THE ATTORNEYS GENERAL OF NEW YORK, DISTRICT OF COLUMBIA, HAWAI'I, ILLINOIS, MAINE, MARYLAND, MASSACHUSETTS, MINNESOTA, NEW JERSEY, OREGON, RHODE ISLAND, AND VERMONT

June 8, 2020

Via Electronic Filing

EPA-HQ-OPPT-2019-0131

Andrew Wheeler, Administrator
U.S. Environmental Protection Agency
Document Control Office (7407M)
Office of Pollution Prevention and Toxics
1200 Pennsylvania Avenue NW
Washington, DC 20460-0001

Re: ***Draft Scopes of the Risk Evaluations To Be Conducted for Seven Chemical Substances Under the Toxic Substances Control Act; Notice of Availability*, 85 Fed. Reg. 22,733 (Apr. 23, 2020)**

Dear Administrator Wheeler:

The Attorneys General of New York, District of Columbia, Hawai'i, Illinois, Maine, Maryland, Massachusetts, Minnesota, New Jersey, Oregon, Rhode Island, and Vermont submit these comments regarding the U.S. Environmental Protection Agency's ("EPA") draft scope documents ("Draft Scopes") for the risk evaluations for the referenced seven high-priority chemical substances for which notice was published on April 23, 2020, with these comments applying equally to the remaining 13 of the initial 20 EPA designated high-priority chemical substances[1] required under the Frank R. Lautenberg Chemical Safety for the 21st Century Act (the "Lautenberg Act"), amending the Toxic Substances Control Act ("TSCA").[2]

Our states have a significant interest in ensuring that the Draft Scopes for the risk evaluations for the 20 high-priority chemical substances are prepared in accordance with TSCA and the EPA implementing regulations at 40 C.F.R. Part 702, Subpart B. EPA selected the 20 high-priority chemical substances because of their potential for substantial harm to public health and the environment.[3] If EPA fails to fully identify the risks posed by the use of these chemicals, the agency cannot then effectively manage those risks to protect human health and the environment.

[1] *See Draft Scopes of the Risk Evaluations To Be Conducted for Thirteen Chemical Substances Under the Toxic Substances Control Act; Notice of Availability*, 85 Fed. Reg. 19,941 (Apr. 9, 2020).

[2] 15 U.S.C. § 2601 *et seq.*

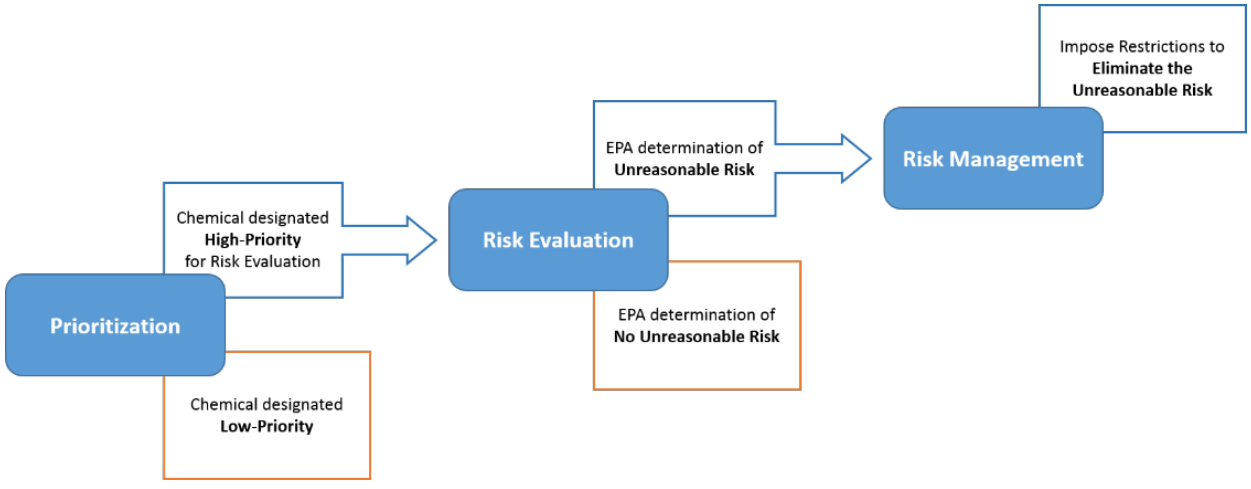
[3] *See Proposed High-Priority Substance Designations under the Toxic Substances Control Act (TSCA); Notice of Availability and Request for Comment*, 84 Fed. Reg. 44,300, 44,301 (Aug. 23, 2019).

