the new chemical substance is managed from its creation (manufacturing), until it is no longer available for release or exposure in the occupational setting (use). The information from the notification is used to refine the output from ChemSTEER, as discussed below.

EPA assesses each industrial/commercial step in the new chemical substance's domestic life cycle. These steps typically include manufacturing, processing, and end use of the chemical. For each life cycle step, the number of sites, facility-level throughputs (kg chemical/site-day), and days of operation are estimated based on available information in the notification and a mass balance. EPA then presents a description of process flow and identifies potential occupational exposure activities and environmental release sources, such as container loading/unloading, equipment cleaning, *etc.* Next, EPA estimates dermal and inhalation occupational exposures in mg/day, including frequency, duration, and number of workers exposed, as well as environmental releases to all media (*e.g.*, water, incineration, landfill, air, and underground injection) in kg/site-day including the release frequency (days/year).

Where relevant data are not included in the notification, EPA will derive estimates using various sources including: exposure and release models within ChemSTEER using default, conservative assumptions;⁴¹ OECD Emission Scenario Documents;⁴² and EPA Generic Scenarios⁴³ which describe industrial practices relevant to the case at hand. Information from previous notifications and assessments may also be used. Generally, in the absence of chemical- or facility-specific data provided in a notification, EPA uses estimates that are intended to be protective of human health and the environment.

Considerations:

³⁹ See, *e.g.*, EPA (2012) *11. Estimating Workplace Exposure and Industrial Releases Using ChemSTEER*, Sustainable Futures / P2 Framework Manual, EPA-748-B12-001, at p. 11-2, available at: <https://www.epa.gov/sites/production/files/2015-05/documents/11.pdf>

⁴⁰ For more information, see: EPA (2012) *Appendix G. ChemSTEER Case Study*, Sustainable Futures / P2 Framework Manual, EPA-748-B12-001, at pp. G2 and G3, available at: <https://www.epa.gov/sites/production/files/2015-05/documents/appendg.pdf>

⁴¹ For more information, see: EPA (2013) *ChemSTEER User Guide – Chemical Screening Tool for Exposures and Environmental Releases*, U.S. Environmental Protection Agency, 399 pp., at pp. 253-261 (Quick Summary of ChemSTEER Inhalation Exposure Models), pp. 263-265 (Quick Summary of ChemSTEER Dermal Exposure Models), and pp. 148-155 (Quick Summary of ChemSTEER Release Models).

⁴² OECD Emission Scenario Documents are available at the following: <http://www.oecd.org/chemicalsafety/risk-assessment/emissionscariodocuments.htm>

⁴³ EPA Generic Scenarios are available at the following: <https://www.epa.gov/tsca-screening-tools/using-predictive-methods-assess-exposure-and-fate-under-tsca#fate>

1. *Process Information and Worker Exposures*

EPA will use generally conservative assumptions when assessing the potential risk(s) the new chemical substance may pose to workers; therefore, submitters should consider whether the following types of information are relevant to their new chemical substance(s).

- The expected worker exposures for each worker activity of the manufacturing/processing/use operations, including information on:
 - What specifically the worker is doing and what physical state and concentration of chemical substance (*e.g.*, unloading slurry of 40% new chemical substance in organic solvent from a 55-gallon drums).
 - If exposure is not expected for a specific activity, EPA may seek a specific explanation of why not (*e.g.*, quick connect fittings and manifold are purged prior to disconnect and supporting schematic of the quick connect equipment is included).
- For manufacturing, the estimated mass balance related information (including throughput rate, number of days of production, and number of batches per day for the batch or continuous operation) for the maximum 12-month PV (for first three years of production).
 - Submitters should consider avoiding gross overestimates of PV values, as this can result in erroneously high estimates for release and exposure values.
- The percent of the new chemical substance in the formulation for each category of manufacturing, processing, and use. This information is one of the five possible input values used in the specific mass balance parameters within ChemSTEER.⁴⁴ For example, for a coating use, provide maximum weight percent of the new chemical substance in the final coating formulation; if different formulations are anticipated, provide the maximum weight percent *for each*. The concentration of the new chemical substance is used in estimating exposure dose in which the highest concentration is used, so it is beneficial to be precise and not over estimate.
- If the new chemical substance is submitted as a Low Volume Exemption and PV is not marked “binding” in EPA Form 7710-25 (Rev. 5-95), provide scale-up batch parameters (*e.g.*, kg per batch or day, hours per batch or day, batch or operation days per year) for a PV of 10,000 kg/yr. See: <https://www.epa.gov/reviewing-new-chemicals-under-toxic-substances-control-act-tsca/low-volume-exemption-new-chemical>. In cases where the binding option is not marked, EPA assesses releases and exposures assuming the PV could be as high as 10,000 kg/yr.
- Dermal exposure data for the new chemical substance or for a structurally similar chemical used in a similar setting. In the absence of data, dermal exposures are estimated using dermal exposure models in ChemSTEER.⁴⁵

⁴⁴ *Id.* at p. 11-7; see also: EPA (2012) *supra* note 33 at p. G-3.

⁴⁵ For more information, see: EPA (2013) *ChemSTEER User Guide – Chemical Screening Tool for Exposures and Environmental Releases*, U.S. Environmental Protection Agency, 399 pp., at pp. 263-265 (Quick Summary of ChemSTEER Dermal Exposure Models).

- Identification of any operations or activities that are conducted under non-standard temperatures or pressures. Activities occurring at elevated temperatures may cause potential inhalation exposures to workers. Conversely, activities occurring at reduced temperatures may lower volatility and the corresponding inhalation exposures.
- The specific type of personal protective equipment (“PPE”) that will be used at the manufacturing site and, to the extent known, at processing and use sites.
 - Information on type of gloves used (*e.g.*, material composition, penetration time of glove material, glove thickness, name/model number). This information will support EPA’s determination whether “impervious gloves” are used. Specific information of the kind of protective clothing (*e.g.*, goggles, facemasks, suits, *etc.*, including specific brand names/model numbers) is also useful for refining the assessment.
 - Information on type of respirator used (*e.g.*, name/model number, cartridge type, breakthrough time *for the new chemical substance* or a close analog with similar properties, assigned protection factors (“APF”), and maximum use concentrations).
 - PPE is generally considered during risk management (at focus and during post-focus). The engineering report is performed with the assumption of no PPE and then if risks are identified, the submitter’s information on PPE (including the specific APF) is taken into consideration as to whether that risk has been mitigated.
- If the new chemical substance is manufactured, processed, or used as a solid or powder:
 - Indicate whether the manufacture, processing, and/or use of the new chemical substance is expected to result in suspended particles (also referred to as dust) in air thereby creating a potential inhalation exposure. If so, submitters should consider providing supporting data on particle size distribution and/or type of solid material (*e.g.*, powder, wet cake with 30% moisture content, paste, or slurry).
 - In the absence of particle size distribution data, EPA may assume there are potential inhalation exposures to the new chemical substance.
 - Provide description and efficiency information (with supporting data) for air pollution control technologies/systems used (*e.g.*, bag filter, dust collector, local exhaust ventilation) and how the technologies/systems would reduce releases and/or worker exposures.
 - Specify the type and size of container transporting the solid new chemical substance for each operation.
 - Indicate in what form the new chemical substance will be distributed to processors and users (*e.g.*, solid, liquid, or paste form).
- Inhalation exposure data (personal and/or area monitoring data) for the new chemical substance or structurally similar chemical used in a similar setting. In the absence of data, EPA may assume a mass concentration limit of particulate in air of up to 5 mg/m³

(respirable) or 15 mg/m³ (total particulates) per the OSHA Particulates Not Otherwise Regulated (PNOR) PEL-Limiting Models.⁴⁶

- Include the Safety Data Sheet (“SDS”) or Materials Safety Data Sheet (“MSDS”). Formerly referred to as MSDS, SDSs are developed by the manufacturer and provided by the product supplier to the user.

2. *Environmental Release and Disposal Information*

EPA often sees submissions that lack specificity with regard to the following types of information on the new chemical substance. In the absence of this type of information, EPA will use generally conservative assumptions when assessing the potential risk(s) the new chemical substance may pose from environmental releases resulted from manufacturing, processing, use and disposal.

- All possible environmental releases of the new chemical substance for the specified operation type or equipment. EPA typically expects releases during unloading/loading, container cleaning, and equipment cleaning.^{47,48} The following types of information are useful:
 - Unit operation (*e.g.*, filter, reactor) or equipment (*e.g.*, process vessel) and capacity or throughput/batch related information (*e.g.*, quantity of batch, # of batches)
 - Description of unit operations and equipment including schematic drawing of the equipment (*e.g.*, reactor or vessel schematic drawing). It is useful to provide a narrative for how the unit operation or equipment is cleaned (*e.g.*, by pumping solvent into vessel to clean residual remaining in vessel and then removing rinsate (containing PMN substance) out of vessel via pumping or by draining through an orifice or valve from the vessel). Providing supporting information (*e.g.*, drawing showing location of orifice or valve and location and elevation of vessel) is also useful. For equipment cleaning, in the absence of specific information about equipment configuration (with supporting schematic drawing), EPA may assume up to 2% of residual from cleanup activity (based on daily throughput or batch) for a multiple-vessel operation.
 - Amount of the new chemical substance released (in kg) per day or per batch and supporting information (*e.g.*, release data from an analogous chemical used in similar process)
 - Media of release (*e.g.*, stack air, fugitive air, surface water, on-site or off-site land or incineration, industrial wastewater treatment facility [“WWTF”], publicly owned treatment works [“POTW”], or other control technology that will be used to limit the release of the PMN to the environment).

⁴⁶ For more information, see: EPA (2013) *ChemSTEER User Guide – Chemical Screening Tool for Exposures and Environmental Releases*, U.S. Environmental Protection Agency, 399 pp., at pp. 253-261 (Quick Summary of ChemSTEER Inhalation Exposure Models).

⁴⁷ For more information, see: EPA (2012) *11. Estimating Workplace Exposure and Industrial Releases Using ChemSTEER*, Sustainable Futures / P2 Framework Manual, EPA-748-B12-001, at p. 11-5, available at: <https://www.epa.gov/sites/production/files/2015-05/documents/11.pdf>

⁴⁸ *Id.*

- Control technology efficiency (*e.g.*, the incineration efficiency for a similar product formulation containing a similar chemical to the chemical substance is between 99.1-99.5%; be sure to provide the supporting information). EPA may not use the submitter’s efficiency absent supporting documentation.
- The frequency of equipment cleaning (*e.g.*, every day, after every batch, once a year)
- The substance that is used to clean the equipment and its physical state (*e.g.*, water, solvent, steam)
- For all releases, estimates of the amount and the frequency of releases is recommended and detailed information on the basis for each estimate is recommended.
- Description of the unit transport container type, capacity and container cleaning procedure and frequency including, for example, the following information:
 - Five 5,000-gallon trucks used to store/transport the chemical substance are dedicated and only rinsed once every 20 deliveries.
 - The rinsate that contains the chemical substance is put down the drain, incinerated, *etc.*
 - The cleaning and disposal of the transport containers are performed by the submitter on site. If the containers are cleaned or disposed of off-site, provide available information including the cleaning methods, frequency of cleaning, and estimated amount of new chemical substance released per cleaning.
 - The information above is then used with release estimation models within ChemSTEER to estimate releases from residuals remaining in different container sizes.⁴⁹ In the absence of specific information, EPA generally assumes that the new chemical substance is transported in 55-gallon drums, and the remaining heel (*i.e.*, drum residual) would be 3% loss fraction to water.
- Detailed description of disposal practices (*e.g.*, surface impoundment, landfill and type of landfill) for the new chemical substance at manufacturing, processing, and use sites for those controlled by the submitter and, if known, at sites not controlled by the submitter.
- The National Pollution Discharge Elimination System (“NPDES”) permit numbers (*i.e.*, non-storm water permit numbers) for WWTFs at a manufacturing site(s), a known processing site(s), and a known use site(s), or the NPDES permit numbers for the POTWs receiving wastewater from the facility(ies).
 - Specify the type of wastewater treatment technologies used at the facility(ies).
 - Provide any removal efficiency information for onsite treatment unit operations. Indicate whether the information estimated or measured.
- The Clean Air Act operating permit numbers for facilities with expected releases to air.
 - Specify the type of air pollution control technologies used at the facility(ies).
 - Provide any removal efficiency information for onsite treatment unit operations. Indicate whether the information is estimated or measured and provide supporting information.

⁴⁹ For more information, see: EPA (2013) *ChemSTEER User Guide – Chemical Screening Tool for Exposures and Environmental Releases*, U.S. Environmental Protection Agency, 399 pp., at pp. 148-155 (Quick Summary of ChemSTEER Release Models).

- Is the facility under a Leak Detection and Repair program (related to the monitoring and management of fugitive releases)? If “yes,” describe the program.

ii. Non-Occupational General Population, Consumer and Environmental Exposures

For the purpose of conducting a review of new chemical substances, non-occupational and environmental exposure assessments are generally performed if there are hazard concerns for the general population, consumers, or environmental receptors. Regardless of identified hazard concerns, such exposures are also assessed if the PV of the new chemical substance is greater than or equal to 100,000 kg/year (*i.e.*, exposure-based trigger), or if the new chemical substance is identified as P2B2 per the environmental fate evaluation conducted for the SAT meeting.

Non-occupational, general population exposures include any types of exposure that occur outside the boundaries of the workplace, with the exception of use of consumer products. Exposure to the general population may occur as a result of releases to the environment (*i.e.*, air, surface water, landfills) from manufacturing, processing, and industrial or commercial uses of a new chemical substance. The associated routes of exposure to the general population include inhalation of ambient air (*i.e.*, air outside the boundaries of the workplace), ingestion of drinking water or fish contaminated by the new chemical substance. Use of monitoring data reflecting actual concentrations of a chemical substance in various environmental media is the preferred approach to examine potential exposures; however, such data are rarely available for new chemical substances. As such, modeling methods are employed in the absence of reliable monitoring data to estimate exposures using the General Population and Ecological Exposure from Industrial Releases Module embedded within the Exposure and Fate Assessment Screening Tool (E-FAST).⁵⁰

Consumer exposures are distinct from general population exposures that may result from releases to the environment from industrial or commercial activities. Consumer exposures may occur through the use of household products through dermal contact with consumer products and/or inhalation of the new chemical substance that volatilizes from consumer products or is released from aerosol products in indoor air. Such exposures are generally estimated using the Consumer Exposure Module (CEM) embedded within E-FAST. The use of consumer products that are added to water during use, *e.g.*, laundry detergents, if applicable, can be assessed using the Down-the-Drain Module embedded within E-FAST.

Environmental exposures resulting from releases to water, either from sites involved in the manufacture, processing, or use of the new chemical substance or from certain consumer uses, as noted above, are reflected by the Predicted Environmental Concentration (PEC) in surface water, which is also estimated using E-FAST. For more information on how to use E-FAST or its

⁵⁰ E-FAST is publicly available software, that is available for download at the following: <https://www.epa.gov/tsca-screening-tools/download-and-install-instructions-e-fast-exposure-and-fate-assessment-screening>

embedded models, please see the E-FAST Documentation Manual⁵¹ or EPA’s Sustainable Futures/P2 Framework Manual,⁵² which contains a chapter dedicated to estimating general population and aquatic exposure using E-FAST.

The general population, consumer, and/or environmental exposure assessment process begins with a review of relevant information contained in the engineering report including the following: consumer use status and weight fraction, if applicable; PV; site-specific information that may inform use of a site-specific NPDES code; media of predicted releases (*e.g.*, water, air, incineration, landfill); number of sites associated with predicted releases; and process description, which may be used to inform Standard Industrial Classification (SIC) code selection and/or consumer exposure scenario and weight fraction. Additional input parameters are gathered from the evaluations on human health hazard/toxicity, environmental fate, and aquatic (environmental) hazard/toxicity. The relevant environmental fate inputs include: fish BCF or BAF value, wastewater treatment (WWT) removal efficiency, persistence and bioaccumulation ratings (*i.e.*, P and B scores), and soil migration. The primary hazard/toxicity inputs include the routes of concern for human exposure (*i.e.*, ingestion, dermal, and/or inhalation) and the chronic COC for aquatic species exposure. Collectively, this information reflects the necessary inputs into E-FAST and CEM. As noted, some consumer uses may also be assessed for releases to water during use and subsequent human and environmental exposures.

The majority of the described input parameters are determined during the preceding evaluations on human health/toxicity, environmental fate, and aquatic (environmental) hazard/toxicity. In the absence of submitted data, such inputs may be based on analog, conservative assumptions, or model estimates. Below is a list of the key exposure modeling input parameters and a brief description of how they are used in exposure assessment:

- **SIC Code:** Each generic SIC code programmed into E-FAST is associated with a stream flow distribution, which is applied to water releases when estimating the PEC(s). Use of an SIC code generally results in a more conservative estimate of stream concentration when compared with use of a site-specific NPDES code.
- **NPDES Code:** Each site-specific NPDES code is associated with a stream flow, which is applied to water releases when estimating the PEC(s). In the absence of a site-specific NPDES code, EPA may instead use a stream flow associated with a more generic SIC code.
- **WWT Removal Efficiency (%):** This input is determined during the environmental fate evaluation and is applied to water release inputs in E-FAST, thereby reducing the magnitude of water releases.

⁵¹ EPA (2007) *Exposure and Fate Assessment Screening Tool (E-FAST), Version 2.0, Documentation Manual*, available at: <https://www.epa.gov/sites/production/files/2015-04/documents/efast2man.pdf>

⁵² EPA (2012) *12. Estimating General Population and Aquatic Exposure using E-FAST*, Sustainable Futures / P2 Framework Manual 2012 EPA-748-B12-001, 26 pp., available at: <https://www.epa.gov/sites/production/files/2015-05/documents/12.pdf>

- **Chronic COC:** This input is determined during the aquatic (environmental) hazard/toxicity evaluation and is compared to the chronic PEC calculated by E-FAST (*i.e.*, the PEC resulting from any water releases occurring over 20 days or more).
- **Production Volume (kg/year):** This input is provided by the submitter. A production volume equal to or greater than 100,000 kg/year will be run for an exposure based case and total releases and dose estimates will be compared against exposure-based criteria⁵³.
- **Incineration Destruction and Removal Efficiency DRE (%):** DRE is applied to predicted releases from incineration releases.
- **Fish BCF or BAF:** This input is determined during the environmental fate evaluation and is applied to the predicted environmental concentration (PEC) to estimate a fish concentration that is then used to estimate general population exposures from fish ingestion.
- **PB rating (1, 2, 3):** This input is determined during the environmental fate evaluation. If a new chemical substance is considered persistent and bioaccumulative, total releases and dose estimates will be compared against persistent and bioaccumulative criteria⁵⁴.
- **Migration Rate (negligible, slow, moderate, rapid):** This input is determined during the environmental fate evaluation and is applied to the estimation of general population oral exposure to landfill releases, when non-negligible leaching to groundwater is predicted.
- **Consumer Product Weight Fraction (%):** This input is one of the major chemical-specific inputs into CEM.

The described input parameters and population exposure factors (*e.g.*, inhalation rate, body weight, drinking water intake) are employed by E-FAST or CEM to generate the following key exposure outputs: acute dose rate (ADR in mg/kg-bw/day); lifetime average daily dose (LADD in mg/kg-bw/day); PEC ($\mu\text{g/L}$) in surface water, reflected by the 7Q10 stream concentration (*i.e.*, the concentration estimated using the 7Q10 flow – the 7 consecutive days of lowest flow over a 10-year period); and the number of days per year a chronic COC has been exceeded in surface water. The population exposure factors are sourced from the 2011 Exposure Factors Handbook⁵⁵ and are pre-populated in E-FAST and CEM for a number of life stages: adult; youth (16-20 years); youth (11-15 years); child (6-10 years); small child (3-5 years); infant (1-2 years); and infant (<1 year).

EPA will use generally conservative assumptions when assessing the potential risks the new chemical substance may pose from exposures to the general population, consumers, and/or the

⁵³ Exposure based exceedance criteria for general population and ecological exposure modeling: Human potential dose estimates $\geq 3.0\text{E-}03$ mg/kg-bw/day; total post-treatment release to all media $\geq 10,000$ kg/year; or total post-treatment release to surface water $\geq 2,000$ kg/year.

⁵⁴ Persistent and Bioaccumulative exceedance criteria for general population and ecological exposure modeling: Human potential dose estimates $\geq 3.0\text{E-}03$ mg/kg-bw/day; total post-treatment release to all media $\geq 2,000$ kg/year; or total post-treatment release to surface water ≥ 200 kg/year.

⁵⁵ EPA (2011) *Exposure Factors Handbook: 2011 Edition*, National Center for Environmental Assessment, Office of Research and Development, U.S. Environmental Protection Agency, Washington, D.C., EPA/600/R-090/052F, available at: http://ofmpub.epa.gov/eims/eimscomm.getfile?p_download_id=522996

environmental; therefore, submitters should consider whether the following types of information are relevant to their new chemical substance(s).

