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 these 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 BackgroundFirst 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 alternativea nd 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 IIIDi For relevant routes of exposure there are accepted methods that allow for extrapolation between routes.
134	Human Haz/Tox	Section IIIDi RE: consideration of metabolic pathways, species sensitivities and mechansims - would like more details. Would AOPs be helpful? MOA data on analogs sufficient?
135	Human Haz/Tox	Section IIIDi Re: selection of analogs - provide sufficient justification. Recognize CBI concerns.
136	Human Haz/Tox	Section IIIDi Re accept information submitted/reviewed by other agencies but want more guidance on how it could be submitted
137	Human Haz/Tox	Section IIIDi states that we "requie 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 IIIDi - agree that absorption is important. EPA should use proven tools and models like they do for REACH
139	Fate	Section Dii 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 IIIDiii 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 thedegree 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-andfate-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
Guidance	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, 125