With a fast approaching statutory deadline, EPA published the Draft Scopes without key elements and without providing the opportunity for meaningful public review and comment. The defects in EPA's Draft Scopes must be remedied now or the agency's 5-year long TSCA safety evaluations of the 20 high-priority chemical substances will be compromised as the reliability of the evaluations hinge on the formulation of comprehensive scopes that fully comply with the governing law.

As discussed in these comments, the Draft Scopes fail to satisfy the substantive requirements of TSCA and EPA's implementing regulations. As a consequence, any risk evaluations and, as dictated, risk management actions developed from these Draft Scopes would also fail to satisfy those legal requirements. The Attorneys General call on EPA to withdraw the current Draft Scopes and issue revised Draft Scopes that fully satisfy those legal requirements, including identifying the hazards, exposures, conditions of use, the potentially exposed or susceptible subpopulations, and the information and scientific approaches that EPA plans to use in the risk evaluations. *See* 15 U.S.C. § 2605(b)(4)(D); 40 C.F.R. § 702.41(c). In turn, EPA must provide the opportunity for public review and comment on the revised Draft Scopes. *See* 40 C.F.R. § 702.41(c)(7)(iii). Further, to the extent that EPA intends to use "systematic review" or other supplemental documentation to address the manifold gaps in the current Draft Scopes, TSCA and EPA's implementing regulations dictate that this documentation be included in—not separate from—the revised Draft Scopes. Accordingly, such documentation must be issued jointly with the revised Draft Scopes and subject to public review and comment. EPA's attempt to provide piecemeal public notice and comment as the agency fills-in missing critical elements of the scopes does not substitute for the meaningful public participation on complete scopes that must be afforded under the law.

A. Overview of EPA's Evaluation of the Safety of Chemicals Under TSCA

EPA is to evaluating the safety of existing chemicals under TSCA via three interrelated stages: (1) prioritization, (2) risk evaluation, and (3) risk management:[4]



[4] *See* https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/how-epa-evaluates-safety-existing-chemicals (last accessed June 8, 2020).

The first stage in EPA's process for evaluating the safety of existing chemicals is prioritization.[5] The prioritization process has been designed to ensure that EPA's limited resources are focused on chemicals with the greatest potential for risk.[6]

The second stage in EPA's process for evaluating the safety of existing chemicals is risk evaluation.[7] The overall purpose of a risk evaluation is to determine whether a chemical substance presents an unreasonable risk to health or the environment, under the conditions of use, including an unreasonable risk to a relevant potentially exposed or susceptible subpopulation. 15 U.S.C. § 2605(b)(4)(A).

The risk evaluation stage EPA is pursuing has three linked components: (1) a scope document that provides the public with information on the focus of the risk evaluation, including the hazards, exposures, conditions of use, and the potentially exposed or susceptible subpopulations; (2) hazard and exposure assessments and a risk characterization to inform the risk determination; and (3) a risk determination stating whether or not a chemical substance presents an unreasonable risk to health or the environment under its conditions of use.[8]

If at the end of the risk evaluation process, EPA determines that a chemical presents an unreasonable risk to health or the environment, the chemical must immediately move to the third stage—risk management action under TSCA.[9] EPA is required to implement, via regulation, regulatory restrictions on the manufacture, processing, distribution, use or disposal of the chemical to eliminate the unreasonable risk. [10] EPA must provide the opportunity for public comment at each stage.[11]

The statutory deadlines related to the safety evaluation process of the 20 high-priority chemical substances, which span 5 years, are set forth below:

(1) Prioritization	
Proposed designation of 20 chemical substances as high-priority[12]	March 21, 2019

[5] *See id.*

[6] *See id.*

[7] *See id.*

[8] *See id.*; *see also* 40 C.F.R. § 702.41(a)(1).

[9] *See* https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/how-epa-evaluates-safety-existing-chemicals#mgmt (last accessed June 8, 2020)

[10] *See id.*

[11] *See* https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/how-epa-evaluates-safety-existing-chemicals (last accessed June 8, 2020).

[12] EPA was required to ensure that risk evaluations were being conducted on at least 20 high-priority substances within 3.5 years of the enactment of the Lautenberg Act (enacted June 22, 2016). *See* 15 U.S.C. § 2605(b)(2)(B).