1. *General Population Exposure*

- Characterization of the magnitude and distribution of direct-release scenarios. Characterization of exposed populations surrounding the manufacturing, processing, or use facilities. The distance to the nearest residence. EPA generally assumes a distance of 100 meters to the nearest residence for general population exposure to incineration or fugitive releases.
- The degree to which a new chemical substance may be removed in POTWs and/or through on-site treatment at a WWTF before release to the environment. Removal efficiency has the potential to significantly impact the resulting exposures to the downstream general population and ecological receptors. In the absence of specific information, EPA will use a conservative removal efficiency based on the EPISuite™ sewage treatment plant (STP) model (typically 90%).
- Information on the potential for the new chemical substance to migrate to groundwater under any conditions where the chemical substance is released to the environment.

2. *New Chemical Substances in Products Used by Consumers*

- Information characterizing the properties of the product such as density, physical form, method of application (*e.g.*, spray, brush, and/or roll-on), and whether and how much dilution occurs during routine use.
- Description and rationale for the expected typical setting for use (*e.g.*, outdoors, indoors, residential, and/or commercial).
- Estimate of the frequency of use (*e.g.*, daily, weekly, and number of times per year)
- Estimate and rationale for the duration of use (*e.g.*, the product is used for minutes or hours).
- Describe and provide rationale for the consumption rate for any single use (*e.g.*, the volume or weight consumed during each use).
- Estimate of the number and types of individuals (receptors) who may use the new chemical substance or product containing the new chemical substance.
 - Examples: high-frequency consumer use (*e.g.*, product frequently used by individual), low-frequency consumer use, estimated extent of consumer use (*e.g.*, size of consumer market, estimated number of users), use by children, *etc.*
- Information on the circumstances of use that may influence exposure such as expected temperatures during use, whether products are manipulated, cut, abraded, or sprayed.
- Information on the circumstance under which the consumer would use the product containing the new chemical substance that may influence exposure in ways not typically considered such as variable on-site application, chemical reaction or degradation during use, potential for abrasion, manipulation, or other physical degradation during use, or other potential for elevated exposures during the range of expected circumstances of the typical use.

3. *Articles*

- Any information or product testing data on the emission or migration of new chemical substances from products or articles (or the types of materials they are envisioned to be made of, *e.g.*, plastic) into environmental media. For examples of types of exposure testing data relevant to the New Chemical Review process, see: EPA Indoor Exposure Product Testing Protocols. Note: version 1.0 is currently available (September 2015);⁵⁶ an updated version is expected in the near future.

IV. RISK CALCULATIONS

A. *Human Health Risk Assessment*

If a point of departure (POD) is identified during the human health hazard/toxicity data review, then risks are quantified. To evaluate and quantify whether potential risks exist in the New Chemical Review process, EPA generally uses the Margin of Exposure approach (MOEs). The calculated MOEs are derived by dividing the POD by the exposure estimates generated from the engineering and exposure assessments. The MOEs are then compared to a benchmark MOE to determine if potential risks of concern are present. Potential risks are identified if the calculated MOE is below the benchmark MOE.

The benchmark MOE is obtained by multiplying the total uncertainty factors (UFs) associated with each POD. These UFs typically include: (1) the variation in susceptibility among members of the human population (*i.e.*, inter-individual or intraspecies variability or UF_H = default of 10), and (2) the uncertainty in extrapolating animal data to humans (*i.e.*, interspecies uncertainty or UF_A = default of 10). The default UF_A consists of a factor of 3.16 for toxicokinetics (TK) and 3.16 for toxicodynamics (TD) (*i.e.*, $UF_A = TK \times TD = \text{default of } 10$); however, the TK factor may be modified, typically to 1, when a human equivalence dose (HED) or human equivalence concentration (HEC) is calculated to derive the POD (*i.e.*, $UF_A = 1$ for $TK \times 3$ for $TD = 3$). An additional UF may be added if the POD is based on a LOAEL, rather than a NOAEL (*i.e.*, LOAEL-to-NOAEL extrapolation or $UF_L = 10$). Hence, in the New Chemical Review process, benchmark MOEs are typically 100 or 1000; however, when specific data are available to justify changes, they may be adjusted downward or upward.

If a POD is not available, a qualitative risk finding may be made. For example, if test data on a new chemical substance indicates it elicited dermal sensitization, EPA generally identifies the new chemical substance as a potential respiratory sensitizer as well; however, it is generally not possible to identify a POD for respiratory sensitization. Therefore, if there are potential inhalation exposures to workers from a suspected respiratory sensitizer, EPA may qualitatively identify respiratory sensitization as a potential risk for workers. In some cases, hazards are identified based on a structural alert (*e.g.*, acrylamides and carcinogenicity), but data are not available to derive a quantitative POD (a benchmark MOE cannot be quantified). In such a case,

⁵⁶ EPA (2015) *Indoor Exposure Product Testing Protocol, Version 1.0*, Office of Chemical Safety and Pollution Prevention, U.S. Environmental Protection Agency, EPA document number: 740-S1-5001, 41 pp., available at: https://www.epa.gov/sites/production/files/2015-10/documents/indoor_exposure_product_testing_protocols_version_1.0.pdf

if there are populations that may be exposed, EPA may qualitatively identify carcinogenicity as a potential risk, based on the qualitative assessment of hazard and estimated exposures.

In some cases, EPA has estimated exposures for a new chemical substance, under the conditions of use; however, there was no hazard information available on the new chemical substance, including no structural alerts or acceptable analogs with test data. Under these circumstances, EPA cannot perform a reasoned evaluation of potential risks and will generally request testing on the new chemical substance.

If potential risks are identified, EPA may refine the risk calculations based on absorption or, if relevant, consideration of the weight percentage of the new chemical substance that the structural alert or component of concern comprises. For example, if the structural component of a polymer is associated with a hazard concern for a particular chemical type, then EPA will generally make adjustments to the estimated exposures based on the weight percent of the particular chemical type and will modify the risk calculations accordingly.

Risk characterization is part of the risk assessment and takes the form of a conclusion about the chemical substance's potential for health and environmental risk. It embodies the effects of potential concern, the route and magnitude of expected exposure, and numbers in the population estimated to be exposed.

B. Aquatic (Environmental) Risk Assessment

EPA evaluates potential acute and chronic risks of concern to aquatic organisms by comparing potential environmental concentrations (PEC) to acute and chronic COCs. The PEC information is provided in the exposure assessment generated using E-FAST.

i. Evaluation of Acute Aquatic Risk

EPA compares acute COCs directly to the PEC. A potential for risks exists if the PEC is greater than the acute COC. For example, if the lowest acute COC value for the three target species (*i.e.*, fish, daphnia, and green algae) is 20 parts per billion (ppb) for algae and the E-FAST General Population and Ecological Exposure module results show a PEC (or 7Q10 surface water concentration) of 45 ppb, then there is a potential risk for acute exposures.

ii. Evaluation of Chronic Aquatic Risk

If the PEC is greater than the chronic COC, then potential chronic risks may exist. Chronic aquatic risk is further evaluated by determining the number of days per year the chronic COC is exceeded. If the chronic COC is exceeded by the PEC for less than 20 days per year as estimated by E-FAST's probabilistic dilution model (PDM), then no potential chronic risks are identified for the environment. If the chronic COC is exceeded more than 20 days per year, then a potential chronic risk of concern is identified.⁵⁷

⁵⁷ The 20-day criterion is derived from partial life cycle tests (*e.g.*, daphnid chronic and fish early life stage tests) that typically range from 21 to 28 days in duration. It is important to note that the PDM model estimates only the total number of days out of 1 year that the COC is exceeded. The days are not necessarily consecutive, and thus the 20-day criterion is a conservative one.

iii. Evaluation of Soil or Sediment Risk

Potential acute and chronic risks to soil and/or sediment-dwelling organisms are assessed by EPA when physical-chemical and fate properties indicate that the new chemical substance will partition into soils or sediments, and there are acute and/or chronic aquatic risks. Use and exposure information are also considered when EPA evaluates soil and sediment exposure pathways. For example, if a new chemical substance has a low water solubility, a high log K_{ow} , a high log K_{oc} , a production volume of 5,000,000 kg/yr, EPA will generally recommend soil and/or sediment toxicity testing.

V. FOCUS MEETING AND REGULATORY DECISIONS

Next in the New Chemical Review process, an interdisciplinary team of chemists, biologists, toxicologists, engineers, fate assessors, and exposure assessors finalize their respective sections of the risk assessment in preparation for the Focus Meeting. At the Focus Meeting, the interdisciplinary team discusses the results of the risk assessment and effects of potential risk mitigation options (*e.g.*, how to limit potential releases or exposure pathways) with risk managers. Preliminary risk management recommendations made at the Focus Meeting or subsequent decision meetings with managers or decisions that further analysis is needed are informed by the results of the risk assessment and may take into account chemical categories, exposure-based reviews, and exemption criteria as they pertain to limiting risks.

VI. STANDARD REVIEW

An outcome of the Focus Meeting may be to put the new chemical substance into “Standard Review.” A typical scenario leading to a Standard Review is when the screening evaluation conducted prior to the FOCUS meeting results in identification of significant risks or studies were submitted with the notification that need a more thorough review. During the Standard Review, EPA will perform a more in-depth evaluation of the new chemical substance, typically based on any newly available information provided by the submitter after the initial notification was submitted. Standard Reviews are subject to a higher level of management review, conducted by the Director of OPPT’s Risk Assessment Division at a Disposition Meeting and, depending on the outcome and complexity of the review, may also require review at the Division Directors’ Meeting wherein the risk assessment results and risk management approaches are presented and discussed among Division Directors prior to the Risk Management decision being finalized by the Chemical Control Division Director.

VII. POST-SUBMISSION COMMUNICATION

If risks are identified in the risk assessment, a program manager (risk manager) typically works with the submitter to identify additional information that would assist EPA in developing strategies to mitigate the risks. Effective communication between the program manager and submitter is essential to this interaction.

i. Communication Recommendations

- It is good practice to inform your EPA Program Manager (e-mail or phone message) that you have electronically submitted an amendment or document *via* CDX or that you have sent a document *via* fax.
- When a suspension of more than 15 days appears to be needed, we encourage you to submit a written request for suspension thru CDX for the longer time period.
- Become familiar with the TSCA Section 5(e) Consent Order boilerplate on EPA’s website (<https://www.epa.gov/reviewing-new-chemicals-under-toxic-substances-control-act-tsca/new-chemicals-program-boilerplates>).
- Consider using the “binding option” in EPA Form 7710-25 (Rev. 5-95). Indicating a willingness to be bound to certain information (see sub-bullets below) in the notification does not by itself prohibit the submitter from deviating after the end of the review from the information (except chemical identity) which had been reported in EPA Form 7710-25 (Rev. 5-95) (unless the submitter and the Agency enter into a binding TSCA § 5(e) Consent Order), but it does provide the starting point for discussions between EPA and the submitter.
 - Pollution control technology and efficiency
 - Physical form(s) of the new chemical substance
 - Worker protection/engineering controls
 - Process description
 - Use information

ii. Additional Information and Training

The Sustainable Futures program provides the public with educational training workshops on the New Chemical Review process and use of EPA’s computerized models and tools. The EPA’s website on the Sustainable Futures training can be found at: <https://www.epa.gov/sustainable-futures/sustainable-futures-training-workshops>.

The program also encourages chemical developers to use EPA’s models and methods to screen chemical substances for potential risks early in the development process or before submission of a chemical substance notification. Prescreening chemicals for hazard concerns helps companies anticipate, and gives them the information and opportunity to avoid, developing chemicals of concern. Sustainable Futures training workshops are open to the public, and EPA encourages companies to host a Sustainable Futures workshop. This website provides all materials for training and can be used in conjunction with a predefined two and one-half day agenda that covers training on each of the models and methods that EPA uses.

New Chemicals Decision Guidelines Manual

Detailed Outline

This New Chemicals Decision Guidelines Manual will summarize how EPA reviews new chemical submissions and the policies and decision guidelines used in making decisions under section 5 of the Toxic Substances Control Act (TSCA). This document will provide an overview of both risk assessment and risk management approaches. In addition to providing an overview of the review of new chemical submissions, the manual is intended to help stakeholders determine what forms of regulation and restrictions on the manufacture, distribution, use, and/or disposal of a new chemical substance may arise from an EPA determination.

EPA is providing an outline for the New Chemicals Decision Guidelines Manual for public comment. In particular, EPA is interested in hearing whether there are other sections that should be added to the outline and thus to the document.

Background

EPA has reviewed more than 55,000 new chemical submissions since 1979. During this time, EPA developed several procedures, policies, and decision guidelines to assist OPPT personnel in assessing data obtained during the review and in developing subsequent recommendations, if any, for the regulation of the new chemicals. EPA has codified these procedures, policies, and decision guidelines into draft decision guidelines documents, the most recent of which was developed in 2001 and was intended for internal use by OPPT in the evaluation of new chemical submissions. EPA intends to use the 2001 document as a model for an updated document - the New Chemicals Decision Guidelines Manual, which will be adapted for both internal and external use. EPA is updating its procedures, policies, and decision guidelines to reflect the amendments to TSCA under the Frank R. Lautenberg Chemical Safety for the 21st Century Act.

New Chemicals Decision Guidelines Manual
Detailed Outline

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EPA Meeting via webinar on TSCA implementation.

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[Begin CC Transcript]

Nancy Beck: good morning, everyone. If you could take a seat, we will get started. Good morning and welcome everyone. My name is Alice Tome. I work for ABT Associate 10M a contractor for EPA and will be moderating today's meeting. The purpose of the meeting is to update and engage the public and the agency's progress in implementing changes to the new chemical review program as a result of the 2016 amendment TSCA. The agency appreciate your participation in today's meeting. We structured the meeting to allow for interactive exchange of ideas and ways EPA's new chemical program can effectively efficiently implement the Lautenberg Act. Written comments are also being accepted. Thank you all for joining us today. We will start by going over a few housekeeping items and then presenters and panels will discuss different aspects of the new chemical review program. In terms of housekeeping for those of you on the run the nearest bathrooms are out the door to the left and through the double glass doors if you are looking for coffee or food there is a food court if you turn left out the door. You will need to go through the double glass doors down the escalator and take a right and you will see signs. EPA hopes and expects that the participants will be courteous and respectful imposing their questions and in spoken remarks and we look forward to a productive meeting. I will turn the meeting over to Dr. Nancy Beck deputy had missed assistant administrator for opening remarks.

Nancy Beck: Good morning, everyone. Hope everyone is doing all right. Thank you, Alice. Wanted to take a few minutes to welcome everyone to our meeting today. Thank you for spending your day with us. For those of you on the webinar you are out there somewhere so thank you for tuning in. I know everyone is really busy, but I think we are here today because we share the same goal and that is to make sure that the chemicals on the market today do not pose unreasonable risks and EPA's new chemical review program plays a tremendously important role in this capacity. The program ensures we have an innovation pipeline that allows new chemistries which do not pose unreasonable risk to make it to the market. This review supports innovation and our ever improving chemical safety. I also believe there's a reason the statute only gives us 90 days to complete these reviews although there's an opportunity for another 90 day extension. I think we need to be very mindful of the timelines in the statute as we think about these reviews. So during the first year of implementing the Lautenberg amendment EPA has worked extremely hard to make sure that the policy and process changes necessary in order to align the program with the requirements of the law are in place. We've also worked hard to streamline and improve the review process. These approaches as you know are continuing to evolve and that's why we are all here today. We like to use the analogy that we are building the house while we live in the house at the same time. When the new amendment took effects we had more than 300 chemicals in our review pipeline. As many of you are aware, these reviews came to a halt as we had to figure out the myriad of legal and policy issues associated with making affirmative determination for the very first time and of course, it was inevitable it slowed our progress. So I'm happy to report that the pipeline of chemicals leading review has decreased substantially where we were months once now I think around 600 or perhaps closer to 700 under review, we are now back to our typical baseline which is about 300. I think when I checked the web last night our specific number was 376 which is not a bad place for us to be. Considering our normal baseline is typically around 300. So our policy and legal framework will help ensure that the program has a strong foundation as we

move forward. We are now rounding the eighteenth month of the implementing the new Lautenberg Act and we want to follow-up on our pledge to keep all stakeholders informed of our framework so we are operating under and we want to be as transparent as possible about our practices and procedures and we want to engage stakeholders in that process. So the EPA administrator is committed to providing a more predictable and transparent process for making safety determinations and committed to continuous improvement and committed to increase transparency. So with that in mind we have some important elements of the new chemical programs including the new chemical decision-making framework and an overview of the document. Both documents are part of the efforts to continue to be more transparent with all of our stakeholders regarding our practices and procedures. The more everyone understands what we are doing, the more we can all work together and the more effective our program can be. I don't think EPA can do it alone without our stakeholders being engaged. We are also going to touch today and where we hope to go in the future and that will include a discussion of a plan discussion guidelines manual as well as some new chemical categories that we will discuss. Most importantly we want to hear about your experiences with the program, how we are doing so far. We want to collect and understand your comments on the documents provided, on the approaches we've been implementing and also want to respond a little to some of the questions we have received so thank you to everyone that submitted questions in advance. I'm hopeful today's meeting will provide a transparent and open accounting of the challenges we are facing today and how we are working through them allowing us to continue the dialogue so we can continue to improve the program. Finally, I think it's important to thank the EP eight new chemical program staff and there are many of them together throughout the room and they have been working extremely hard since the Lautenberg enactment were amended. The team of experts cuts across multiple branches, programs and they work hard to ensure that newer more innovative and safer chemistries are making their way to the market. So in addition to the day-to-day aspects, the team has put together a great program for you today. I think them for all their hard work on this and I think we should all benefit not only in the program but all the stakeholders from what they put together from the information shared in the discussions we will have. Again, thank you for participating, thank you in advance for your feedback. I want you to know we value everyone's input. With that I would like to turn it over to Dr. Jeff Morris our Director of the Office of Pollution Prevention and Toxics to get us started. Thank you.

Jeff Morris: Thank you, Nancy and everyone. As she said we are a year and a half into implementing the new chemicals program and we have learned a lot, but any time you are setting up a new program around new statutory requirements you want to get to a point where you can lay out a framework for how you are executing on the statute and making decisions and that's what I'm going to talk about. But before we get there to the next slide just a reminder particularly on the first bullet that a profound change to how the new chemical programs operate was our requirement to make a permanent finding every one of the new chemical cases that we received in the toxics program and just as a reminder, when you look at pre-manufactured notices, exemptions, we get about 1,000 cases a year, about 100 a month in each one of those cases the log requires us to make an affirmative finding. So I wanted to touch on on the next slide just to remind us why we need a new chemicals framework. So there are five types of determinations to make the fifth of one not on this slide is one that really has not changed the exposure release finding, the criteria around decisions has not changed and really the questions, comments, input that I have received for the past 18 months have really been around these 4 so I want to take just a minute to review the bidding on these four determinations one of which we need to make. And the first two on the left the presents an unreasonable risk and they not likely to present unreasonable risk are predicated on the assumption that we have enough information to conduct a reasoned evaluation of the chemical. Recall that the Section 5 of task of the section under which new chemicals are governed does not require the development of data to support so using data we received and tools we have, information we have on analogous substances, if we have enough of that information to conduct a recent evaluation then we can make one of these two determinations on the left. And if indeed we find concern then Section 5 of TSCA allows us to make a risk finding and then issue an order to take action on a chemical restrictions and what have you in order

to address those concerns. The second finding on they left they not likely for reasonable risk is a new finding under TSCA if looking at the conditions of use the intended and reasonably foreseen recall that TSCA requires to review recent -- new chemicals and these are new substances premarket we are talking about the uses. And if we believe that the intended and reasonably foreseen they're not likely to present an unreasonable risk we present that finding and the submitter is allowed to provide a commitment and move to market. Now the two determinations on the right-hand side are two types of determinations where we don't have sufficient information to conduct a reasonable evaluation. And they fall in the insufficient information category, but there are two types. There is just plain insufficient information we can't do a reasoned evaluation. The statute then requires us to issue an order and that would typically be in the form of testing or to get that information as well as insufficient information where we have some indication of concern and it could be a structural alert, analogous substance for which we may have concerns that we don't have enough information to conduct that reasoned evaluation. That is the main present finding which is under that insufficient information area. And in those cases we would then issue an order. So when I talk on the subsequent slides about the digital framework mostly talking about how we evaluate where we lie with respect to these types of determinations. And the feedback that we have heard is that the way that we have been making those determinations has resulted in the marked difference from how the EPA operated prior to the Lautenberg Act particularly in terms of the number of orders that were issued for the program. So we are going to talk about that. At the next slide we are going to move into the decision framework now and what I have done is the framework document is on the website and hopefully you've all had a chance to get a copy and take a look at it. I've excerpted a couple of parts of the framework based on the comments that we have received so far to this meeting in particular focused around the framework. So the first think that I have pulled out of the framework is the idea that where we have concerns with initial submission of the pre-manufactured notice and we are going to look at -- discuss those with the company and if during the evaluation period there is time to amend that submission, then we will make our determination based on what the ultimate determination is whether that's original or amended. In some cases the submitter will determine they would like us to evaluate on the submission as originally submitted and in other cases based on issues we've identified in our review and typically around the third week of review we are at the point where we can articulate those. Then I am sure the submitter decides to amend their determination then we will evaluate around that. Now that assumes a timely amendment of the submission because we do have the statutory deadline under which to review the submission. And I will just say that this implies this being this willingness of the agency to consider amendments and make a determination on those amendments, implies a time dimension as I've said. We need to have those discussions early on to allow amendments to be done in a time that will allow us to make a time and determination on the submission but it also implies work for all of us. The more back and forth that needs to occur between a submitter and the agency around potential amendments involves staff time from all of us, certainly within my program and often requires rerunning models, making new calculations and so we are going to talk later in the meeting about a point to consider document about pre-notice consultation. So when I talk about executing on this aspect of the framework it really implies I think broader programmatic changes in different ways of doing business for all of us in terms of how we approach submitting a PMN and how we go about doing that because really where we want to be obviously is in a position where we can make a determination on initial submission and have enough information to do that and move on and go forward. But the framework is going to allow us to have that engagement early on as long as we can do it and meet our statutory obligation.

Now the next slide gets into an issue that probably generated the most comments and that is where in the cases where we get a submission that comes in, we look at the submission, which we would consider to be the intended use of a chemical substance and we believe that the intended uses as described in the pre-manufactured notice are not likely to present unlike -- unreasonable risk. However, as I mentioned the statute also requires us to look at reasonableness. So if there's an analogous substance that has uses not identified in the pre-manufactured notice or conditions of use around that substance and different ways of applying for

substance or manufacturing it, different ways of handling it and we believe that those other conditions of use have the potential to present risk and to raise concerns for us then one way to address that is by issuing a rule that indicates that if anyone wants to deviate from the condition described in the pre-manufactured notice for which we don't have concerns then they would need to come in with significant use notice so we can evaluate what we consider those new conditions of use to determine whether or not they presented an issue. So it is our belief that reasonably foreseen uses could be controlled through a significant new use. I will point out that in the cases where we issued a consent order because we had concerns of reasonably foreseen uses and found the submitter to conditions in that order, we were only finding the submitter so therefore, we needed to go out with the SNUR anyway who holds the rest of the world to those conditions until the significant new use notice. So in our view this particular approach what it does is it allows us to go from those two actions issuing an order followed by SNUR to issuing the significant new use rule which we believe would accomplish the same objective. So that was an important comment -- why are you moving from orders and really is there a distinction between doing an order followed by a SNUR and/or just going directly to a Significant New Use Rule. And it's our belief that really they could be equally protective, but eliminate that one step. There's also the question around this about testing. Typically when we would issue a consent order based on reasonable -- concerned with reasonably foreseen uses and followed up with the new rule, in that order would be testing often called panda testing. Pending any changes in the submission could trigger a test. For example, if a pre-manufactured notice said we are putting restrictions in place to ensure no release to water and we had concerns for aquatic toxicity then we may say a pending test is an aquatic toxicity test pending any changes in that order. We would not do that unless there was a change in the conditions of use and we believe that if using the non-order SNUR approach of someone came in with a significant new use notice and wanted to change the conditions then we would look at whether that type of testing might be needed. So in our view in terms of the actual impact on testing done there is not really [inaudible]. There was concern or questions about whether the civic -- significant new use notice would track the PMN the notion being if EPA did not have concerns with the pre-manufactured notice but had things like no relief to water or release to a certain concentration with the Significant New Use Rule mirror that PMN in a way that would ensure that the protections for which we believe there was no concern of PMN, are captured in the SNUR so that we could be sure that anyone would deviate from that it would be clear which deviations would be in the required notice and the answer is yes that we would aim to do because that is how you ensure that not only the submitter but anyone else who wants to deviate from those conditions notice so that we could have assurance that that determination be made still held regarding any changes in the conditions of use.

So there was a lot of comment on this. I suspect there will be more, but we do believe this one approach that not only can be equally protective, but can also be more efficient and that it does eliminate that one step in the process. So the next aspect of the framework is to reasonably foreseen uses. Now this is the idea that as we understand reasonably foreseen, reasonably foreseen is not anything that is possible. It's not respect about this it's grounded in some sort of understanding knowledge, and experience. And some of the comments we got on that referred back to the final Risk Evaluation Rule that we promulgated articulating this notion of reasonably foreseen grounded in information that would make it less than speculative and it looks like what EPA is saying that reasonably foreseen means a probable use. I think that's a misinterpretation of what we have been the rule so I would ask folks to look at the rule language carefully and I'm only reading this because I think it's very important because to me this really is fundamental in determining whether we need to do more than make a not like determination where we don't have concerns for the PMN you so if you look at the Risk Evaluation Rule it says when we are talking about reasonably foreseen what we are saying is that it is reasonable to foresee it's a condition of use. For example, where fact suggest the activity is not only possible, but over time and under proper conditions probable. So, I mean, so I think if you read that carefully and first of all, is the general concept is grounded in knowledge, understanding, experience and it is saying that a good case is to look at when you look at a chemical substance you could envision that over time should the proper conditions warrant

then you could see that chemical substance is used in a way different from that described in the PMN in a way that makes a difference for an environmental or public health protection and it's a reasonably foreseen condition of use that's different and would warrant evaluation on its own. So I think that's important because again it is our belief that the notion of reasonably foreseen doesn't mean possible and this is going to be very important because in the new chemicals area as compared and contrasted with the existing chemicals, these are new substances so there is uncertainty there. And so I think we want to be clear that we are looking at these submissions, these chemistries in ways that is practical and protective. And I think you can only do that based on knowledge we have over the decades accumulated quite a bit of knowledge on analogous substances and the way these chemistries operate. I will just say in referring to the rest of the meeting we talk about points to consider and pre-notice consultation that the experience that submitters have on how their chemistries can be used can be valuable information in understanding whether they might be reasonably foreseen uses. So going both ways whether we believe the chemistry could be used in different ways and here is how or no, we have decades of experience suggesting that they are not likely to be used in other ways. All of that information would be very important to us in our evaluation and will allow us to ground these types of determinations in knowledge and information. So next slide.

We are going to stop now. I wanted to make sure we had at least a full 15 minutes for questions and comments. There is a lot there, so we are going to move now to the Q&A portion of this. So I'll turn back over.

Speaker: Thank you, Jeff. Before moving to questions I will describe and explain the process for questions and comments and we have until 10:00 a.m. for the question so we will allow time for questions on the frameworks just discussed. To the extent EPA can answer those questions readily and as time allows they will do so. And maybe that some of these questions will require EPA to go back and consult with a technical expert, the legal team or may even require a policy decision so in those cases questions that are broadly applicable it may take longer to address but EPA will try to provide answers in the docket. Just so everyone knows there's also time reserve this afternoon for questions that were submitted in advance of the meeting so if you've already submitted a question in advance, please know EPA will make every effort to address it. There's also time reserved at 11:00 a.m. and at 3:15 p.m. this afternoon for public comment. So for those in the room who have question on the presentation we just heard I would appreciate if you would line up at the microphones. You can choose the microphone you wish and when it is your turn to speak please state your name and affiliation before asking your question. We will take 3-4 questions in the room and then 3-4 questions from our webinar participants. For those of you on the webinar, if you are participating and would like to ask a question please call into the phone number on the slide and the key will be managed by the operator. When it is your turn your phone line will open up and you will be able to ask your question. Please also state your name and affiliation before asking that question. So, again, on the phone before you begin to speak mute your computer speakers and press the speaker icon on the webcast interface. If you are experiencing any technical difficulties click on the help tab and explain your issue and a member of the tech team will assist you. Starting now, is there anybody in the room with a question? If you could come up to the microphone and state your name and affiliation.

Speaker: I'm Bob Shusterman representing Schaefer chemicals and Jeff, in your presentation there were two important points that I don't think were addressed and I will pursue them in the form of questions. First where EPA believes the amendments to the PMN address the concerns about the PMN substance, is EPA than going to make a determination that the PMN substances unlikely to present an unreasonable risk and if so what is the timing of that determination in relation to the SNUR. Will it be before the SNUR is issue? Will it be at the time a SNUR is proposed. Will it be at the time when EPA issues a final SNUR? How will that play out?

Jeff Morris: Thanks. So my only point on that slide was that we would allow time for amendment to make a determination. What that determination might be would be solely based on that amended submission. So it could be a not likely determination but it could be something other than that as well. It could be any one of the

determinations. It's just the point was that there are many cases where we get a submission and we have questions or concerns and need additional information on that and that information can often refine our estimates of risk and our ultimate determination so where that determination would land is just very much case specific, but in those cases where you mentioned where based on the amendment to the submission we believe that any concerns that we may have had regarding the intended use have been addressed and I will just say that those changes can be generally of two types. One, it is additional information on what the submitter was going to do anyway. Sometimes we will get a submission in and it will be unclear on industrial process, personal pieces of equipment, relief, et cetera and that can clarify had. In other cases when we identify a concern and let's say it's related to a worker exposure and/or it could be related to water, but whatever it is the submitter said I will make this change to address those concerns and amend accordingly adding a personal piece of equipment requirement or some sort of change in process. And then we make the final determination on that. In those cases where we believe now the intended submissions does not raise concerns to us but we still do have concerns as to unreasonably unforeseen uses should we pursue the SNUR path, then one of the things we are trying to work out now and what we would like to concede back from everyone -- we've gotten some of the comments now, but it still an active area for discussion and I appreciate input are the timing issues associated with making the determination and promulgating the SNUR for both proposed and final. I think that is an important set of considerations so it's useful to get comment on that because we have a number of issues at play here. We have the issue wanting to get a SNUR when we employ a SNUR get that in place so that not only the submitter but everyone else is held to those conditions and we also have the issue of the statutory review period as well which just so we are on the same page for a pre-manufactured notices 90 days with the agency's discretion to increase that additional 90 days up to 180 that is it. So there is that consideration as well. Of course, I should say as well there is also -- there are cases where submitters may need to extend the review period but we like to operate as much as we can within the statutory considerations given. But, just the point is is that we've got these two things that we need to work out to ensure we are both being protective and we are meeting the statutory review obligations of the statute. So, again, I think this is an area of active discussion. I appreciate the input we have gotten and I welcome more.

Alice Tome: Thank you. Next question.

Speaker: Rich Engler representing the chemicals coalition. Has EPA made any not likely to present findings for a new chemical for a substance for which EPA has identified a hazard? So on the website the only not likely findings are low hazard to health and the environment. If the website hasn't been updated in a while then I understand the new SNUR processes being contemplated but have there been any substances so far that EPA has found not likely to present for which EPA has identified a hazard?

Jeff Morris: Rich, I will have to go back and look at these submissions and consult with folks and get you that information. Happy to do that. The only I guess question I would have around that is being able to articulate when you say identification of a hazard, what exactly you mean by that or what you mean by that because obviously given and affects database where your call comes out hazard is on a spectrum.

Speaker: Absolutely so new chemical departments anything other than a low low.

Jeff Morris: I think we've got that so I'll have to go back and follow-up.

Alice Tome: Any other questions in the room?

Speaker: [Off Mic]

Alice Tome: All right. It's a race. I will let you go first and then we will follow up behind.

Speaker: Karen Schmidt, ACC. My question goes to reasonable foreseeability. I'm hoping Jeff, you can elaborate a little further about how you determine reasonable foreseeability in a temporal spectrum and by that,

I mean, how far in the future are you able to project, what's the methodology used to do that and at what point does future uncertainty and the injection of different variables kind of swamp the ability to make that projection? Thanks.

Jeff Morris: Yeah, that is what I was trying to get at by reading that risk evaluation language because it tries to capture that notion as well and I'm hoping -- and that's right. Over an infinite span of time or over decades -- you get to a point looking forward where you are obviously you have uncertainty that grow so the farther out you go the more difficult it's to predict how a substance might be used and so I think we look to the language of the statute reasonably foreseen as important and there is a reasonableness to that that I think you've got to do your best based on what, you know, now and based on your decades of experience with the chemistries and looking at what they are and how they might be used. There is no particular I think algorithm you can follow to get there, but it's got to be based, as I said. There is somewhere between possible and certain where you've got to make that cut. I think possible is not the same as reasonably foreseen and so you've just got to I think look at experience with those chemistries and look at what you did in the past to try to indicate what the future might bring for you because that's been extremely helpful. Most if not all, some chemistries are entirely unique, but I would say in most cases you can draw from experience about how chemistries are used and how they tend to evolve over time. So I think we take that all into consideration and as I said before and I don't say this enough, I think that those who have experience manufacturing these chemistries and those who have experience using them to the extent that can be brought in early is not pre- submission at least submission on understanding of how the particular chemistries have been used that can be very helpful in understanding whether there are reasonably foreseen uses beyond those described in the pre- manufactured notice or I think to the extent that we look at analogs, we do a lot in terms of understanding how analogous chemistries how their uses may differ from these submissions. Understanding whether those analogs really are analogous in terms of the conditions of use, that could be helpful as well because they may be structurally analogous, but there may be attributes of them that do not correspond with the new submissions chemistry and therefore, know that the new chemistry is not going to be used that way and here is why and all that information can be very valuable to help us make that determination.

Alice Tome: Thank you. We will take two more questions in the room and then go to the phone. Go ahead.

Speaker: Richard Donovan Environmental Defense Fund on August 7 of this year administrator Pruitt issued a press release that included a set of new operating principles for the new chemicals program. As we read the framework document that is now available, there are at least two places where there are significant discrepancies between the two. One is beyond the issue we were just discussing having to do with reasonably foreseen. Whether the operating principle clearly states it needs to be probable. And Jeff, if I heard you right, I think you are taking a step back from that in describing what you are saying now. Maybe I'm wrong about that so please clarify. The other area where there seems to be a difference is an operating principle that from our perspective began to re-create the Catch-22 that plagued EPA under the old TSCA where EPA could require testing where it had evidence of risk and it does appear the framework has rephrased that operating principle in a way that at least to some degree is a concern. So my question is are those operating principles in fact going to be modified to reflect changes that are made through this process of developing a framework and getting comments on it or are they going to remain the same? If they are going to change, how is that going to be announced publicly? Thank you.

Jeff Morris: So on reasonably foreseen, the press release is an extractor of or a paraphrase of the Risk Evaluation Rule language and what we tried to do in the framework's site back to the Risk Evaluation Rule language and I think that is important. We put that out there in our role and as I read it, I think the agency is more nuanced than saying reasonably foreseen equals probable. It's not that. But it is certainly not just what is possible. So I think that to the extent that we need -- if it helps at all to clarify in the framework, it's not quite there yet then part of this meeting and the docket in the comments we get here and in subsequent meetings will

help improve that framework and we are happy to do that but I think this is what is going to guide us going forward so I think being very clear on that is important. The other issue is on the testing issue. That is one thing we tried to do in the framework and what I tried to do with that second slide when I laid out those determinations, separated them into two groups, those on the left that were presents and the not likely as being those for which we had sufficient information and those on the right both the insufficient information and the information may present as those where by definition have insufficient information where testing can help improve our understanding. I think another part of that that is in the framework and in the discussion is the whole idea of reasonably foreseen uses of when testing ought to be conducted. And that is why we believe that should we take an approach where we issue a SNUR there could be value in identifying in that SNUR I welcome comments on this as well. Into whether it would be useful for the agency to put in that SNUR some indications of possible testing that should someone submit -- the clear example for that is where an intended user to water somebody wants to commit that we want to release to water and if an aquatic hazard is indicated in the review but didn't lead to a risk concern for us, but nevertheless I hazard concern you can see where you might want to indicate where that type of an aquatic toxicity test could be useful to someone to come in with a significant new use noticing those indications for testing I think could be helpful. And then finally, we will talk later today about chemical categories and I think there is a whole discussion that ought to occur around how you get information around categories of chemical substances to improve our understanding of them. All those testing considerations as you point out are important considerations for how we act on the framework.

Speaker: My apologies but my question was much simpler. Administrator Pruitt put out a set of operating principles. The framework seems to move away from a couple of those in significant ways as you just described, Jeff which trumps, and will those operating principles be brought into alignment with the framework? That's the question.

Jeff Morris: Right so ... I believe we viewed the operating principles outlined in August as they are consistent with our framework. If indeed it turns out that the way we have described it in the framework seems to be at odds of that, I think we should use the comments in this meeting and the comments to clarify that in the framework but I don't believe that again I am not seeing that discrepancy but I can certainly see how maybe we need to clarify because the way that I described reasonably foreseen, for example, again in going back to the place where we identified that in the rural in this evaluation is the correct way to read this but we are going to move forward -- we are acting on this framework now. It's another question by the way, that came up in the comments is EPA acting on the framework now or are we taking comment on it and waiting to act on the framework as we develop comment. As a framework for making our decisions, we need to make decisions as the 100 submissions per month keep coming so we are doing that and we are acting on the framework and governing ourselves by the framework, but the extent that we can enhance that framework or clarify aspects of it including in the two areas that you mentioned, then we should do so and we should be transparent about that and use that as our transparent way of holding ourselves accountable and helping you hold us accountable.

Alice Tome: I've been told there are no colors right now so if you are interested in participating by the webinar and are interested in speaking, please do call and right now and until then we will continue to take questions from the room.

Speaker: I'm Joe with People for the Ethical Treatment of Animals. My question concerns transparency but first I would like to mention what Jeff just asked about including suggested testing in's nerves and we are in favor of that we would like to see agencies doing that. So the amended task that requires EPA to make its determinations to Simmons and consent orders publicly available so my question is would you please clarify EPA's policy, what information is being made available, when it's being made available and where I found some of it on chem view. Is that the only place we would look? Thank you.

Jeff Morris: Thanks. So we are looking to make Cambio the primary source of that information. We would like to get to a point where people feel comfortable going to chem view and finding that information so I think the answer to that is yes, and I think we will continue to work to get that information up and available and I will say that I would fully expect that as we take comments on the framework, as we begin to act on various parts of the framework that how we describe things will change a bit. We just need to be transparent about that. So I guess that is my simple answer to the question is yes, we will be looking into Chem View and to evolve the information we put up there as we added on the framework.

Alice Tome: We will go to the back first. I will go to the front. Go ahead.

Speaker: You were first.

Speaker: I'm Larry with [inaudible]. Jeff, could you address one thing that was implied, but not stated in your description of the framework. To the extent that PMN form allows submitters to indicate their willingness to be bound by certain attributes that they respond to in the form, to what extent is that being or is it anticipated that would be part of the deployment of the framework, which might enable you to get to significant new use rules more swiftly? I will just add as a comment, I did not hear you state it specifically, but it's in the policy forever that the proposal of a Significant New Use Rule defines what uses would be considered new and that's why I think the future of the finding box may be something on which you would want to comment particularly to extent your framework has discourse of amending their submissions to accommodate risk use. Thanks.

Jeff Morris: So it's my -- I don't believe we plan on making any changes to the binding option I laid out in the PMN. There's no change there. To the extent to could be useful, I suppose so. But I guess should we ... should we take the SNUR approach, I think that it is very important that we do that in a way that is linked, if I could use that word, to the protections, restrictions, identified in the PMN so to the extent the buying option helps with transparency or clarity on that, I suppose that is useful. But should we go the SNUR route in a specific case we want to make sure that is very clear on how that links to the what is outlined in the PMN and relates to our protection because people have to be clear, they have to understand what degrees of freedom they have short of submitting a S and UD when they use the chemical substance so all of this can be used to help make clear on that. Because everyone wants to understand should we make that not likely determination and have the SNUR other that they know what parameters are in operating and what conditions in the submission and what conditions in the SNUR govern operations and how deviations -- what deviations [inaudible]

Speaker: Good morning Jim Cooper with the American cap petrochemical manufacturers. I've one for you. Sent some people may not be as familiar with the pre- notice consultation processes others can you confirm when the clock starts on that 90 day review? Is that when the actual final PMN get submitted, which would be after the pre- notice consultation?

Jeff Morris: One caveat to what you just I would be the final. We are talking about amendment but initial submission [Overlapping Speakers]

Speaker: Before the amendment.

Jeff Morris: The whole point of pre- notice consultation would be to have a consultation prior to submission prior to the start of that clock -- we will get into this later in the meeting, but to answer any questions based on our guidance so that when the submission comes in and the clock starts, then you can move forward.

Speaker: That's what I wanted to confirm. Thank you very much.

Alice Tome: Time for one more question. [chuckling]

Go ahead. Unless they are fast.

Speaker: Jamie Conrad, Conrad law and common Council. I wonder if you could clarify in the decision framework document it speaks only of Section 5 notice, never specifically refers to the availability of exemptions under Section 5(h). It seems to class them and PMN together as if they are the same thing. I wonder if you could comment on to what extent the five each exemptions continue to exist or differ any way from PMN how they are processed under this framework.

Jeff Morris: In a general sense I think that the principal holds in terms of finely -- timely review meeting the deadline, to the extent we need to have those discussions. Exemptions sound on the face that it's an easier thing so the review period is shorter and there are considerations and exemptions that could benefit from some pre-notice consultation and discussion prior to the submission. So I think those aspects of the framework hold, but I would see provisions around exemption. I think they remain as an author of the statute, there was no intention to I guess collapse the exemptions. By the way, folks have of the submissions we get our exemptions.