Comment period on proposed priority designation (90 days)[13]	August 23, 2019 - November 21, 2019
Designation of 20 chemical substances as high-priority[14]	**December 20, 2019**
(2) Risk Evaluation	
Draft scopes for 20 high-priority substances	April 2020
Comment period on draft scopes for 13 of 20 high-priority substances (45 days)[15]	April 9, 2020 – May 26, 2020
Comment period on draft scopes for 7 of 20 high-priority substances (45 days)[16]	April 23, 2020 - June 8, 2020
Final scopes for 20 high-priority substances	**Due June 20, 2020**[17]
Draft risk evaluations for high-priority substances	TBD
Comment period on the draft risk evaluations (60 days)[18]	TBD
Final risk evaluations for high-priority substances	**Due December 20, 2022**[19]
(3) Risk Management	
Publish proposed rule to address unreasonable risks	**Due December 20, 2023**[20]
Comment period on the proposed rule to address unreasonable risks	TBD
Publish final rule to address unreasonable risks	**Due December 20, 2024**[21]

[13] *See* 40 C.F.R. § 702.9(g).

[14] Final designation as a high-priority substance initiates a risk evaluation. *See* 40 C.F.R. § 702.17.

[15] *See* 40 C.F.R. § 702.41(c)(7)(iii).

[16] *See id.*

[17] Due within six months after EPA initiates the risk evaluation process. 15 U.S.C. § 2605(b)(4)(D).

[18] *See* 40 C.F.R. § 702.49(a).

[19] Due within three years after EPA initiates the risk evaluation process. 15 U.S.C. § 2605(b)(4)(G).

[20] Due within one year of publication of the final risk evaluation. 15 U.S.C. § 2605(c)(1)(A).

[21] Due within two years of publication of the final risk evaluation. 15 U.S.C. § 2605(c)(1)(A).

B. EPA's Designation of the Initial High-Priority Chemical Substances

As part of the TSCA prioritization stage, EPA must use reasonably available information to screen candidate chemical substances under its conditions of use against the following criteria and considerations:

- the hazard and exposure potential of the chemical substance;
- persistence and bioaccumulation;
- potentially exposed or susceptible subpopulations;
- storage near significant sources of drinking water;
- conditions of use or significant changes in the conditions of use of the chemical
- substance;
- the chemical substance's production volume or significant changes in production volume;
- and other risk-based criteria that EPA determined to be relevant to the designation of the chemical substance's priority.[22]

Following its review, EPA concluded that each of the initial 20 designated high-priority chemical substances "may present an unreasonable risk of injury to health or the environment because of a potential hazard and a potential route of exposure under the conditions of use." 15 U.S.C. § 2605(b)(1)(B)(i).

EPA designated seven of the chemical substances as high-priority for the following reasons:

- *Formaldehyde*:

  EPA believes that formaldehyde may cause human health hazards, including acute toxicity, repeated dose toxicity, genetic toxicity, irritation/corrosion in the upper respiratory tract, eyes and skin, dermal sensitization, respiratory sensitization, and carcinogenicity. EPA also expects that formaldehyde may cause environmental hazards, including aquatic toxicity and terrestrial toxicity.[23]

  Formaldehyde is used in industrial, commercial, and consumer applications, including textiles, foam bedding/seating, semiconductors, resins, glues, composite wood products, paints, coatings, plastics, rubber, resins, construction materials (including insulation and roofing), furniture, toys, and various adhesives and sealants.[24]

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[22] *See, e.g.*, EPA, *Proposed Designation of Formaldehyde (CASRN 50-00-0) as High-Priority Substance for Risk Evaluation*, p. 1 (Aug. 22, 2019), *available at* https://www.regulations.gov/document?D=EPA-HQ-OPPT-2018-0438-0013; *see also* 40 C.F.R. § 702.9.

[23] *See id.* at 70.

[24] *See* EPA, *Draft Scope of the Risk Evaluation for Formaldehyde*, p. 10 (Apr. 2020), *available at* https://www.regulations.gov/document?D=EPA-HQ-OPPT-2018-0438-0029.