Speaker: In 1995 the agency said it would only, "Make an affirmative determination not likely to present risk" so in some ways you were ahead of the statute then.

Jeff Morris: Right, right.

Alice Tome: Thank you very much for those questions. We are now moving on to the next part of the program. Dr. David Tobias from the risk assessment division of OPPT will provide an introduction to the points to consider document.

David Tobias: Thank you, everyone for coming this morning. I'm going to give an overview of our point to consider document. If we could get to the next slide please. I will go through each stage of the document and then a pilot we conducted to get or refine the document and the comments received and then I will have a brief discussion at the end. So we could go to the next slide again and start talking about the purpose of the document. The purpose of the point to consider document PTC is to provide precise guidance to improve submission and this document is based on our experience with interacting with submitters and what we have had to request to improve and refine our assessment but it is basically a CliffsNotes version of the sustainable future program which we will talk about later today. We hope this document when finalized will help to loose - - reduce delays in the multiple back-and-forth we have with submitters and just as examples to common problems we find is that when we get information that are not submissions to alter or does not allow us to refine the risk assessment. Examples of that would be that we need to have sufficient documentation on record now to change from our defaulted models and another thing we notice after focus is that useful information may have been in the submitters possession but they did not realize they should submit it when they sent in their PMN. So as I mentioned we have sent this document out to industry participants and have gotten comments as part of a pilot. If we could go to the next slide please.

So for PMN submissions the slide is an overview of the general information requirements. Chemical company has to submit their chemical identity, structure and a chemical name, described their production volume weathered be important only and give a description of their intended use of the chemical. But under TSCA there is not a basic set of guidelines testing either OPPT for TCAM, fate, ECO toxicity or human health that must be provided so commonly we are working with models to perform our assessment. Next slide down please.

So this is to elaborate on the risk assessment part of our process that appears in the point to consider document. What we've done in that risk assessment is focus on information that we hope can expedite review and as I said this is based on our past as one of the commenters pointed out there are pre- notice consultation's. We encourage companies to participate in those. What they provide is a lower tier then a PMN review so what we will have as a conversation with the submitter about the types of information they can turn in and how they should presented to expedite review of the PMN it's not the same thing as a full PMN review process. Getting

back to the point to consider document it does have sections to cover all the parts of the risk assessment process including chemistry, hazard, different exposures, environmental fate and ecological exposure. Also within the document there are examples of the assumptions that are commonly made in absence of information and so these are what I call our defaults in conducting PMN assessments. Next slide please.

So one thing we always advise submitters is to know your chemical. So you want to begin when you think about your chemical with the TCAM information because during the review we will consider participating metabolism and degradation products and all of those will be evaluated part of the PMN process so any information you can submit to make it clear to us what is going to happen with your chemical will expedite the review. So by thinking about absorption, thermal, inhalation, ingestion and what the following effects could be. So there are already existing guidance that would help understand the chemical types so later we will be talking about chemical categories document, but also based on commonly understood alerts you can save your chemical is likely to hydrolyze we will assess decadence for eco- toxicity. If your chemical fits into one of our existing new chemical categories you should look there and consider what's presented there in terms of the testing which is a significant parts of those document so you can understand where our thinking process may go. If we could go to the next slide please.

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So this is again for the points to consider document we give some examples of useful information to provide upside -- up front to expedite the review. So on the exposure side particle size distribution. That's commonly and strongly impacts worker exposure, and we have a preference that you turn in information that will help us understand particle size distribution as the location where the worker will be exposed or during that process. And in the absence of data, as we point out our default, one of them is particles are assumed to be respirable. The other thing that we describe in terms of exposure is that the better process information we can get particularly at submitter -controlled sites, the better our review and the more refined our risk assessment will be, but in the absence of that information EPA has a generic scenario we will rely upon and of course, they are intended to be conservative. Next slide.

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So on the toxoid the document has information both on human health and eco- toxicity. Commonly a good place to start is with physical chemistry to understand your absorption and potential routes of exposure. We encourage submitters to search for analog and structural alerts. We discussed the documentation how we do analog searches. There is a description of AIM and other tools that we commonly use. So as I mentioned before, we are also going to consider metabolites and decadence and when you submit data or if, you know, of data and want to describe how that was generated when there is an established guideline if not we may ask for more information or rationale to explain why that is relevant to the PMN and use in assessing hazards, but we always state we do consider certain cases not guideline studies and that can assist us in assessing the hazards from your chemical. One more.

So the next section of the points to consider document briefly goes over each of the next three sections how we do risk calculations, what happens at the focus meeting and what could happen in standard review for your chemical in all sections of the PMN go there, but for human health we use a margin of exposure for noncancer endpoints in a slope factor for cancer. For ecological risk 2 determinations acute concentration risk and chronic in both depend on the COC chronic is 20 days or more in surface water. And many of, you know, the focus meeting is where this is all pulled together and the risk assessment is finalized. At this stage, this is where submitters after this meeting are routinely advised about identified issues, for their information they should submit to assist us in refining their assessment. So this points to consider document should help in improving the information we get so we can move away from default assumptions if we get a sufficient rationale for doing so. And as I pointed out for cases that we have concerns about they have to move to standard review where we do a more in-depth analysis. Thank you.

When you enter that stage of post submission communication with your Program Manager or risk manager, it is important that you notified that person when you send in new information. As I point out in the bullets there, we do get a large amount of information and it's important to try to package that information to help us review it. That's always to your advantage when using CDX. You should consider use of a binding option when discussing the case with the PMN and as an example EPA commonly is looking to refine estimates of the kind of controlled technology in place, worker protections, the descriptions of your process and use information.

We received a question about what could happen in post submission and we stated that we are looking to mitigate risk or assess mitigation perhaps to move completely to a low concern. But obviously it's a case-by-case situation. The outside of this points to consider document there are other sources that companies can go to to look for information about how our process works to improve their submission. We have examples of future programs and documentations been created for that publicly available online. As I point out here, it does contain a lot of description and step-by-step details on how to run can steer which is what we use for workplace exposures and releases so I strongly encourage everyone to consider that if they are preparing a PMN. And this is commonly something we pursue is the EPA it may request a rationale for the parameters that are default in the Kim's dear program. So the next stage of my talk is on after we created this draft points to consider document we thought it was important to kind -- try to refined it so we worked with ABT to gather industry participants and had a pilot with companies and they've submitted comments to improve clarity in the utility of the document. We thank you for those comments and it's always important to get the perspective of the users of a document.

The comments that we ever received from industry are actually all posted on the same website where you found out about the meeting today. The draft that we release does reflect some changes from those comments that we've received but we can also release the initial document that we distributed to ACC when the pilot began.

Just one thing to clear up, as I discussed a few of the more frequent comments, sometimes or several times there was a request for expanded scope but point to consider document is meant to be concise. So as I pointed out there other places to look for references or more in-depth discussion of this part of the process.

So going through more comments that we've received, a lot of submitters had questions about when model information was used as opposed to submitted data. We have consistently had the data hierarchy I show here and we prefer to have high quality information on the PMN, the next tier down would be high quality information on an analog and then we have to drop down would be modeled data. So why is the submitted -- why isn't submitted toxicity data you so when the information comes in we do a study to conclude if there is insufficient information and that may require us to use a different tier in the assessment hierarchy. And sometimes the submission -- submitted information is not sufficiently needed. So the example is we also considered fish in doing eco- hazard assessments. Next one please.

So some of the submitters also would like a complete list of needed testing during this pre- notice stage. So as we heard comments already and as I've indicated it is not a full PMN review. So since we have not done a complete consideration of pathways we cannot give this during the pre- notice consultation. So these recommendations under TSCA are based on risk concerns and the opposed -- exposure pathways to identify populations and the risk assessment and this is all the information we have when it's complete. These are not performed before pre- notice consultation. So for the worst case assumption several submitters asked for the complete description, but many of these are already in the a Sustainable Future material and explained how we approach models such as ChemSTEER and EFAST that allow us to calculate worker and environmental exposure and also FB suite is available online which is what we use for bio accumulation. Many have documentation and that explain how the documents are generated. I've described ChemSTEER is what we do for worker exposures and E fast has a description within it of how you use general categories to get low flow scenarios and there is also an exposure model that is set up to provide investment of consumer exposures. Assessment of consumer exposures. So lastly, the future for the points to consider document is that we do plan to seek a broader set of comments after this meeting, after this document, after another set of documents and all of our pre- public requirements EPA will update the draft and that will be the official version for use for submitters that wish to use the document for PMN.

As I've mentioned throughout the talk, we hope that in moving forward that submitters can take advantage of the points to consider document. It contains information that we really hope will improve the timeline of how we have to conduct back and forth with submitters to clarify and refine our risk assessments so that as focused we have hopefully a complete set of information that would be the end of the risk assessment stage. That is the last slide of my talk. I think [inaudible]

Alice Tome: Thank you, David. We will now take a 15 minute break and reconvene at 10:30 a.m.

[break taken]

Speaker: Thank you. Next we have [inaudible] Jensen.

Speaker: Good morning and thanks for being here and thank you, EPA for convening this session to give us an opportunity to share input on the points to consider document. My name is Dr. Jensen from Dow Chemical Company. I'm a risk assessment specialist in the development of pre- manufactured notifications for companies. Dow Chemical Company supports the implementation of the revised TSCA and looks forward to ongoing improvement and scientifically rigorous risk-based evaluation of new chemicals and we are committed to developing robust information to support future materials. Points to consider document specifically we would like to thank EPA for taking the effort to capture lessons learned from past experience which is a huge win for all of us. My comments will be high level and focus on three primary areas. First, around communication between EPA and PMN submitters. Clearly we have heard clear and timely communication between agency and submitter is critical and that's a burn both on EPA as well as submitters. We think the approach with the pre- notice consultation is an excellent one and the agency should consider developing this. Indeed there may be other experiences from other parts of the agency or other agencies that would inform this effort as other groups conduct similar pre- notice consultation Senate might be helpful as the agency gets more

experience if you could provide more specific guidance on what you are looking for during that meeting. And what we can prepare ahead of time and in the spirit of open communication we would recommend the agency recommend providing their notes as a matter of course. The document revised stated that would only happen upon request, but most submitters would like to have that documentation. Further down the road in the PMN process as mentioned previously it would be very helpful for the agency to prepare to submit engineering reports and FAC reports these are informative and our understanding of how the agency has the pre-manufactured notice in the general timing is a major consideration in submitters in general would like to see more predictability and timing throughout the PMN process. We also like to emphasize that risk-based evaluation is at the forefront and just as low hazard of a substance may reduce the need for refining risk assessment, low exposure should also be a consideration for managing that. As well as uncertainty around the hazardous assessment should not drive risk management measures without further consideration of exposure as risk. We feel exposure information is key to understanding the risks from these chemicals when submitted to the agency in a hazard only approach on the risk side of the equation. Numerous models exist for evaluating new chemicals and they range from screening all the way through higher tiered assessment. And we feel the framework for assessing chemicals needs to remain open and it took to accommodate new additional information to [inaudible] when necessary. And finally, my comments will talk on the nature of the guidance. Firstly application-specific PMN. One of the challenges we often run into is that much of the information, for example, in the point to consider document our high level and can present a challenge when you are looking at a specific case-by-case PMN, but we consider the pre-notice consultation process is a great opportunity for submitters to work with EPA to get specific feedback on hazard exposures and other areas to be addressed and as was alluded to in previous comments we look forward to additional more specific practical guidance on how to evaluate difficult to test substances, and we'd also like to understand better how agency identifies analogs on what they are looking for when a PMN submitter uses an analog and how that should be justified and also information about the assessment of qualitative endpoints that are not necessarily amenable to a quantitative risk assessment. With that thank you very much. Appreciate the time.

Speaker: Thank you. We also had one other speaker on the agenda was Michael Walls from the American Chemistry Council. He had to have surgery last night so he had a good reason for not attending today. We used the ACC to help try to coordinate and identify companies that might be willing to participate and some folks mentioned we were looking at first solely at sustainable futures graduates who were intending to submit PMN's in the future. So he performed several there and also I think to help coordinate their activities a little bit. So I hope he gets better soon. And I will pass this back to Alice.

Alice Tome: Thanks, Greg. Now we will open the floor to questions on the points to consider document and our pilot panel discussion we just heard and we will use the same procedure we've before taking three or four questions in the room and then go to webinar participants and we will continue to alternate with the time we have, which is until 11:30 a.m. For the webinar participants, the call in number is on the webinar slide and we will start here in the room. And I think -- go ahead.

Speaker: I'm Linda Rice team with the [inaudible] awareness organization. I have two questions. It was mentioned there were eight panelists. I would like to know who the other four are. We know Mike is in the hospital. We hope he has a speedy recovery. Who are the other 4 companies and the other part of my question is why are stakeholders environmentalist and trade unions absent from a pilot panel when you have the firefighter Association and many others here today that would love to lend their expertise on chemical review. Those are the two questions.

Speaker: There were actually eight companies. Michael Walls is with ACC so there are five other companies. Not all of them had originally agreed to had their identities disclosed. As I explained, this was part of an effort to identify companies that were ready to submit PMNs and so it's tied in with the confidentiality of the PMN. But I will try to get the identity -- those companies contacted and find out if they will agree to have their

identities made public and we will put something in the docket. Your second question, why wasn't this open to non-PMN submitter participants. The purpose of the document is to enable PMN submitters to provide more robust submissions to us that will speed up the process. It was not meant to exclude the expertise of other NGOs and the like. And that opportunity is now being made available. We wanted to make a first cut to save this document document was useful for its intended purpose, which is PMN submitters. I think we are off to a fair start. As David said, we took their comments, we are taking comments now from everybody in this room as to whether or not they think that Points to Consider Document is a useful tool so there are comments and we are more than willing to accept them.

Speaker: I will put formal comments into the docket.

Speaker: Thank you.

Alice Tome: Thank you. Next.

Speaker: My name is Herbert Schweikert. Had a question or comment concerning the need to submit full study reports. And the tension of that requirement with the unnecessary animal testing. You are probably where most of the data on chemicals as publicly available to some degree for each program and generally only robust study summaries are available to companies that purchase post study reports are generally not provided to companies that want access if they did not in fact conduct the study themselves. So my question is can a mechanism be developed to allow EPA to use robust study summaries in connection with their assessments. I know you worry about quality and it may be possible to use a third-party assessor to certify that the robust study summary is consistent with the full study reports. Same question around full study reports has to do with publication of full studies. In the past prior to the substantiation there was not uncommon for companies to submit redacted studies in connection with a PMN or maybe totally redacted. Is this possible under the new section 14 and so do you still intend to publish studies or through MP ISR make them available in the docket? If that is the case, there are data rights associated with those studies and data sharing opportunities Europe, Korea, Taiwan and elsewhere so there's a problem. Thank you.

Speaker: I think David will answer this. [Laughing]

Speaker: I am not sure. So do I have to stand up or will this work? [Off Mic]

Okay, in the document we indicated a preference for full studies. That does not mean we won't consider study summaries independent upon the review of the chemical in the information we have on hand to do a full description of the hazard for fate or the relevant properties. The need for full studies is based upon the studies that are posted and are not previously reviewed for quality and we want to make sure in some cases that the study and its extracted conclusions meet how we would review studies. So that is how our need in the document is a preference and that is case dependent.

Speaker: Not to avoid my second question, would you consider certification by third-party assessor's? With the assurance that the robust study summary is a full description?

Speaker: I don't think we have considered it but we certainly can pick what you put this in your comments?

Speaker: Yes.

Speaker: Second question publication of the full study reports by [inaudible] and elsewhere.

Speaker: I don't think we have anybody here from the environmental assistance division that's and charged of the substantiation. Put it in your comments.

Speaker: Absolutely.

Alice Tome: Are there other questions in the room? All right. Are there any callers online? All right. Nobody interested in getting access to the expertise here. [chuckling]

A great opportunity. All right. We have a question in the room.

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Also if you are on -- listening via webinar or would like to call in, this would be a good time to do so and ask a question. There is time available. While then I am going to thank our panelist and we are going to move on to the next section which is just the public comment.

Thank you.

Speaker: Thank you. Next we have [inaudible] Jensen.

Speaker: Good morning and thanks for being here and thank you, EPA for convening this session to give us an opportunity to share input on the points to consider document. My name is Dr. Jensen from Dow Chemical Company. I'm a risk assessment specialist in the development of pre-manufactured notifications for companies. Dow Chemical Company supports the implementation of the revised TSCA and looks forward to ongoing improvement and scientifically rigorous risk-based evaluation of new chemicals and we are committed to developing robust information to support future materials. Points to consider document specifically we

would like to thank EPA for taking the effort to capture lessons learned from past experience which is a huge win for all of us. My comments will be high level and focus on three primary areas. First, around communication between EPA and PMN submitters. Clearly we have heard clear and timely communication between agency and submitter is critical and that's a burn both on EPA as well as submitters. We think the approach with the pre-notice consultation is an excellent one and the agency should consider developing this. Indeed there may be other experiences from other parts of the agency or other agencies that would inform this effort as other groups conduct similar pre-notice consultation Senate might be helpful as the agency gets more experience if you could provide more specific guidance on what you are looking for during that meeting. And what we can prepare ahead of time and in the spirit of open communication we would recommend the agency recommend providing their notes as a matter of course. The document revised stated that would only happen upon request, but most submitters would like to have that documentation. Further down the road in the PMN process as mentioned previously it would be very helpful for the agency to prepare to submit engineering reports and FAC reports these are informative and our understanding of how the agency has the pre-manufactured notice in the general timing is a major consideration in submitters in general would like to see more predictability and timing throughout the PMN process. We also like to emphasize that risk-based evaluation is at the forefront and just as low hazard of a substance may reduce the need for refining risk assessment, low exposure should also be a consideration for managing that. As well as uncertainty around the hazardous assessment should not drive risk management measures without further consideration of exposure as risk. We feel exposure information is key to understanding the risks from these chemicals when submitted to the agency in a hazard only approach on the risk side of the equation. Numerous models exist for evaluating new chemicals and they range from screening all the way through higher tiered assessment. And we feel the framework for assessing chemicals needs to remain open and it took to accommodate new additional information to [inaudible] when necessary. And finally, my comments will talk on the nature of the guidance. Firstly application-specific PMN. One of the challenges we often run into is that much of the information, for example, in the point to consider document our high level and can present a challenge when you are looking at a specific case-by-case PMN, but we consider the pre-notice consultation process is a great opportunity for submitters to work with EPA to get specific feedback on hazard exposures and other areas to be addressed and as was alluded to in previous comments we look forward to additional more specific practical guidance on how to evaluate difficult to test substances, and we'd also like to understand better how agency identifies analogs on what they are looking for when a PMN submitter uses an analog and how that should be justified and also information about the assessment of qualitative endpoints that are not necessarily amenable to a quantitative risk assessment. With that thank you very much. Appreciate the time.

Speaker: Thank you. We also had one other speaker on the agenda was Michael Walls from the American Chemistry Council. He had to have surgery last night so he had a good reason for not attending today. We used the ACC to help try to coordinate and identify companies that might be willing to participate and some folks mentioned we were looking at first solely at sustainable futures graduates who were intending to submit PMN's in the future. So he performed several there and also I think to help coordinate their activities a little bit. So I hope he gets better soon. And I will pass this back to Alice.

Alice Tome: Thanks, Greg. Now we will open the floor to questions on the points to consider document and our pilot panel discussion we just heard and we will use the same procedure we've before taking three or four questions in the room and then go to webinar participants and we will continue to alternate with the time we have, which is until 11:30 a.m. For the webinar participants, the call in number is on the webinar slide and we will start here in the room. And I think -- go ahead.

Speaker: I'm Linda Rice team with the [inaudible] awareness organization. I have two questions. It was mentioned there were eight panelists. I would like to know who the other four are. We know Mike is in the hospital. We hope he has a speedy recovery. Who are the other 4 companies and the other part of my question

is why are stakeholders environmentalist and trade unions absent from a pilot panel when you have the firefighter Association and many others here today that would love to lend their expertise on chemical review. Those are the two questions.

Speaker: There were actually eight companies. Michael Walls is with ACC so there are five other companies. Not all of them had originally agreed to have their identities disclosed. As I explained, this was part of an effort to identify companies that were ready to submit PMNs and so it's tied in with the confidentiality of the PMN. But I will try to get the identity -- those companies contacted and find out if they will agree to have their identities made public and we will put something in the docket. Your second question, why wasn't this open to non-PMN submitter participants. The purpose of the document is to enable PMN submitters to provide more robust submissions to us that will speed up the process. It was not meant to exclude the expertise of other NGOs and the like. And that opportunity is now being made available. We wanted to make a first cut to save this document document was useful for its intended purpose, which is PMN submitters. I think we are off to a fair start. As David said, we took their comments, we are taking comments now from everybody in this room as to whether or not they think that Points to Consider Document is a useful tool so there are comments and we are more than willing to accept them.

Speaker: I will put formal comments into the docket.

Speaker: Thank you.

Alice Tome: Thank you. Next.

Speaker: My name is Herbert Schweikert. Had a question or comment concerning the need to submit full study reports. And the tension of that requirement with the unnecessary animal testing. You are probably where most of the data on chemicals as publicly available to some degree for each program and generally only robust study summaries are available to companies that purchase post study reports are generally not provided to companies that want access if they did not in fact conduct the study themselves. So my question is can a mechanism be developed to allow EPA to use robust study summaries in connection with their assessments. I know you worry about quality and it may be possible to use a third-party assessor to certify that the robust study summary is consistent with the full study reports. Same question around full study reports has to do with publication of full studies. In the past prior to the substantiation there was not uncommon for companies to submit redacted studies in connection with a PMN or maybe totally redacted. Is this possible under the new section 14 and so do you still intend to publish studies or through MP ISR make them available in the docket? If that is the case, there are data rights associated with those studies and data sharing opportunities Europe, Korea, Taiwan and elsewhere so there's a problem. Thank you.

Speaker: I think David will answer this. [Laughing]

Speaker: I am not sure. So do I have to stand up or will this work? [Off Mic]

Okay, in the document we indicated a preference for full studies. That does not mean we won't consider study summaries independent upon the review of the chemical in the information we have on hand to do a full description of the hazard for fate or the relevant properties. The need for full studies is based upon the studies that are posted and are not previously reviewed for quality and we want to make sure in some cases that the study and its extracted conclusions meet how we would review studies. So that is how our need in the document is a preference and that is case dependent.

Speaker: Not to avoid my second question, would you consider certification by third-party assessor's? With the assurance that the robust study summary is a full description?

Speaker: I don't think we have considered it but we certainly can pick what you put this in your comments?

Speaker: Yes.

Speaker: Second question publication of the full study reports by [inaudible] and elsewhere.

Speaker: I don't think we have anybody here from the environmental assistance division that's and charged of the substantiation. Put it in your comments.

Speaker: Absolutely.

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done that group, we will move on to the questions in the remote participants. To accommodate as many registered speakers as possible they may present oral comments only without visual aids or written materials. For those in the room who have registered to provide comments, you can -- you have been given a number and I will call you up by groups of three. And each speaker will have up to 4 minutes. I will keep track of the time and give speakers a one minute warning and after four minutes are up we will move to the next speaker to allow as many commenters as possible. Then halfway through we will take oral comments from remote participants but remember again later this afternoon at 3:15 p.m. we will also have additional times for comments from both in person participants and those on the phone. All information obtained during this meeting will be considered in the agency is considered -- continued implementation of TSCA. If you provide an oral comment today you don't have to submit the same comment in writing to be considered. For those making an oral comment the views of the organizations don't reflect those of EPA and mention of commercial products or systems doesn't mean EPA endorses them. We will make available a copy of the slide presentation used today. We would like to call forward the first three speakers, one, two, and three. Hope you are in the room. And if you would state your name and affiliation before giving your comments, please. They are organizing themselves.

Speaker: Joe from People for the Ethical Treatment of Animals. I have a brief mainly supportive comment for the agency. We support EPA's decision to use SNUR to address uses. The amended TSCA directs the agency to reduce and replace animals and the testing of chemicals and based on the agency's initial implementation we were very concerned that calls for animal testing were actually increasing. At last year's new chemical meetings we heard from industry that they felt that the reason for this was that the agency had shifted from SNUR's to consent order so we are hopeful that they switch back to SNURs, but we present any increase in animal use. And we also support identifying reasonably foreseeable conditions of use identifying based on specific facts or knowledge. I was glad to see that in the decision document. At last year's meeting, again, a number of industry representatives described conditions of use that the agency was claiming were reasonably foreseeable, but they were in fact, quite possible. One example was, for example, I think it was a polymer that a 90 day study was requested and that polymer was never [inaudible]. So we are glad to see that being typed up. And ... we would like to thank the agency for affirming that any request for testing will be structured to reduce and replace animal testing, but we remind the agency that it must explain any decisions that require the use of animals and that is among the information that I would like to see publicly available. With regards to the points to consider documents, the only comment I had there was concerns voluntary development of information. The amended TSCA is very clear that any person who is developing information on a voluntary basis needs to first consider non-animal methods and the language in the Points to Consider Document was kind of soft and almost apologetic. Instead I would like to see that requirement very clearly stated and even how that would be enforced and followed up. And those are my comments. Thank you.

Alice Tome: Thank you, Mr. Montebello. Next and please speak into the mic.

Speaker: I'm Linda Weinstein. I'm the cofounder of the asbestos disease awareness organization a DAO and a member of the safety chemical healthy chemicals coalition so Texans matter to me professionally and personally. I'm very concerned and we had a short beer because we were not given all the documents in advance of this meeting. For many of us who worked for nearly a decade with Senator Lundberg to move forward chemical review. And one of your panelist talked about the history of chemicals on what we can learn from the past to move forward. The conditions of use for us right now is in jeopardy of the way the law was written and we feel that it will jeopardize public health and our environment so we are deeply concerned. That being said the scoping doc if we look at history right now so if we are trying to bring reviewed new chemicals to markets and of course, I am brays health and safety and innovation like all of you, I feel that it is deeply concerning to know that the review process fails to me that ACC is at the helm whether you have a pilot program or letters of the agency that the transparency is not exactly what I believe you would like to have. Going forward, conditions of use is important. All aspects of condition of use for new and existing chemicals.

If we ignore legacy expressed us exposure with the firefighters being at list quite the rate of American people how can you fully evaluate a chemical and rule on that chemical to protect public health and the environment? We know for safer control use don't work. The government last week through that out and the sole user the industry is promoting safe and controlled you so we would like to encourage EPA to continue with a strong review, evaluate the scientific information that you are given and reach out to your stakeholders to truly make sure that you have a balance of stakeholders at the helm. Since Alan was diagnosed, hundreds of thousands have died in the last 18 months since TSCA was signed into law nearly 1,000 tons of asbestos has been imported and 22000 Americans have died from preventable asbestos caused disease. People will lose faith in the chemical industry of chemicals are not properly evaluated but more importantly, it will signal a failure to TSCA once again. Thank you.

Alice Tome: Thank you. Next.

Speaker: Good morning, I'm Jessica Ryman Rasmussen at the API. API is a national trade association representing all facets of the oil and natural gas industry, which supports 9.8 million U.S. jobs on a percent of the U.S. economy. And provides most of the nation's energy. API is more than 630 members include large integrated companies as well as exploration and production, refining, marketing, pipeline and marine business and service and supply firms. APIs members are involved in all major points of the chemical supply chain from natural gas and crude oil production to refinery production of fuels and other products to service companies using chemicals. Some of our member companies develop and bring to market new chemicals and file pre-manufactured notices or PMNs under TSCA. API and the members are dedicated to protecting human health and the environments while developing and supplying energy resources. We recognize our responsibility to work with the public, government and others to address the risks that may be associated with new chemicals. API has a strong interest in EPA's implementation of the new chemicals program which has a significant direct impact on our member companies to move forward with technology and business plans evolving new chemicals. Earlier this year API submitted comments to EPA with concerns about delays and difficulties that arose in the TSCA Section 5 new chemicals program after passage of the Lautenberg Act. API now commends the agency on the work it has done to reduce the disruptions and review of Section 5 notices and design ways to implement the post Lundberg program in an efficient transparent manner. This meeting and the associated documents EPA has prepared have increased transparency and are very helpful to the regulated community, which needs to understand the specific requirements of the program and how EPA conducts its reviews. We also appreciate EPA's work to craft a process that addresses Lautenberg Act TSCA Section 5 revisions without unnecessary program changes that delay or impede the review of new chemicals. In particular we agree with EPA's decision to maintain practice of using significant new use rules or SNURs when appropriate to address concerns appropriated with reasonably foreseen use that are not within the intended condition of use described in the submission. API members are still in the process considering an understanding the practical implication of the agency drafts and the decision-making framework, Points to Consider Document and decision guidelines document. API appreciates the additional information and transparency in the agency's openness to dialogue which we hope will be ongoing. We share an interest in answer to the questions others have already offered and summarized in the overview of comments that EPA has prepared for this meeting. We encourage EPA to respond publicly to all of those comments. In addition, API would like to reinforce a few points. First, it would be helpful for EPA to provide more information on how it determines reasonably foreseen conditions of use. In other words, conditions of use not described in the submission. The decision-making framework Inc. discusses that EPA will address reasonably foreseen conditions of use with SNURs and identification of such conditions will be based on facts and knowledge. However, they Points to Consider Document simply says that this will be a case-by-case determination and does not provide information on it. The outline for the decision guidelines include a section on reasonably foreseen uses and we hope it will be robust. Second, we encourage EPA to continue to find scientifically sound ways to scale needs for additional hazard and exposure data to focus on the end goal of assessment of risk. EPA should scale its needs support exposure information to reflect the

chemicals known hazard profile, in other words, less detailed exposure information would be needed for lower hazard chemical. Similarly the agency also should be able to adjust hazard information requirements based on known exposure profiles. Third, we encourage EPA to consider global harmonization to the extent appropriate. API generally supports using the UN globally harmonized system of classification and labeling or DHS criteria as part of hazard assessment and also EPA should consider the use of tools developed for other regulatory frameworks such as some of the exposure tools developed for use in the assessments.

Alice Tome: Could you wrap it up?

Speaker: I will wrap it up. I have in closing, in closing we support EPA's effort to new chemical review and assess information needs more transparent. We look forward to addressing all information and guidance from EPA and continued engagement. Thank you.

Alice Tome: Thank you very much. Numbers four, five, and six please come up.

Speaker: I am Bob Shusterman and I am here representing healthy chemicals healthy families. We are very troubled by the new framework that Jeff described for the PMN program. We believe EPA is on very thin ice and is also taking a big step backward in the protection of health and the environment without any offsetting benefit except perhaps to industry. We should remember that last year Congress significantly strengthened the PMN program and it did so by requiring EPA very explicitly to issue five orders and a host of scenarios except for one which is where EPA determines and can demonstrate by credible evidence that the new chemical will probably not harm health and the environment. What is happening here is that the new law is being turned on its head with an explicit goal of reducing the number of orders and replacing them with SNURs although that is not entirely clear and so EPA is explicitly disavowing and downplaying a tool that has been the cornerstone of new chemical regulation certainly under the new law and even more so under the existing law. The notion here seems to be that EPA can make the finding that a chemical is unlikely to present and unreasonable risk based on controls that at EPA's suggestion the submitter includes in the 5(e) order but these are unenforceable and can really be voluntary commitments by the submitter and the very purpose of these Section 5(e) order is to ensure that the potential unreasonable risk is effectively and in forcibly addressed. So that critical premise is one that is being violated. We don't think SNURs are an adequate substitution for 5V orders. They were never intended to be the primary mechanism for addressing new chemical risk. They are not mentioned as a statute except where EPA has promulgated a 5V order and follows up on that. SNURs are not based on findings of risk. The type that EPA is required to make under Section 5(e) 2 in the statute and there is no obligation to include in SNURs the full range of requirements of Section 5(e) orders contained as a matter of force. We are very concerned that EPA intends to jam these SNURs through by greatly truncating the period for public comment. This would be a slap in the face to groups like ours that are concerned about the questionable legal and public health implications of using SNURs for this purpose and it would also be a violation of the orders provided in the SNUR regulations which would say when a direct final rule is issued there is a 30 day period for interested parties to express an intent to comment and then a 30 day subsequent period to file the comments. And from what we understand that is thinking of departing from that process, finally, I would say, Jeff, that it is a big mistake to implement this new framework in the absence of the public comments that all of us are going to be submitting in January. These are very momentous issues, agencies should have the benefit of those public comments. For EPA to rush ahead and start issuing SNURs and eliminating five key orders would I think be reckless and irresponsible. Thank you.

Alice Tome: Thank you, Mr. Sussman. Next speaker.

Speaker: Richard Donovan Environmental Defense Fund I will offer some broader comments about the overall picture here and my colleague will follow up with more specific comments about the action EPA is proposing. Before Lautenberg the new chemicals program was virtually a black box and essentially run on a bilateral basis between EPA and industry with little accountability an opportunity for public engagement. A number of

features serve to undermine public confidence in the robustness of EPA reviews and therefore, in the safety of new chemicals once they entered commerce. Because the great majority of new chemicals don't include and notices don't include health and safety information, EPA had to rely on estimation approaches with little ability to know the level of uncertainty this entailed and for many health and points of greatest concern reliable models simply do not exist. Absent information sufficient to establish that a new chemical may present an unreasonable risk EPA simply dropped that chemical from further review. The result was that EPA rarely attached any conditions in the chemicals and more rarely required testing. And once added to the inventory those chemicals could then in the vast majority of cases be used without restriction and in any manner without informing EPA. Even this morning we had one industry representative acknowledge that companies often don't know how their own chemicals are being used and certainly don't have control over how those chemicals are being used once they are in commerce. So the Lautenberg Act forms -- reforms were intended to address the problem. EPA lacks sufficient information and submit an order restricting the chemical to mitigate potential unreasonable risk. EPA must evaluate potential risk and mitigate those risks where it finds that a chemical under the conditions of use poses such risk. That includes reasonably foreseen clearly in the way the statute is written. Sadly EPA's recent changes actively undercut these reforms and threatened to cut the public entirely out of the process and turn it into essentially a service operation for the chemical industry. EPA appears to be working to avoid at all costs issuing new orders on new chemicals. That means it won't be able to require testing, it will defer any evaluation of reasonably foreseen uses to a later separate, more speculative process and thereby is undermining EPA's Congress' intent EPA reviews reflect the new chemicals may very well be produced in ways beyond those that the PMNs that are initially identified. Once EPA declares a chemical is not likely to present an unreasonable risk and allows commencement the only option for dealing with risk associated with that chemical is through a far slower and much more constrained Section 6 process. Based on what we have gleaned from talking to companies, EPA staff, reading press reports, seeing industry and agency webinars, EPA's day-to-day practice appeared to skew far in the industry's direction. EPA used to argue it was not its role to serve as a coach or a focus to company to help them fix problematic PMNs, but now it is routinely doing so. Working with companies to iterate their PMNs in order to be able to make them not likely finding and the review to those companies now revise. For companies that were initially subject to an order we understand EPA is now offering the alternative of a SNUR only approach. That is companies get to decide whether and if so how their chemicals are to be regulated. Where orders with progress required testing, companies are apparently successfully arguing to remove the testing requirement based on the view that the SNUR only approach as an alternative would not require it. Despite claiming a commitment to greater transparency, EPA has shared numerous written documents with the industry to the exclusion of other stakeholders. We've already talked about points to consider. Let me add to that list of category documents that EPA has developed regarding toxicity concerns have never been shared with the public at EPA has actively solicited input from the industry on those documents and apparently revised them in response. EPA has recently slowed or ceased updating its online PMNs status database, which has existed for decades depriving the public of its only reasonable means to discern what interim and final decisions EPA is making on new chemicals. Through these actions many of which are contrary to law, EPA is effectively returning the new chemicals program to its dark ages under the old TSCA. It makes it into a black box it within EPA is acting as if the only stakeholder is the chemical industry.

Alice Tome: Thank you, Mr. Dennison. Next.

Speaker: Good morning. My name is Robert Stockman and I'm here on behalf of EPS. EPA proposes to adopt an approach to new chemicals review that violates the statutory text and structure of Section 5 as amended by the Lautenberg Act. Today I will briefly discuss some of the legal problems with that approach and end by touching on two areas with the current program is already legally deficient which EDF urges EPA to address proactively. TSCA does not allow EPA to avoid issuing a Section 5(e) order for new chemical substance based on a SNUR. If a chemical substance may present a risk or if EPA has sufficient -- insufficient

information the plaintext of Tesco requires EPA issues a Section 5(e) order. The review process is built around the analysis of chemical substances as a whole. TSCA Section 5 83 requires EPA to make determinations about each, "Relevant new substance" as distinct from determinations about a new use. Nothing in the language governing new chemicals allows EPA to analyze only some uses of the chemical. In addition, nothing in the language allows EPA to limit review for a new substance based on whether or not a SNUR has been or will be issued. If EPA makes one of the Section 5 83 findings on the substance and EPA must issue a Section 5(e) order to prohibit or limit the uses of substances to the extent necessary to protect against unreasonable risk. Nothing in Section 5 83 or 5B authorizes EPA to rely on a SNUR to avoid analyzing a substance under all the conditions of use or to avoid a mandatory order. In addition, nothing in these provisions allows EPA to limit the review or determination to intended users. Under TSCA section 83C they are likely to make a finding on a chemical substance, "Under the conditions of use" . Conditions of use expressly defined to include circumstances under which a chemical substance is intended, known or reasonably foreseen to be used. Whether or not a SNUR is contemplated it cannot change the requirement for EPA to change all the uses and the PMN including because a SNUR does not preclude some uses and if a SNUR is not legally in place and enforced at the time EPA makes a decision on the substance EPA cannot rationally give it any weight under any theory. Among other things it's arbitrary and capricious to consider speculative future SNURs that have not been promulgated through rulemaking and do not yet have legal effect. TSCA five F4 establishes a 5(e) order should lead to a SNUR. But using a SNUR to avoid a Section 5(e) order completely inverts the relationship Congress expressly created between the two. Congress intended for 5(e) orders to come first and to trigger SNURs by identifying any use that doesn't conform to the order. EPA's proposed using a SNUR to avoid issuing an order rejects a congressional theme. Rather than adopt the new illegal approach EPA should focus efforts on bringing greater compliance and transparency to the rest of the program. Under Section 5(e) each PMNs shall be made available subject to section 14 for examination by interested persons. Another regulation of the public file for each PMN should be electronically available. Despite those requirements PMNs in the public file generally are not available online. EPA should take steps with these regulatory -- to comply with these regulatory requirements and to ensure the new chemicals program is transparent. EPS issuance to date of the statement of administrator findings required under Section 5(g) for each not likely determination is not adequate in view of the best available science particularly given the interpretation EPA has adopted in its regulations of that term. I've read every not likely finding page since July and they are largely boiler plates on cursory summaries that do not suffice. EPA needs to release more detailed findings or at a minimum the underlying documents that provide the actual analysis for those findings involving hazards, exposure and analysis. Thank you.

Alice Tome: Thank you. Will number seven, eight, and nine come up please. Go ahead.

Speaker: Hi, I am Jennifer Sachs with NRDC and also representing healthy chemicals healthy families. I want to make a point and ask a question. First of all, the passage of TSCA very fundamentally focused on the lack of data and testing done for testings for decades and Congress recognized that and required in the new Costco that chemicals be surfaced -- carefully reviewed before their introduction into commerce so that the threat to human health could be identified and evaluated and prevented or removed before there was widespread exposure and the reversible harm. This approach is now important more than ever as chemicals replace existing chemicals in larger numbers. Under the new EPA -- under the new TSCA EPA must make an affirmative determination of safety for every new chemical. It can't do this if it doesn't have quality reliable and robust data and information to make these determinations so we very, very much encourage EPA to use the authority that was given to us by Congress and by the public to ensure that any new chemical reviewed by EPA is reviewed with robust and reliable data and information made available to the public to support those decisions. And my question to EPA is what are your plans for going back over chemicals that were bootstrapped or relied upon to the relationship information to extrapolate across chemicals and chemical families when you find harm in a chemical or some of those chemicals as you go forward with your testing program, how will you go back and look at other chemicals

that were reliant on those in the new chemical program? I knew I was going to have trouble with phrasing that so I can tell you are curious. The program should be able to go back and look at any chemicals that was reliant by any other chemical to make a new chemical decision. So as new information comes, we want to see EPA go back in the program and look at chemicals that were never properly tested but that may now be considered to be potentially harmful because of new information that has come to light under testing requirements through the new TSCA.

Alice Tome: I think there is time if you wanted to address that question.

Speaker: So if I understand the question correctly, let's say there is a chemical that went to the new chemicals program and later when it became an existing chemical, information suggests that the problem is to evaluate it. So if we were to evaluate the chemical under Section 6 of TSCA using reasonably available information to do that that would pull in all available data to us that could be new information after the new chemical evaluation, there may be information in an analog to about Section 6 requires us to evaluate a substance using all reasonably available information. So I think that would be helpful.

Speaker: Thank you.

Alice Tome: Next speaker.

Speaker: Good morning, I'm an attorney and appreciate the opportunity to be here today. We are concerned EPS approach to reviewing new chemicals has clear demands of the revised TSCA. Congress recommends the revise of new chemicals was insufficiently protected. New chemicals could enter the stream of Congress without any finding if they did not pose an unreasonable risk. To remedy that problem the Lautenberg Act requires EPA to evaluate the risk proposed by a new chemical. EPA may allow a new chemical on the market if it determines the chemical is not likely to present an unreasonable risk under the conditions of use.