- *Butyl benzyl phthalate (BBP) (1,2-Benzenedicarboxylic acid, 1-butyl 2-(phenylmethyl) ester)*:

  EPA believes that BBP may cause human health hazards, including acute toxicity, repeated dose toxicity, genetic toxicity, reproductive toxicity, developmental toxicity, dermal sensitization, respiratory sensitization, neurotoxicity, and carcinogenicity.[25] EPA also believes that BBP may cause environmental hazards, including aquatic toxicity and terrestrial toxicity.[26]

  BBP is used in industrial, commercial, and consumer applications, including adhesives, paints and coatings, personal care products, printing ink products, building and construction materials, fabrics, textile, floor coverings, and food contact surfaces.[27]

- *Dibutyl phthalate (DBP) (1,2-Benzenedicarboxylic acid, 1,2-dibutyl ester)*:

  EPA believes DBP may cause human health hazards, including acute toxicity, repeated dose toxicity, genetic toxicity, reproductive toxicity, developmental toxicity, dermal sensitization, respiratory sensitization, neurotoxicity, and carcinogenicity.[28] EPA also believes that DBP may cause environmental hazards, including aquatic toxicity and terrestrial toxicity.[29]

  DBP is used in industrial, commercial, and consumer applications, including cosmetics, adhesives, arts and crafts products, and cellophane and is present in certain home furnishings, paints, vinyl flooring, floor wax, and fragrant products such as household cleaners and auto products.[30]

- *Dicyclohexyl phthalate (1,2-Benzenedicarboxylic acid, 1,2-dicyclohexyl ester)*:

  EPA believes that dicyclohexyl phthalate may cause human health hazards, including acute toxicity, repeated dose toxicity, genetic toxicity, reproductive toxicity, developmental toxicity, dermal sensitization, and respiratory sensitization.[31]

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[25] *See* EPA, *Proposed Designation of Butyl Benzyl Phthalate (CASRN 85-68-7) as High-Priority Substance for Risk Evaluation*, p. 21 (Aug. 22, 2019), *available at* https://www.regulations.gov/document?D=EPA-HQ-OPPT-2018-0501-0011.

[26] *See id.*

[27] *See id. at* 20-23.

[28] *See* EPA, *Proposed Designation of Dibutyl Phthalate (CASRN 84-74-2) as High-Priority Substance for Risk Evaluation*, p. 34 (Aug. 22, 2019), *available at* https://www.regulations.gov/document?D=EPA-HQ-OPPT-2018-0503-0010.

[29] *See id.*

[30] *See id.* at 5-15, 32.

[31] *See* EPA, *Proposed Designation of Dicyclohexyl Phthalate (CASRN 84-61-7) as High-Priority Substance for Risk Evaluation*, p. 34 (Aug. 22, 2019), *available at* https://www.regulations.gov/document?D=EPA-HQ-OPPT-2018-0504-0009.

Dicyclohexyl phthalate is used in industrial, commercial, and consumer applications, including adhesives, sealants, plastic and rubber products, commercial building and construction materials, printing inks, painting and coating materials, arts and crafts products and flooring materials.[32]

- *Di-ethylhexyl phthalate (DEHP) (1,2-Benzenedicarboxylic acid, 1,2-bis(2-ethylhexyl) ester)*:

  EPA believes that DEHP may cause human health hazards, including acute toxicity, repeated dose toxicity, genetic toxicity, reproductive toxicity, dermal sensitization, developmental toxicity, carcinogenicity, and neurotoxicity.[33] EPA also believes that DEHP may cause environmental hazards, including aquatic toxicity and terrestrial toxicity.[34]

  DEHP is used in industrial, commercial, and consumer applications, including paint and coating materials, electrical and electronic products, fabric, textile, and leather products, plastic and rubber products, food, beverage, and tobacco products, medical devices, food packaging and personal care products, arts, crafts, and hobby materials, and lawn and garden products.[35]

- *Di-isobutyl phthalate (DIBP) (1,2-Benzenedicarboxylic acid, 1,2-bis(2-methylpropyl) ester)*:

  EPA believes that DIBP may cause human health hazards, including acute toxicity, repeated dose toxicity, genetic toxicity, reproductive toxicity, developmental toxicity, dermal sensitization, respiratory sensitization, neurotoxicity, and carcinogenicity.[36] EPA also believes that DIBP may cause environmental hazards, including aquatic toxicity and terrestrial toxicity.[37]

  DIBP is used in industrial, commercial, and consumer applications, including adhesives and sealants, air car products, cleaning and furnishing care products, fabric, textile and leather products, floor coverings, ink, toner and colorant products, paints and coatings, paper products, and toys, playground and sporting equipment.[38]

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[32] *See id.* at 5-7, 15.

[33] *See* EPA, *Proposed Designation of Di-Ethylhexyl Phthalate (CASRN 117-81-7) as High-Priority Substance for Risk Evaluation*, p. 42 (Aug. 22, 2019), *available at* https://www.regulations.gov/document?D=EPA-HQ-OPPT-2018-0433-0011.