Alternatively EPA it lacks sufficient information to conduct this evaluation may only allow the chemical if it also issues a 5(e) order. This order must limit uses of the chemical to the extent necessary to protect from unreasonable risk. Once the EPA issues a 5(e) order it may issue a SNUR to restrict other companies from engaging in activities that do not conform with the limits contained in the 5(e) order. That's 5(e) orders are the first line to all that Congress gave EPA to deal with the uncertain effects of new chemicals. EPA is upending the statutory scheme by bypassing the issuance of 5(e) orders. Instead simply approving PMNs based on an incomplete evaluation of the risk posed by the chemical and justifying this decision by claiming the authority to use SNURs as a primary means of risk regulation. This approach is unlawful. I'd like to highlight specific aspects of this approach that are legally deficient. First EPA said that in determining whether a 5(e) order is required it would only analyze [inaudible] submitted by the PMNs submitters. It will be left to future SNUR. This violates the clear statutory command of known, intended unreasonable foreseeable activities when evaluating a PMN. By ignoring reasonably foreseeable uses of the new chemical EPA unlawfully narrows the 5V analysis making it easier to conclude that the chemical does not pose an unreasonable risk and avoid issuing a 5(e) order. Second EPA said it will consider whether potential hazards could be addressed through SNURs when deciding whether or not it's able to evaluate the risk posed by a new chemical. This is unlawful. Nothing in the text of Section 5 V authorizes EPA to assume that a SNUR will be in place when evaluating whether new chemical poses and unreasonable risk. Congress silence on this point must be understood as prohibiting EPA from considering the possibility of a future SNUR when determining whether a 5(e) order is required. There's been a robust discussion today of what the meaning of reasonably foreseeable is. I will just note it would be unlawful for EPA to define that turn as meaning probable. In sum, EPS approach is that of the very definition of arbitrary and capricious. Ignoring factors Congress would consider an considering factor is not section and interpreting statutory terms as a patently unreasonable fashion. This is part of an important pattern which EPA under the leadership of Dr. Beck has chosen to implement the statutes in an unlawful matter. As long as Dr. Beck is in charge of the program the public and have no confidence EPA will implement the statute and a

lawful impartial matter and restore public companies and get implementation of the landmark bipartisan legislation on track we urge Dr. Beck to recuse herself from this decision and for EPA to return to Congress' mandate.

Alice Tome: Thank you. is number nine, jeans Dominic James Cooper here? [Off Mic]

That's perfectly fine. Thank you. Let's move on to Numbers 10, 11, and 12.

Speaker: I'm Susie Kim from NBC. I just have a quick question. I wanted to ask about the timeline that the agency is planning to abide by in terms of issuing SNURs for reasonably foreseen uses and it could be a common process that could take longer than a consent order. Will the agency expect that if the SNUR be in place before the manufacture of a new chemical begins and will manufacturers either the submitter or others be able to engage in these significant new uses before the SNUR is finalized?

Speaker: As I mentioned in my presentation, this is an area we are actively discussing and will be informed by that comment here. So we would like to understand [inaudible] subsequent to it in terms of how they believe the non-order SNUR approach ought to fit in as a potential tool in the program. So I think as I said it's a active discussion and look forward to comments on it.

Speaker: Thank you.

Alice Tome: Speaker 11. [Off Mic]

I was going to see how many people were on the webinar. I don't want to start the webinar comments too early because people are calling and specifically at that time so I was planning on breaking after that. Do you have a suggestion?

Speaker: [Off Mic]

If your break at noon I suggest we break for lunch now.

Alice Tome: Okay. I tell you what -- why don't I go to the phone and see if anyone has a few comments and then maybe do it that way. So just want to know if anybody participating by webinar would like to provide a comment. If you would like to do so, you can call the phone number on the slide. The key will be managed by the operator and when it is your turn your phone will open up and you will be able to ask your questions. We ask you state your name and affiliation before asking the question. Before you speak please mute your computer speakers on Presley computer icon on the webcast interface. When the speaker button turns red you have muted your computer or audio. If you experience technical difficulties click on the help Ted and explain your issue and a member of the Tech Team will issue. There is public comment and several people have alluded to at 3:15 p.m. this afternoon. If you would prefer to go then. But I would like to see if right now we don't have any colors. So I guess what we would do is let me ask is there anybody who does have a number who would like to speak now? Why don't you go ahead and you folks can speak and tell me what your number is.

Speaker: My number is 18. I'm Molly Rauch with mom's clean air force. Moms clean air force is a national organization of more than 1 million moms and dads working to fight pollution for the sake of our children's health. The process by which new chemicals are brought to market is a major concern of our million plus members. Our members across the country are literally shocked when they learned that new chemicals have come onto the market by the hundreds every year without any significant evaluation of health risks. This was a major failing of TSCA. The Lautenberg Act codified a fundamental change of that process the idea was to transform the new chemical review process from a rubber stamping party a legitimate effort based on public health and we are very happy about the change. Safeguarding public health may not be as easy as rubberstamping, but consumers and members understand that. It takes time to determine whether new chemical

might be harmful to health and the reasonably foreseen uses. Speaking as a mom and consumer I can assure you I do not want chemicals to have a free pass. So any system not looking comprehensively at chemicals is not protecting children, families, or communities and represents a failure of the promise of the Lautenberg Act. From my perspective as an advocate for children's health, what I see is that the changes to this program reduce the circumstances under which EPA would ever require testing. And that is bad news for public health. EPA is now taking companies at face value when they say how they think they're chemical will be used. If -- it is a very narrow view of exposure. I'm very concerned about the changes that have been introduced. Is the purpose of this program to get chemicals on the market ASAP? Is it to make it easy, as easy as possible for industry to sell their product? I urge you to make public health it clear priority instead as is the intention of the Lautenberg Act and is the formal mission of EPA which is to protect public health. Putting health entirely aside for a moment I want to comment on the importance of trust. The erosion of consumer trust in the chemical industry was one of the factors that helped spurred the bipartisan cooperation that led to Lautenberg Act. That law was supposed to be [inaudible] and the chemical industry. On behalf of more than 1 million members I can assure you that a new chemicals review process that appears to have these 4 industries as the primary goal is not a recipe for restoring trust. Thank you.

Alice Tome: Thank you. Next speaker.

Speaker: Good morning. I am the National Field manager for moms clean Air Force. As Molly said we are a community of our 1 million members from across the country working every day to protect children from dangerous chemical exposures. I'm here on behalf of our more than 1 million members and also here is a mother of a child who has suffered from health impacts of a toxic chemical exposure. I live in New Jersey and manufacturing chemical facilities and factories. In 2012 my family was exposed to the toxic chemical vinyl chloride as a result of a train derailment. My young sons and I became extremely sick from this exposure and my now seven-year-old suffers long-term health effects and every year we uncover yet another symptom that can be correlated back to his exposure from when he was just two years old. There is not a day that goes on that I don't question whether the next symptom we uncover will be cancer. So when Congress passed the new bipartisan bill last year to regulate toxic chemicals, which started with the efforts of the New Jersey's some of the tour Frank Luxemburg I regained hope for improved chemical safety. Under the previous lot new chemicals go on the market, get formulated into products and hit store shelves all without being tested for safety. Some of these chemicals found in everyday products like carpet, shower curtains and other things raise red flags due to concerns about how they impact our lungs, and endocrine systems, brains, reproductive systems and so on. What this means is that every day American families like mine are being exposed to potentially toxic chemicals from the products we are using in our homes. The new bill, the Lundberg chemical safety act addresses a critical flaw and requires new chemicals to undergo a safety review before coming onto the market. It ensures that experts, not industry executives decide which chemicals should be regulated and guarantees that families have access to vital information regarding chemicals from health and safety studies. As the mom who has watched her son suffer uncontrollable nosebleeds, unexplained simple memory loss and a host of other health issues from his toxic chemical exposure I have major concerns about changes to the new chemical review process. Manufacturer should not be allowed to introduce new chemicals into the market without proper testing. I need to know that the products my children use every day whether it's the toys they are playing with, the mattresses they lay their head down on each night or the carpets they run their toys across will not harm my children's health. My son's experience shows that In Real Life we are exposed to chemicals in ways that don't always follow the manufacturer's plan. It's important that EPA keeps a comprehensive review of chemical exposure when evaluating safety instead of considering exposures based on what manufacturers say they will do with the chemical. They have a vested interest in providing a best case scenario that may not represent real-world exposure. And the mom of a child who has been harmed by chemical exposure I can vouch for the fact that such an approach threatens the health of my children. On behalf of moms clean air forces and as a mom

who watches her son struggled due to his exposure to toxic chemical, please help me understand how these changes will protect our families health.

Alice Tome: Thank you. Next speaker.

Speaker: My name is Barry Castleman. I'm an environmental consultant and I have been an EPA consultant in the past, more recently for the World Health Organization world bank on the issue of asbestos and I'm on the board of the asbestos awareness organization. I want to talk about the importation of asbestos. It's only used by the chemical industry and plants which is consistent on continuing to use it. We've got news from Brazil last week, Brazil's Supreme Court issued a ban on asbestos specifically asked by the chlorine industry to make an exemption for the use of asbestos and clerical I'd plants for diaphragms and were told that 12 of the 13 manufacturers of chlorine in Brazil were already asbestos free. Only Dow still wanted to use of asbestos and the Brazil Supreme Court concluded that there is no safe or controlled use of asbestos and may know exemption in issuing a ban and the asbestos mines have been shut down. We will have to be importing asbestos from Russia in the chlorine industry wants to keep using asbestos and the EPA allows that. Last year I was in -- a year ago I was in Italy and met with people at one of the companies that makes non-asbestos diaphragm materials. I sent you, the EPA, the PowerPoint program they presented their showing among other things that nonasbestos diaphragms are available for all of the plants that use of asbestos, that the nonasbestos diaphragms in terms of the product performance, energy consumption and other things pay for themselves in 4 years. Unbelievably industry has resisted just making the conversion on its own. And this is an open and shut case for government regulation. The guy at did nor said the industry wants a two year payout time before they would do it for strictly business reasons. Chlorine Institute in its submission when EPA was talking about banning asbestos submitted data showing that exposure is one and half times the current permissible exposure limit for asbestos to the OSHA limit in diaphragms processes and numerous parts of the diaphragm processes and the lifecycle of the diaphragms can give rise to airborne asbestos and this is noted in the guidelines on asbestos handling for the chlor alkali industry published by the chlorine Institute. As to the importation of asbestos, just one industry importation of asbestos products no justification for that. There are no defenders for that. We are importing brake lines, importing gaskets, who knows whether -- nobody is even looking to see if their warning labels being put on these products by the fly-by-night distributors bringing them into the country and they are competing unfairly against manufacturers of nonasbestos products for those same purposes. Based in the United States. And the last thing I want to mention is legacy asbestos. EPA has indicated it will not do anything about that. We have 15-35 million homes that have Libby vermiculite which is contaminated with deadly asbestos materials and 15-35 million homes people go up in their attic and kids play up there, exposures are substantial. People are going to die and this is something EPA really needs to do something about and has not done much about. I think there are matters of some urgency. Very last thing I want to do is pay tribute to the civil servants at the EPA for hanging in there during these very difficult times. I hope that you will continue to serve the public and serve the mission of the EPA and we support you despite the present pressures of the chemical industry and management of the agency.

Alice Tome: Thank you. Okay. So now we are going to go to the commenters on the phone. I understand that there are two commenters on the line. Go ahead and mute the phone.

Speaker: The first commenter will be Patricia best up with humane society. Please proceed.

Speaker: Thank you. Yes, I'm providing these comments on behalf of the humane society. Its members and supporters who share the common goal of promoting the use of reliable and relevant regulatory testing methods and strategies that protect human health, the environment while reducing and ultimately eliminating the use of animal testing to determine chemical toxicity. So an important new aspect of TSCA as revised by the Lundberg safety chemical act is the mandate to reduce testing on vertebrate animals as described under section 4H. The law specifies that this may be accomplished through a number of different approaches including the use of

alternative methods that do not use animals such as toxicology, in vitro high throughput screening and the use of integrated testing strategy. Testing on animals may also be avoided through the use of existing toxicity information on chemical analog read across and by demonstrating there is no need for certain animal test due to the chemical property hazard concerns route of exposure or how it is used. Importantly this mandate also applies to any person developing information for submission under this title on a voluntary basis and not pursuant to any specific request and requirement. It is there for an overarching requirement for any data generated to address information needs under TSCA. Does cite the importance of the requirements to avoid vertebrate animal testing the Points to Consider Document never once described mandates. In fact, TSCA section 4H on page 14 in reference to alternative test methods however, the context is not given nor is the significance of using alternative methods in relation to the goal of minimizing animal use described. The process of information generation and review needs to incorporate the principle of minimizing animal use. It is now stipulated in TSCA section 4H of the mandates to reduce animal use must be a primary concept throughout the process of generating information on new chemicals and should be considered early in the chemical evaluation process prior to the development of data. It should therefore, be discussed in the introduction section of the guidance document and integrated throughout the subsequent sections where appropriate. There should be a detailed discussion in the guidance document likely under section 2C, test data where the concept of minimizing animal use and the various approaches to achieving that goal can be presented. Companies not familiar with the goal of section 4H are unsure of how it will work going forward will benefit from having a clearly stated and described in the beginning of the process. For example, the first pre- notice consultation with company should occur before any new animal test have been carried out and include discussion of the various ways animal testing could be avoided and are minimized. In this and any subsequent consultation EPA should urge companies to test on animals only as a last resort after first identifying all sources of data and any opportunities to avoid certain animal tests based on the chemical properties, use and exposure routes. This approach encourages EPA to think about what information it will need to make a determination before resources and animal lives are wasted generating data that are never used. Thank you.

Alice Tome: Thank you. Next caller.

Speaker: Are next, as from the line of Amy Kyle with University of California. Pease just please proceed.

Speaker: Hello. Thank you. My name is Amy Kyle and I'm affiliated with the University of California. I wanted to talk about some of the science issues related to this. I realize it's not your focus today but it still seems germane to keep the goal of having good science in our decision-making. So I have three points I want to make and they might be questions to. The first one is with regard to this Points to Consider Document and the sources that it points to, et cetera and first of all, I want to say I appreciate that you have tried to pull that all together in one place because it is very hard to find all the pieces of this on your own I've found. But some of the sources and other compilations that you cite are literally decades old and some of the stuffed dates probably from before when some of the people in the room were born. And so we have learned an awful lot in the last decade or two about the effect of chemicals on children and the importance of prenatal exposures and the synergistic or combined effects of different chemicals. All of that stuff is later than some of the sources you are giving here and I'm just wondering how you are thinking about that. Are you really going to go back to 1993 or are we going to be in the twenty-first century in terms of how we think about the science? I don't mean to exaggerate too much and some of the stuff is nowhere, but there are some foundational stuff here that really is long ago now in terms of what we know so I guess that is a question. And then my second point is that some other people have brought up the issues of -- the related issues of how to contemplate what happens downstream from your decision point and also what happens over time. And the way that this is being designed with the data systems now are very static. Is this to get an approval on a chemical and that is it? There is not much design toward following up and seeing how the uses change and what we know about the chemicals change and so on. And, you know, the chemical data reporting system does a little bit toward that but I would say it is

inadequate and should be further developed. So good science depends also -- evolves and some thought about how to really make the information that you have underlining this better very important as you work through the legal issues and the tools you are using. I'm not speaking to that. I think other people have already discussed that. And then the last one I wanted to make is that again related to data systems. The data systems are so outdated it's painful really in a way to watch and I think it is time to move into systems that allow more transparency and are more current and let you see across what is happening here versus other parts of the EPA and chemicals that are more able to reflect what is happening in real time. I know there's a lot of foundational work at EPA for that and I would encourage you to think about this. This is not just a one-time process, it should be a management system that helps us all understand that the chemicals that we have in our homes are safe. And I would hope that could be incorporated into your thinking as well. I thank you for the opportunity to comment.

Alice Tome: Thank you.

Speaker: Thank you for that and just to respond to a couple of your questions so first of all, on the comment about some of the information being old, I guess one thing that I would say is that for some of the approaches, guidance, et cetera, ages not necessarily a reflection of whether or not it's valid. Some disciplines of fact have been perhaps the change. That said if you identify particular sources we are using, approaches we are using that you believe have been superseded or enhanced by newer science, please submit that as a comment. We would like to know because we are attempting in our new chemical evaluations to use the best available and most current scientific information approaches so if you have identified something by all means we would like to know that. Second is on information systems and reporting. You mentioned that the chemical data reporting system, for example, is his on existing chemicals so a comment of what happens to chemicals once they go to market how their use evolves. So to the extent that you have comments on that, we are always looking for ways to enhance that tool that we have but even more broadly, I get your point about information systems in general and that is also an area we want to continue to evolve so, again, if there are -- if there's information you know, about in the approaches that we could apply we would like to know that so, thank you, and if you can provide additional information we would appreciate it.

Alice Tome: Thank you. I just want to confirm there are no further callers on the line. Okay. I think what we are going to do is we will break just a little bit early for lunch. It is 12:15 p.m. so we need to be back here at 1:30 p.m. for the next portion of the meeting. Thank you very much.

[break taken

Afternoon Public Comment Session

Speaker: They are not categories of concern. They are new chemical categories, not necessary.

Speaker: I feel much better with law and order. [Laughing]

Speaker: I thought I made the point.

Speaker: Fair enough fair not fair enough.

Speaker: So I would say that it's partly because of the data for the eco- that is in fact, exactly what happened and you will note one of my slides had this tallied, there are more categories -- new chemical categories for environmental eco- then there are four health. But that is quite like how we keep our eco- star new version coming in, not only from PMN, but if we get data or required data that eventually goes back into the model and then our updates are based on that as well as any new literature identified data. And, again, depending on the robustness of the tool or model that we use to do the predictions we may or may not ask for testing. The

categories are a test tool and will help with efficiency and transparency, but because you are in one of those doesn't mean we always ask for that.

Speaker: One other point is that yes, they will -- there may be testing in the consent order but testing that is triggered often takes many years for the testing to come in, so in the end we still may have fairly limited data.

Speaker: Let me take an example and let's say, for example, you have a category, not a concern but a chemical category and you conclude you have a study and you already have data on members of that category. Does that impact the respirator protection factor and what's the interplay between the information you've collected on the categories over the years and the risk management measures that you propose?

Speaker: So often when there is no data on the specific chemical my colleagues and the risk assessment division in doing the risk assessment they will look at analogs. So it is based on the analog and the respirator that would be used to protect against such risk based on the risk assessment based on the analog so the uncertainty is there depending on the difference between the analog and the PMN.

Speaker: Thank you.

Alice Tome: Thank you. Other questions.

Speaker: If I could just follow up B1 could you identify yourself and your organization.

Speaker: I'm Bob Sussman same as I was this morning.

Speaker: For those that can see you.

Speaker: So you mentioned that the level of respiratory protection will be based on the analog to the PMN substance but isn't there a possibility that the PMN substance in fact may be more toxic than the analog and wouldn't you want to develop some data to determine or to increase your confidence in the level of respiratory protection that you are affording and to make sure that indeed you don't need more respiratory protection because the PMN substance is more toxic than the analog?

Speaker: So good scenario. And it gets back to the last question a little bit so when we are doing our very first quick evaluation and then when we do the subsequent risk assessment that David went into great lengths this morning about how we considered degradants and the possibility of metabolites and whether that metabolite might be more reactive or less reactive or whatever, same thing with the PMN cannot buckle. -- chemical. We judge whether we think that PMN might be more or less toxic because of structural features are based on that class of 'chemicals has a bunch of data and this kind of space that this PMN is out here is a little different, that one that may be a different consideration on how the uncertainty there would be greater than if it falls in the cluster of a whole bunch of other ones. Then we hand it over with all due caveats around uncertainties.

Speaker: So I think taking into account what she said about the factors into consideration we still do estimate the respirator based on the numbers generated with the analog. I think some of this uncertainty may go into the length of timing and the trigger but you are correct the testing does because the data are not on the PMN substance of the testing is to address the uncertainty.

Alice Tome: Could you please speak into the microphone?

Speaker: To finish that thought so when you talk about the trigger the trigger is the type of trigger that is customarily included where for additional testing on the PMN substance, often based on some level of production or the nature of the use and so forth, but the idea there is that at some point we need additional data to reduce the uncertainty and protectiveness that exists because of reliance on the analog.

Speaker: So in consent orders that is what is articulated in consent orders.

Speaker: Thank you. Next question.

Speaker: My name is Rob Stockman I'm here from EDS. Thank you for addressing some of our questions. I did want to ask a follow-up question about the electronic docket. The ranks have long required that so EPA is currently in violation of them by not having them and my follow-up question is does EPA have an expectation of when we can expect to start seeing them and while they include not just the sanitized PMN, but the full public docket for each submission because it was very helpful for outside stakeholders to assess the final decision EPS -- EPA is making with that material. Thank you.

Speaker: [Off Mic]

Can folks hear me on this? Okay, so as I mentioned in my slides, all of the information you have just asked for you can get by requesting it from the Docket Center. It's just not as readily available through a click on line, but it is all available, the PMN as well as attachments are available through the Docket Center. As far as timing is concerned, we are working as quickly as we can to address a number of the I.T. issues that need to be addressed just to make the information more readily available. It is a priority of ours. I would say at this point, we are working to get as much done as we possibly can by next year, 2018 but I cannot commit to that but I would say our goal is to get as much done by 2018 as we possibly can.

Speaker: If I could come back a moment to the question of testing because it was a very important set of comments that have come in so far and I know it's going to continue to be an important subject. The latest exchange was about trigger testing within the context of a consent order, but I also saw questions that have come in so far as well, if you are not going to issue orders and you are going to SNURs and making the unlikely determination are you then foreclosing on the opportunity to get important testing data to reduce the uncertainty because the new chemicals environment makes an inherently uncertain although I would say that the findings don't require to have a not likely or a likely of unreasonable risk. So I think the question -- that question about testing and I don't think where we have sufficient information to conduct a reasoned evaluation that in the general case that argues for more testing because it's in the contradictory to the findings of the recent evaluations because you have enough information for reasoned evaluation you may not have 100 percent confidence you've had the evaluation anyway, but if you ask for testing if you made that unlikely or not likely determination but I think it relates to the current discussion because it relates to how we understand chemical categories and how we go about getting information on substances. There are different ways. One approaches to do it on a PMN by PMN basis whereas everyone comes in and you ask for data and collect data that way. Another way to get people to gather around classes or groups of chemical substances that are similar and look for representative substances and do testing on that smaller set so that you can use that to make decisions across. And I think that is not limited to the current categories and the discussions we are doing that. Continue to think along those lines can be very helpful to us and not only helpful to us, but also consistent with the statutory requirement that we try to reduce the amount of animals testing we do. I think there are lots of good reasons for thinking that way so I don't think that the need for testing for specific PMNs is ever going to go away, but I don't think it's the only way to think about it and the other ways of thinking about how to get data to support chemical decision-making maybe much more discussions than we've had so far.

Alice Tome: We will take one question in the room and then go to those on the phone.

Speaker: Richard Denison, Environmental Defense Fund. Tanya, I need to come back to three of your responses. The first is the follow-up around electronic access to PMNs. Your regulations already require that they be electronically accessible not by going to a basement room somewhere in the bowels of EPA to look for them. We tried that and we've been told that may not work either because they don't actually have them and they would have to make an inquiry that has to be started by a letter in writing and then pursued with a program officer in order to determine whether they have the information and if so if they don't how long it would take. You should try that yourself if you think that is a way to get this information. The reason this is so important is

you all are headed down a road where you are expecting the public to trust that the information in the PMN is a sufficient basis for making regulatory findings of not likely to present an unreasonable risk. And to then pursue perhaps a snort that is supposed to mirror those aspects of PMN that allow you to make that finding. And there is simply no way to know whether that is happening unless there is ready access in every case when you are making such a decision to the under mount -- underlying documents to allow the comparison to be made so it's not a trivial just why do we need this information. It is the bedrock to the ability to have any faith whatsoever in the process that you are starting to embark on here. The same thing applies to EPA is not likely findings where if EPA is making a non-likely finding, the summary document that has been posted there right now is nice, but it does not provide any basis for an independent evaluation of that decision. For example, you may say that there is not a risk to -- because the level being released into water is below a level of concern. That level of concern is not identified, how far below or whether -- what the margin is is not provided. It's a very, very high level summary document that does not provide anything for further evaluation by somebody from the outside. To that and, are common to end our to the agency was will you be making redacted versions of the documents that you produce in the review of a PMN which in our view constitutes in many cases health and safety data as defined under TSCA that is not eligible for protection as CBI. So when you generate an exposure document that predicts releases to the environments or other types of releases, for example,, is that the agency's view that that information is not health and safety data and is not subject to the provisions of section 14? The final question I want to ask has to deal with this updating of the PMN status database. I have been tracking this for months and in the last three months, 17 new entries have been added to that status database. 17. I cannot believe you have only reviewed and made interim or final decisions on 17 PMN ends in the last 90 days. So when I say that database has not been updated, that is what I mean.

Speaker: So responses to a couple of them. First -- second one first, I think it is true that we have been a bit slow to go back to interim determinations. I think for the very simple reason is that I think it is could lead to some confusion when we are trying to implement a new framework to post interim decisions when we are at -- when trying to review the recommendations and decisions and we are trying to get to a point where we are working within the framework to issue posting interim decisions is something that I think we have taken a pause on or been careful of. We need to get to greater transparency to do that. On the first point regarding the document and supporting of the decision. We agree with you that came up in the discussion we had earlier today about the pilot for the point to consider and the desire for the engineering reports and all those documents go into supporting the discussions at the focus meeting and it goes beyond that. I think that's a very reasonable thing to ask for and we need to get to that point and it's been -- in information management and technology challenge, information management part of the child should pull these together in a way that are easily understood by anyone who picks them up and reads them because quite frankly, some of these reports that we've been using internally we are kind of shorthand that make it difficult to be transparent so we need to get to that point with those reports inform editing, but we want to be there. We've heard these comments many times before and they are good ones. We need to act in that way. And on the I.T. part of this, part of it is that that the process moves quickly through and with high volume, as you know so getting our system up to date so that we can put this information out in a way that's meaningful and timely is another challenge for us to work through.

Alice Tome: Thank you. Are there any callers? First color.

Speaker: The first comic comes from Amy Pyle, University of California.

Speaker: Hello, it's me again. I didn't know I got to go first but thank you. I have several comments and a couple of questions and I guess given this format I will do them all at once though that might not be the best way to do it in a different world. The first one is about your efficiency policy goal and you know, I'm all up for efficiency and I'm sure we would love to see some efficiency with the data systems, for example. That seems like that's very far behind. But I guess I don't think I have heard one time the word validity. And one of the previous speakers was trying to get at this and it's great to have efficient methods but it doesn't matter if they are

efficient if they are not valid. You can throw a dart at a dartboard it's a big category that would be very efficient, but I doubt anyone would argue it would be valid. And I have to say I'm a little shocked that that doesn't seem to matter. It doesn't seem to be part of this discussion at all because it really should be a central part of the way that these reviews are done and also the way you are conceptualizing and managing your system. I realize it's very compartmentalized and you are not so aware with the people that deal with it down the stream stuff but it should all be working together to make determinations and update the new information when it becomes available and particularly with regard to some of the old methods, the methods of the '90s I can tell you they didn't have much in there about prenatal exposures and children's -- the differences in children and biology et cetera compared to adults. So maybe they were state-of-the-art in 1993, I really doubt that they are state-of-the-art now and I'm just not hearing when is that going to be revisited. If we are drawing this category and if we are using this read across are also the methods are they really valid, a lot of those were adopted under the old TSCA where they were the only thing you had and of course, of its the only thing you had it's better than nothing. Maybe that reduces your uncertainty from 100 percent to 50 percent or something but we are not in that world. We have stronger statutes that require EPA to make a positive finding out about this and empowers EPA to get data if needed. So the methods we use to use because we had nothing else, that is not the standard anymore and I have not heard one word really speaking to that and I'm a little shocked and a little of pause and I'm hoping that one of my questions is is there any validity to any of this or is that not a concern? And then I guess my second comment in question is this issue of the policy demands and how they pertain to what you are doing to you and your science and I've heard several statements that are utterly erroneous about that about why methods have not changed and I think someone said children were worried about the differences in exposure. That is just not the case. We have a much more profound deepening of understanding of how children are not little adults. There are many ways in which both the prenatal experience and the childhood experience affect health. They were not part of the older methods and it's not just because children drink more water. I'm not getting a sense that EPA is fully understood the significance of the policy direction from this act in terms of its scientific basis for its review and the way it's conducting it. So if anyone could comment on the validity issue and the larger question of really updating your scientific underpinnings to reflect the policy elements one of which is related to children, not the only one, those are all my questions. Maybe they are not appropriate for this meeting, but it does seem those issues would need some attention.

Speaker: Thank you. This is Jeff Morris I'll start and then turn it over to Tala Henry. My response would be to first to push back on the assumption that our scientist in our scientific -based reviews don't embody the best available scientific information. Our scientist are very active in the scientific community and I would argue that the information that's available and the literature regarding the exposure to the subpopulation as well as others related to exposure or effects for that matter are well understood by our staff and to the extent that we have information in new chemical submission that allows us to incorporate those approaches into the evaluation of the substance we do so. And regarding the information we believe there's a particular method or approach that we use and hopefully for the documents we talked about today related to et cetera to give pointers to where we need information than we would welcome that but I think that we are quite aware of the state of the science in areas related to environmental health and safety so there is that. I think your introduction to that was scientific validity or strength or integrity with respect to I think you said efficiency and I want to be sure that it's understood that it's true, it's inherent in the new chemicals program and the way it's set up in statute in law because there are statutory deadlines in there for a reason, the intent being the evaluation of a substance to not take very long is to -- part of that objective, of course, is to provide a way for new substances to enter commerce given the new substance in many ways for all of us could provide enhancements to society in a way that's environmentally protective and protective of public health. Those are both important attributes of this program and nobody is suggesting here that quite frankly, that one be sacrificed at the expense of the other. And we know that our mission is environmental Public health protection and that's what we strive for in this program but I don't know whether to tell yet you have anything to add with respect to specific scientific approaches.

Speaker: As we stated earlier and I am really confused as to what you mean by what methods that are so bad because I just don't understand what context you are talking about so if you could provide that in comments, that would be great. But all of our various models are peer reviewed over time. Again we do many, many things in the context with OECD so we are actually chair of the hazard assessment as well as the exposure assessment task force so we have been international peer venue for our approaches. There is just generally we follow well-established EPA risk assessment guidance generally, but of course, they need to be fit for the purpose of new chemicals, which is something that not very many people have to do to conduct essentially full lifecycle analyses of an approximately 90 days. But on the flipside of that because it is constantly new thing, it is a venue from the science perspective where we can introduce new approaches like new assessment methodologies, non-animal screening, this fund that on an ongoing basis. And we will take and consider anything, any type of data that someone would submit with their PNM and we are on the hook to come up with a strategy for non-animal testing and as I said this is really two PMN submitters we know if some of you have whole research programs on some of these kinds of things and we are just waiting to have some of that newer scientific approaches on the PM ends. Are all for it. If you could clarify more specifically what methodologies you are specifically Kern -- concerned about, that would be helpful.

Alice Tome: Thank you. Is there another caller.

Speaker: Our next comment comes from Nelson of [inaudible] consulting.

Speaker: Good afternoon. I wanted to talk a little bit or at least to get your feedback on unknown or variable compositions. Complex reaction products and biological materials, which are commonly known as UV CB. I would like you to discuss if you could how you intend to approach the hazard assessment of you CBC substances? Will you use the test data on the whole substances if this is available and considered to be valid or are you attempting to go toward a use of a representative component approach? In other words, you pick a chemical out of see you CBC is an estimate the toxicity of that and then if you have more than one representative component you add up all of those to get an overall estimate of the toxicity or the hazard of that particular UV CB substance. And what will influence your decision to go in which direction?

Speaker: This is Tala Henry. We would use any of all of those approaches depending on the case so sometimes we would get a case where there might be testing on the whole substance and, again, we would have to sit down and evaluate that substance and how variable it really is and whether or not we think in the test system that was used, doesn't really represent the whole thing or did it fractionate or what ever or we don't usually get a lot of that so we may also do a lot to pick a representative so if we understand -- and maybe these are variable as you know, so we can change them over time so we can tend to identify the one that either is most predominant or might be most hazardous and so forth. Again we can't do 25 different renditions in the timeframe that we have so we tried to take a protective approach and pick ones that we think prevail for the substance. If we actually got one where all the components were there and some very characterized Ray, that would be swell. It doesn't happen very often, but suit to your question what influences our decision it goes back to one of the points to consider know your chemical. If you can provide us a better description of what might be in that UVCB and how variable it is batch to batch, and so forth, we can do a better job of characterizing it and if we don't know, we will go with something that is protective as the first screen. So if you're UVCB has been scenes and hydrocarbons if that's the most popular one there and some reasonable proportion, that might be how we do it. If you have more specifics, we can do something more with that.

Speaker: Supposing the material is poorly soluble in water,.

Tala Henry: That is an issue. Time and time again. Someone commented this morning that somehow we are supposed to solve this whole UVCB issue. That is an active area of research around the globe. There are several people here who are actively working in this area. This is a tough nut to crack. We are very involved. We go to the workshops, participate and provide a perspective on regulatory program and we have expertise in

this area to offer. It's a difficult situation. So, again, don't blindly go off and do an aquatic waterborne test when you know, it is not in there. Come in and increase consultation and maybe we can come up with some strategies on what might be the best media to test based on some ideas about where it will go in the environment in the first place and then talk about what would be the most beneficial testing, but honestly these are scientific issues that are not resolved so I think those are particularly where having scientist to scientist and, I mean, scientist to scientist not lawyer to scientist discussions about this would be beneficial. No offense to the lawyers. [chuckling]

Speaker: Is there a point person there at U.S. EPA that is heading up that kind of research?

Tala Henry: Our program does not do research. But in our office of research development their people but, again, as far as testing your PMN substance and moving forward on that that would be the OPPT program managers. You should contact them first and foremost.

Speaker: Okay, thank you very much. Appreciate it.

Alice Tome: Thank you. We can return to questions in the room. Does anybody have a question here?

Speaker: This is Susie Kim from NBC. I had a question, I understand that a lot of these changes are in the process of being hammered out and being worked out and being implemented. But in terms of the specific transition to using SNURs for reasonably foreseen uses and skipping the two-step consent order process, are you guys already in the process of developing SNURs in this way for substances and what is your sort of timeline in terms of making this transition?

Speaker: So as part of acting on the framework, we are looking at those cases now that we think could be amenable to those, in other words, ones where we have concerns only with the reasonably foreseen uses and working through our decision process to determine whether they are amenable to a SNUR. So I think the answer is yes, we are working through that and we have not yet landed on a specific set of cases that we are ready to quite move forward to promulgation but we are actively working to move this aspect of the framework forward.

Speaker: Any sense in terms of time a very broad sense of timeline in terms of weeks, months, when we might expect the SNURs to be promulgated?

Speaker: I guess the first question we need to decide on for each case is whether in fact, it is amenable to a SNUR so step one is that we are working through that very actively. Once we decide that, then if the decision to say yes is made, then we will need to move forward in a time period that is not that long because we do want to adhere to the principle to try to stay within the statutory timeframe if not 90 days then 180. So I think they will be working within those parameters and working through and to get the decisions. So that is the timescale we are looking at right now to work through.

Alice Tome: Thank you. Any more questions? In the room? Is there anyone online? Okay. Why don't we take -- I want to to yank the panel very much and we will take a 15 minute break and we will be back about 3:10 p.m.

[break taken]

Alice Tome: If you could work your way back, we will get started. Welcome back we will now continue the public comment period. As it with the previous session participants in the room I will call your number in groups of three to line up at the microphone and state your name as well as your comment. There will be a timer, 4 minutes and you get a one minute morning and after that we will ask you to wrap up your comments. After those in the room have spoken we will go to those on the phone. I would like to start now with numbers 11, 12, and 13.

Speaker: Thank you so much for the break. I hope everyone can hear okay. Thank you very much EPA for hosting this workshop. I'm Karen Schmidt on behalf of ACC happy to present comments today. I've several other colleagues who will present comments and we do intend to follow up with written comments as well we hope will be helpful to you. I will present some very general comments and then my colleagues will provide some additional detail of key points. The first comments are on the PMN process and framework so I would like to start with that. As it will be no surprise to you, the chemical industry continues to have concerns with the PMN process and they are really in three big buckets. The first major concern the length of time that it's taking EPA to complete the review. That continues to be a concern. The second issue relates to the predictability uncertainty of the process and the third on going concern as EPA is overly conservative approach with respect to making a risk determination. The value of this workshop is that we are here to see and participate in substantial work by the agency to address these issues and we think substantial progress has been made but of course, there is more to be done so we look forward to continuing toward the agency to address these three issues. These significant delays of the review process have a significant impact on R&D expenditures, planning lunches, developing greener or more sustainable chemistries and innovativeness and competitiveness. It should be well known, but we wanted to reiterate that point. The PMN currently in the review system collectively represent tens of millions of dollars of R&D investment in new planning so, again, it's very important we address these issues and address them promptly. From a timing standpoint we are hopeful to hear EPA's comments that it doesn't tend to stick to 90 day, 180 day framework outlined in the statute and we look for to working with you to achieve that while maintaining of course the scientific rigor that's necessary to make this program work. We also note that predictability and certainty are every bit as important to industry as timing and expeditious review. Since the enactment of Lautenberg predictability uncertainty have been harder to come by. PMN submitters have been reporting as a result they are delaying or withholding the submission of PMN for substances that may have fewer impacts across the lifecycle or in specific sustainability considerations like energy, water use, health effects. We've also noted that some submitters have taken the extreme step of bringing chemistries to market in other jurisdictions outside the U.S. and Europe or elsewhere in the globe. This is an unfortunate trend. One if it increases would hurt capital investment jobs in U.S. competitiveness. So something no one wants. We do think that the greatest opportunity for process improvements appears to come from focusing on how best to streamline the PMN review process and review again while meeting statutory requirements set out in the Lautenberg amendment. We also know there are two critical points in the process where we think there is an opportunity for the review. One is prior to submission and we spent significant time talking about that and how the pre-consultation process would work on the second is one EPA has reached determination that the substance will go through standard review. To the extent we can move the second point further back in the 90 day process toward the beginning, the better. The earlier the better. Most of the time it should not take 90 days for that determination to be made. That's particularly the case with the not likely to present determination. Prior to submission we think the PMN submitter may be in a position to develop the targeted information that EPA will need to address its potential concerns. It's a critical period for consultation discussion sent to the extent possible decisions on part of the submitter. We understand the agency cannot reach any decisions at that point. Once EPA decides on standard review, EPA is likely to affect -- request additional data as appropriate. We do encourage the agency to provide additional guidance and outreach to encourage PMN submitters to develop key data and include that in the PMN. Again we are appreciative of the points to consider document. That's an excellent start. We will have more substantial comments on that document but this is one terrific way to get started. We encourage the agency to think of other ways to provide that guidance in addition to or in that document. We also note that once EPA decides that a PMN substance will go through standard review at that decision point in the process it should try to present the PMN submitter with a complete request for data as possible. We've already seen in comprehensive request may not be possible, but as complete a request as possible should be made. Of course, this will help to avoid follow-up requests and the need for amendments and those create the requirement for additional delays and the necessity for additional delays as should be avoided. Last, but not least we want to point out there has been no

fundamental change to the underlying decision-making standard for new chemicals review. That is very important as you think about the decision framework and what constitutes sufficient information. We will have additional comments on reasonable foreseeability. We do look forward to additional discussions of the probable versus possible distinction set out in the Risk Evaluation Rule and the document itself. But we will leave that to the written comments. I have two other colleagues who would like to speak so thank you very much for the opportunity to present today and I will put my next colleague on.

Alice Tome: Thank you.

Speaker: Good afternoon, thank you for the opportunity to comment. My name is Richard Starr from the American Chemistry Council. We are concerned EPA are not meeting the 90 day requirement. These delays industry concerns of section program is not predictable. Submitters cannot approach PMN with certainty in Congress did not intend to create this. The concerns extent to the consideration of a non-order submitter where the PMN review period remains open until the submitters published. It does not begin work until finalizing a five-year PMN substance. Then use of the non-order SNUR would substantially delay and ability to commence manufacture of the PMN substance. And analysis of the data from the SNUR demonstrates little progress toward timely decisions. There are a number of reasons why this is the case. These include information provided by submitters, issues related to submitter EPA communications, EPS request for extensions where there is no alternative for the submitter except to withdraw from the PMN and delays caused by reassessment upon the receipt of new information or reruns of engineering reports among other reasons. And amending TSCA it's intended to ensure sufficiency of information and [inaudible] populations and pure reviews. Congress did not extend the existing statutory deadlines for Section 5 access. The data points for significant need for better metrics of Section 5 program and increase transparency relative to the time associated with Section 5 reviews. We believe the points of consider document should be helpful in addressing information up front. However, EPA should make public the number of extensions for specific PMN submissions and the general reasons for the extension request. Tracking this metric will provide a better view whether EPA is making progress to eliminate some friction in the system. At a minimum EPA should ensure that the effective date of a five-year order is made public for all relative PMNs. Some information is not currently available and therefore, the entire universe of Section 5(e) orders during that time periods cannot be assessed. EPA should consider issuing performance goals for 5F4, 5G actions. These would provide useful way of benchmarking the efforts to meet the 90 or 180 day deadlines as established by Congress. We intend to elaborate on these points and analysis on Section 5 data in written comments and we will be submitted later next year.

Alice Tome: Thank you.

Speaker: Robert with [inaudible] specialty chemicals. Ticket for the opportunity. To give you a tiny bit of background we represent the specialty chemical industry, which is the small -- small amounts but high-value chemicals. So they are different than the commodity chemicals we have a whole different process for manufacturing everything. EPA has cleared up the post LCSA backlog of new chemicals and that's terrific, but our members are still reporting they are having significant slowdowns and significant delays. EPA recently published the fiscal year 18-22 transformation strategy and you specifically note in the goals that one of the goals is to complete TSCA pre-manufactured notice final determinations in accordance with the timeline set forth with the statute. But our members are still seeing EPA asked them to waive the Section 5 timelines without any report of a need for guidance, a need for additional materials. EPA's new chemical decision-making framework doesn't really acknowledge the fact that Congress didn't change the 90-180 day review for PMN end in fact requires EPA to refund submitters fees when it misses those deadlines. These facts all suggest that Congress did not intend to create a system under LCS where EPA significantly needs more information on more time. Combined with the frequency, which with EPS issuing SNURs the new rope you -- review process is moving in the direction of a registration program and that is absolutely not what Congress intended and

EPA's stated goals that conflicts with EPA's stated goals and strategic goals. It also does not appear that EPA envision scenarios where submitters can result uncertainty within the review period. The points to consider doc makes note of using additional information to develop risk mitigation strategies to be contained in SNURs but does not indicate such additional information could be used to recharacterize the perceived risk is not likely to be unreasonable. Similarly the framework document implies that the provision of additional information to understand the hazardous potential hazard and exposure of a substance will result in a SNUR. We hope that at least in some cases submitters will be able to provide sufficient additional information to allow manufacture to commence without the need for a consent order or a SNUR. Finally, we are concerned that the framework and Points to Consider Document treats exemption applications exactly the same way as PMNs. When by definition they are supposed to be exempt from some portion of the requirements of PMNs. In 1995 EPA actually said that the LV E exemption applications would only be granted on the basis of affirmative findings and no reasonable risks. So these decisions should not have been significantly affected by the LCSA. Thanks for your time.

Alice Tome: Thank you. All right, I would like to call up numbers 14, 15, and 16. We may be a little out of order with the numbers but we will make it all work out.

Speaker: Good afternoon. Rich Engler, I offer these comments on behalf of the test a new council coalition a group of two dozen companies with specific interested EPA's new chemical program in the implementation of Section 5. The new chemicals decision-making framework is a good start to EPA's effort to clarify the policies and procedures under Section 5. We look forward to reviewing the additional details as EPA develop specific criterion policies used in making determinations for PMN SNURs. Transparency and predictability are vital for a new program for submitters, stakeholders and program efficiency. The new chemical coalition is interested in the interpretation of reasonably foreseen conditions of use and how that is different from any possible conditions of use. As it stands EPA has proposed regulating every substance for which EPA identified a hazard that is not a low low. That hazard based approach cannot possibly be the correct interpretation of TSCA as reformed otherwise Congress would not have left the standard in place in the amendments. The new chemicals coalition also request more clarity on EPA's interpretation of how certain EPA must be about hazards and conditions of use to Reese the not likely determination. We recognize EPA must balance a variety of interests in his thinking on testing however, EPA should neither default to including testing and every consent order nor difficult to know testing. When balancing test on whether testing should be required is whether the test results will change the assessments. For example, company submitted a PMN for substance close analog to several existing chemicals that have a demonstrated high toxicity. EPA predicted one part per billion. In the draft consent order EPA out to request toxic texting to what end. The result could not be worse and confirming one part per billion will not change their determination or proposed restrictions. In this case testing would be a waste and of no benefit to the environment. In Section 5(f) five EPA is required to consult with OSHA and Section 5(e) and F. We recognize OSHA has nor the expertise orc SAP -- capacity to review the new chemical substances. It's entirely appropriate and in our view required by TSCA for EPA to include workplace exposures and the assessments. However, rather than imposing workplace restrictions in SNURs EPA should work with OSHA to develop a mechanism for EPA to inform companies and OSHA of the assessments. By doing so EPA activates the allegation under the OSH act and OSHA's regulation for each company to assess workplace exposures and ensure that the employees are properly informed and protected. Duplicating that regulation is neither required by TSCA and our good policy and doing so consumes scarce EPA resources while placing potentially conflicting burns on companies with no apparent protection. Absent extraordinary circumstances EPA should rely and OSHA's establishments and enforcement mechanisms to ensure workplace protections for chemicals. Beyond this consent orders in SNURs duplicate and conflict with OSHA's requirement for liability to substances in the supply chain. Many companies especially far down the supply chain maybe less sophisticated will deselect substances with SNURs and preference for existing products that have clear OSHA regulatory obligations. In this way customers avoid the TSCA record-keeping including the export notices. In

some cases customers have deselected substances and this is frustrating when the new substance is less hazardous than an existing substance it may replace but does not meet the criteria for low hazard currently required to receive a not likely determination and avoid regulation. If substances both require gloves, goggles and respirators to ensure a safe workplace but one is a SNUR requiring self protection and the other applies to protections based on the general duty clause and OSHA's regulations there's little to be gained and must to be lost by an unequal regulatory burdens that favors the safer alternative. The coalition applauds EPA openness to novel approaches in managing risk for new chemicals particularly the flake that EPA has used to embed the exemption criteria into the substance. This way a company may manufacture the substance that meet the preestablished criteria. Any manufacturer outside those pounds would not be meeting the identity and would require PMN. Embedded in the criteria the identity has the same effect as the SNUR imposing the same criteria. In either case EPA receives a Section 5 notice and has an opportunity to review the substance and use. We encourage EPA to expand this linking to other polymers that may not meet the exemption criteria but are still low hazard as described in the notification. The new chemicals coalition would appreciate if EPA would clarify the legal thinking related to the flag just as EPA has specified definition of associated is an integral part of the identity. We suspect this to be the case but have not seen it. We look forward to working with EPA to strengthen the Section 5 program. Thank you.

Alice Tome: Thank you.

Speaker: Sorry. Good afternoon. Christina friends with the American Chemistry Council. I actually had comments to make and then at lunch we decided ACC did not want to be making so many comments so I was not going to at all, but now I've been reminded that there is one point of clarification that I think we will undertake to make in our written comments that we will be submitting, but we think that EPA ought to take the opportunity and its documentation to clarify these points as well. There seemed in some of the comments that were made by some organizations earlier today that there might be some confusion about what significant new use rules achieve and that they are in fact, regulation and control of substances. I just was really surprised at some of the comments earlier today that were suggesting that EPA is reneging on its responsibility to control risks that it may not be able to review in the review of a particular PMN. That is how you use significant new use rules when you don't have a concern for the use that is identified by the PMN submitter. It sounded to me as I heard the comments this morning that some people might believe that only a consent order is in fact, regulation of a substance. Thank you for the opportunity to comment.

Alice Tome: Thank you. 17 and 20.

Speaker: Thank you. I am cerebral Xena with the American Chemistry Council and I appreciate the time you all have taken to help all of us understand the new program better. I'm going to make a few general comments, more in the nature of some suggestions on some of the points you all raised today and that we think are important going forward and we will embellish on more in our written comments. These suggestions really are relating to some specific hazard identification issues and exposure assessment issues and these suggestions we think are important not just to improve the PMN process, but really sort of the bottom line, what we are all about here is assuring reliable science -based consistent decisions in the new chemicals program. So the first to hazard identification issue I want to bring up is we think that EPA really should help submitters better anticipate your concerns about hazardous chemicals. And this would help prevent the loss of opportunity to actually develop test data as needed. Some ways that EPA might do this, some suggestions we thought of our perhaps more outreach on your concerns or hazards that you might undertake via webinar or updating webpages et cetera. We think an update of the chemical category document to effectively communicate concerns there and recommend testing for categories would be helpful. We also think that updating the Sustainable Futures training and encouraging all PMN submitters to use these more would be very helpful in the broad categories of better understanding where hazard concerns might lie and how companies could address those before it is too late in the process. A second suggestion on hazard identification relates to concerns about low molecular

weight species in or a company PMN substances. Some PMN submitters we understand have found that EPA is concerned about species with higher molecular weights than were indicated in the statements in the chemical categories document. We think EPA should clarify the scope of molecular weights likely to be of concern and explain the basis for that scope. On exposure. The commenter that preceded me two points back raise some specific issues on workplace exposure considerations. We had some suggestions there that these workplace exposure considerations in the PMN review process really should obviously consider OSHA regulations and criteria and should probably do that and also consider the result of OSHA's audits and certifications, for example, the results of OSHA's national program inspection should be a factor in EPA Section 5 reviews. You also might consider opportunities for your new chemical review staff to conduct site visits of facilities to better understand what are the workplace exposures regulations that are being met today, how this -- how they are protected et cetera et cetera. A second exposure issue is about releases to water. We would like EPA to clarify the concerns about predictable or purposeful releases to water. About half of all SNURs and half of all Section 5(e) orders include a release to order provision. And in Section 5(e) orders we think EPA should endeavor to identify a release to order concentration of one part per billion of greater rather than having no release to water provision unless it's clearly justified by the aquatic toxicity of the PMN substance. The no release provision is difficult and made lead to extended discussions with EPA delaying issuance of the 5(e) order and therefore, the submitters ability to enter the market. EPA also should clarify that a release to or water clarification relates to concentrations in water of the U.S. that receive PMN substance and make that clear and also make clear the existing resources that are already available to help PMN submitters calculate expected concentrations of their substances and waters of the U.S. All of this we think will help make it easier for PMN submitters to submit the information needed on this topic. We will embellish on these topics in our comments due in January and we appreciate your time today. Thank you.

Alice Tome: Thank you.

Speaker: Hi, good afternoon I'm Alexis and a toxicologist from the environmental working group. Thank you for your efforts this afternoon and communicating with all of us. First and foremost we feel in order to make an affirmative finding TSCA needs to be implemented in the framework designed by the Congress supporting efforts to use all available tools to ensure thorough and complete data sets regarding hazard and exposure before making a decision. Including the use of ordering new data to fill gaps before creating a Significant New Use Rule. The comment came up this morning including recommended testing with a new use rule showed the new use arise and while we absolutely support this effort we believe EPA should not resort to this in the absence of order authority and require the testing first is a more effective way to prevent risk. During the Points to Consider Document there were several references to general population exposure and health effects. However, we should emphasize that includes vulnerable populations that are of course workers, but also pregnant women, infants and children and that these populations are updated in new vulnerable populations generated and their differences and biological response should be considered along with differences in exposures. Similarly this needs to be included in the reasonably foreseeable exposure to vulnerable populations beyond the intended uses. For example, reasonable and foreseeable product is intended for adults maybe used by children and workplace controls could potentially be ignored or implemented and therefore, risk should still be assessed. We support and encourage the increase in data sharing and assessment of chemical analogs are chemical categories especially those emphasizing biological response and not structural alone, but are concerned that reliance on structural activity relationships to make decisions with safety is flood and requires development and, again, continue to urge EPA to request new data where predicted models are vulnerable populations are at risk and to use systematic review when possible. Therefore, EPA should not default and not likely to present an unreasonable risk because complete data is lacking in the PMN and should never find no reasonable risk when significant data gaps still exist. Lastly, we are concerned about critical evaluation of cumulative or aggregate risk as required by European policy especially of similar PMNs are submitted were similar uses are not analogous chemicals are already in use would support the consideration of similar modes of action that could

potentially contribute to the same adverse health outcomes and/or a cumulative concentration concern. Similarly we feel the risk to chemicals are not considered an evaluation of PMN and encourage EPA to include these in point since adverse health effects can occur in low dose exposure scenarios and they will evaluate these effects. Thank you for including us in this process and we look forward to continuing the conversation.

Alice Tome: Thank you. So if you are going to call in, please do so now and meanwhile we are going to take those remaining in the room who have numbers. I could not remember your number.

Speaker: I think they just made it up. [chuckling]

Hi. I'm Jim Cooper with the American Fuel and Petrochemical Manufacturers and want to reiterate a big thank you. I'm a big fan of these public meetings. There was a dearth of them for a while and I'm glad EPA has returned to this kind of open dialogue. I also appreciate the reemphasis on pre-notice consultation. I cannot stress the importance of this step in the process. Back in the day when I was at a different organization I use to help small companies through this process and that was one thing I insisted on before offering help is you have to get in and talk to EPA. When they did they came out with an understanding of expectations and it made the whole process more efficient and less surprising. That black box started disappearing so I applaud EPA for that. Also it looks like the points document is going to be another very positive step forward making people aware of how EPA looks at things in the process. And things of that nature and also I am a big fan of Sustainable Futures. This is personally, not now speaking on behalf of AFPM because our members don't make that many new chemicals to warrant them becoming part of that program, but I was part of that when it was getting off the ground so just wanted to express an appreciation for the emphasis there as well. I have a different view of Congress' intent regarding changes to Section 5 and a difference from a few other stakeholders. Congress, if you read it and compared to the original Section 5 there are not a whole lot of changes in language. There are some additions that will go through in a minute but that lack of change sent a message because you look at sections four, six, other sections they were significantly changed so there's a reason obviously and that is Congress did not intend to revamp the entire PMN approach and the review process. And so I think people should keep that in mind when they are trying to take a look at what Congress' intent was. During these changes. And part of that change was an expansion of EPA's tools. This whole notion of the order or consent agreements and these things becoming part of it was the same thing a Section 4. The whole intent was to bridge and enhanced EPA's tools by including the tools they are already using. EPA has been using these tools in the new chemicals program and this kind -- I don't know what the word is but it makes it official by putting it in the statute and it's reemphasizing hey, EPA, keep using the approaches you were using. And it was not in the original statute so they did that additional language. I don't read any preference in one tool versus another tool in there and don't read much preference -- I read a whole lot of kind of giving EPA discretion on how they are going to use those tools. But beyond that I don't read much more into that language. Let's see, sorry,, I'm skipping all over the place here. I did hear a lot of stakeholder criticism of the new chemical process and let me give a little historical perspective because I have been involved or used to be involved in that quite a while ago. I have heard characterized as a cursory look at a chemical with a wink and nod approval process and obviously the stakeholders who hold that have never submitted a PMN. For those who have to be clear it's the entire lifecycle of the chemical being evaluated. It's information that is not sufficient EPA will use default assumptions that are built into those and unless stakeholders know those models they will never understand how conservative these assumptions are. I may disagree with them, but the one good thing is it's predictable. You know what, the assumptions are and the onus is on the submitter to come back with information challenging those assumptions and that is what's important to understand here is there is the ability to change those default assumptions but they are productive and conservative and that seems to be at least a livable system and I have not heard a whole lot of you get some complaints when manufacturers are new to the process and we first find out how conservative it is, but once they know they can in subsequent submissions challenge those effectively. And also just in general remember back in the years of the National pollution prevention toxic

advisory committee there was actually a proposal by certain NGO stakeholders that were part of that committee to use the new chemical process and tools to evaluate non-HPV existing chemicals so that tells me from a historical perspective I am not sure what the beef is with the new chemicals program that was a no nothing evaluation process. I hold the exact opposite view. I think it's a rigorous process and helping smaller companies through what I've learned a great deal about how EPA approaches these things in a conservative manner. And I think -- the last thing is we are supportive of reducing animal use as well and we think that the testing should be based on plausible and not just hypothetical exposures. In the testing burden should fall on manufacturers to enter comments. For specific uses that are outlined in the PMN and they should not be placed with a burden for testing for the uses of other manufacturers. That's not the way it was intended to work and so we hope that EPA keeps that in mind moving forward. Thank you very much.

Alice Tome: Thank you. Next speaker.

Speaker: Good afternoon my name is Melanie and I'm an attorney with the environmental working group. It may not surprise you that I have a different interpretation of congresses intent and the changes to Section 5 then my colleague at AFPM head. So if you agree with the industry responsibility to provide robust information regarding the entire lifecycle of the chemical. We are in agreement on that but I actually think that the changes to Section 5 were significant and actually a year ago when you had a similar meeting I heard sort of similar comments from industry talking about while these were really minor changes that were not intended to change the process significantly and I'm a bit surprised I'm hearing less of that today. I think maybe that means that people have come around and realize that actually these are very quite significant changes that address the core of how Section 5 is intended to operate and I appreciate the context in the history that Mr. Dennison gave earlier today where there really was a distrust particularly among the environmental and community about the lack of data that was often behind new chemical decisions. So the shift in requirement to making an affirmative decision based on the conditions of use which is very clearly defined in the statute to include all intended, known, reasonably foreseeable uses for the entire lifecycle of the chemical is actually quite significant. And it's reflected in the Congressional record and it's intended to be a significant change. Jonathan from the Senator's office came to a meeting last year and read a statement from the Senator reflecting the congressional intent that the changes are significant and because those changes are significant it's not surprising the program over the last year has gone through some growing changes resulting in delays. Also in part because those changes took effect immediately which is often not the case when there are really significant regulatory changes so I have a little bit of sympathy for the work that EPA has had to do to catch up and I think that EPA should ask for a little bit more patience from the industry as they are better understanding EPA's own process and information requirements and I think it's hard to argue that the new law doesn't require significantly more information requirements than what was previously case when chemicals could go through the system with hardly any help data. I quickly in the little bit of time I have one to reemphasize some of the other points that were made by NGO colleagues today though I'll try to not be too redundant. We share concerns about unlawfully narrowing EPA's review to focus only on the intended use is included in the PMNs. Everyone agrees you have to look at reasonably foreseeable uses, but the scope of what that means there seems to be quite a bit of disagreement. I would agree with my colleague from root justice who said limiting that interpretation to probable uses would be unlawful. I know in one of the documents EPA mentions looking at concentrations of concerns based on your presentation earlier today I would hope that includes acute and chronic concentrations of concern expedience is. I would also agree with the need to use high-quality data and to seek that early and that some people have discussed earlier today. And then also I would just reiterate the concern that other NGOs have expressed today about the allergy that has developed in the last six months or so to using orders and order authority and developing consent orders and that is a particular concern because once a chemical has been approved to go on the market, it's on the market and a consent order allows you to go back and re- review how that chemical is being used. Once it's on the market and as new information becomes available and just implementing Section 5 correctly from the beginning based on adequate data that fully takes into consideration health data points,

vulnerable populations, it's really, really important to get it right and we can't sacrifice those health points and environmental data points for expediency because then you push it off into Section 6 and that's a much more involved, link the process and so I just want to encourage EPA to really try and get it right at the beginning and we will follow-up with written comments and we appreciate the opportunity today. Thank you.

Alice Tome: Thank you. I just want to check. I understand there are no comments on the phone. Is that still true? Okay. So if you are on -- listening through the webinar, this is about your last chance to call in and make a comment. Are there any more commenters in the room? All right. I just want to emphasize that as been stated several times, and you can make a written come in through regulations.gov. The information is on the slide here in the room. Mail your comment or submit a written comment via hand delivery and remember when you submit a written comment please reference the correct Docket ID number. That is provided on the slide and the docket will be open until January 20, 2018. Just doing one more check on the phone making sure nobody has called in. Nobody. All right, I will turn it over to Jeff for closing remarks.

Jeff Morris: Thanks Alice, but especially thank you to all of you in the room and online who participated. It's extremely helpful to us. A lot was covered here and the documents that we put out, the framework documents points to consider, the decision guidance, the Sustainable Futures categories, all of the input on that is extremely helpful as we continue to build the program. It's also very clear that there are other areas that warrant further discussion. We heard a lot about transparency and much of that has to do with a need for focus on as I said the information management and technology in both of those things because it's important that if we are going to move this program in a way that balances the need to be both protective and practical, the only way we are going to get there is if the support that all of you have given to the Lautenberg Act and TSCA continuous. That is only going to happen if we have a shared understanding of what the agency is doing every step of the way and how we are making decisions. We are not all going to agree as a group on any individual decision or approach, but it is going to be tremendously complicated if we don't even understand what those decisions and approaches are. So transparency is really critical and has to be a renewed and I think enhanced focus of this program so it will be. You know, another issue is timeliness and that is true. Just a fact I think that learning a new program, executing on it and working through all of these issues that you have raised has caused slow downs and that is a problem for all of us. Whether it is ensuring that environmental protection gets in place or new technologies and chemistries get out in the public domain. It's important we do a better job there and so we are working very hard toward that. The issue of worker protection came up repeatedly. It has to be a priority area because -- so in my new enhanced responsibilities of looking over every single decision, many, many of these relate to worker protection and in personal protective equipment and potential exposure scenarios be they for the intended use of the reasonably foreseen. So I think the comments that have been made both here and in the docket about one, the need for EPA to exercise its responsibility in PMN and chemical review to ensure workers are protected is adhered to, but then second, that we look to do that in a way that just makes sense as practical so being practical and protective so I think this will be an area where we will have continued dialogue and discourse on how we do that. It is not the only thing. It's not the only set of considerations by any means, but it is clear that it's a very important one and we don't find a way to move forward on those that will be a big hang up in the program. Finally, I am in the camp that the new determinations that the Lautenberg Act gave us are important new considerations and the determination of not likely to present unreasonably risk and unpacking that and what it means and being transparent about what distinguishes not likely from may present and what unreasonable risk means, those are important considerations. We try to highlight those in the framework that we don't elaborate on them enough. So as we continue to dialogue on how we distinguish between when presented with scientific information not likely to present risk or may present or present or whether we would have sufficient information to make an evaluation in the environment we work and are really important. I think we did not spend a whole lot of time on that here and maybe it's because you really can't have that discussion outside the context of actual decisions but we need to get to a point where whether you agree with it or not you understand how EPA made a determination of not likely to present unreasonable risk or

may present or didn't presenter didn't have enough information. So, again, it's the predictability, transparency and understanding most of all about how we are operating and I think if we can get there then the confidence that we all have that the new substances that inter- commerce and do indeed enable so many of the things that we enjoy as a society are doing so in a way that is environmentally protected. I'm confident that if you all are able to hang with us and continue to show the commitment that you have shown today to resolve these issues that we will get there. So, again,, thank you, and I look forward to your continued engagement. [Applause]

With that we are done so have a good rest of the day.