[34] *See id.*

[35] *See id.* at 24.

[36] *See* EPA, *Proposed Designation of Di-isobutyl Phthalate (CASRN 84-69-5) as High-Priority Substance for Risk Evaluation*, p. 17 (Aug. 22, 2019), *available at* https://www.regulations.gov/document?D=EPA-HQ-OPPT-2018-0434-0010.

[37] *See id.*

[38] *See id.* at 6.

- *Phthalic anhydride (1,3-lsobenzofurandione)*:

  EPA believes that phthalic anhydride may cause human health hazards, including acute toxicity, repeated dose toxicity, genetic toxicity, developmental toxicity, irritation/corrosion, dermal sensitization, respiratory sensitization, and carcinogenicity.[39] EPA also believes that phthalic anhydride may cause environmental hazards, including aquatic toxicity and terrestrial toxicity.

  Phthalic anhydride is used in industrial, commercial, and consumer applications, including dyes, paint and coating additives, colorant products, personal care products, adhesives and sealants, and building and construction materials.[40]

Given their widespread use, multiple exposure scenarios, and associated environmental and human health hazards, it is imperative that EPA evaluate the risks of these designated high-priority chemical substances thoroughly, comprehensively, and in full accordance with the requirements of TSCA and the EPA implementing regulations.

C. EPA's Draft Scopes for the Initial High-Priority Chemical Substances Fail to Satisfy TSCA and the Agency's Own Regulatory Requirements

TSCA and EPA's implementing regulations at 40 C.F.R. Part 702, Subpart B set forth the requirements for the Draft Scopes. EPA must within "6 months after the initiation of a risk evaluation, publish the scope of the risk evaluation to be conducted, *including the hazards, exposures, conditions of use, and the potentially exposed or susceptible subpopulations the Administrator expects to consider*." 15 U.S.C. § 2605(b)(4)(D) (emphasis added). Specifically, the Draft Scopes must include the following information:

> (1) The *condition(s) of use*, as determined by the Administrator, that the EPA plans to consider in the risk evaluation.
>
> (2) The *potentially exposed populations, including any potentially exposed or susceptible subpopulations* as identified as relevant to the risk evaluation by the Agency under the conditions of use, that EPA plans to evaluate; the *ecological receptors* that EPA plans to evaluate; and the *hazards to health and the environment* that EPA plans to evaluate.
>
> (3) A description of *the reasonably available information and science approaches EPA plans to use in the risk evaluation*.
>
> (4) A conceptual model:
>
> (i) The scope documents will include a *Conceptual Model that*

[39] *See* EPA, *Proposed Designation of Phthalic Anhydride (CASRN 85-44-9) as High-Priority Substance for Risk Evaluation*, p. 31 (Aug. 22, 2019), *available at* https://www.regulations.gov/document?D=EPA-HQ-OPPT-2018-0459-0011.

[40] *See id.* at 18.

describes actual or predicted relationships between the chemical substance, the conditions of use within the scope of the evaluation and human and environmental receptors.

(ii) The conceptual model will *identify human and ecological health hazards* the EPA plans to evaluate for the exposure scenarios EPA plans to evaluate.

(iii) Conceptual model development *will consider the life cycle of the chemical substance*, including manufacture, processing, distribution in commerce, storage, use, and disposal, relevant to the conditions of use within the scope of the evaluation.

(5) An analysis plan:

(i) The scope documents will include an analysis plan that *identifies the approaches, methods, and/or metrics that EPA plans to use to assess exposures, effects, and risk*, including associated uncertainty and variability for each risk evaluation. The analysis plan will also identify the strategy for using information, accepted science policies, models, and screening methodologies.

(ii) *Hypotheses about the relationships identified in the conceptual model will be described*. The relative strengths of alternative hypotheses if any will be evaluated to determine the appropriate risk assessment approaches.

(6) The Agency's plan for *peer review*.

40 C.F.R. § 702.41(c)(1)-(6) (emphases added); *see also* 40 C.F.R. § 702.41(c)(7)(i).

The Draft Scopes must provide an appropriate framework for the risk evaluations to follow with respect to the subject chemicals, as well as for EPA's subsequent risk management action. Meaningful public review and comment on the Draft Scopes is an integral part of the process. *See* 40 C.F.R. § 702.41(c)(7)(iii).

On April 23, 2020, EPA published the Draft Scopes of the risk evaluations for seven of the 20 high-priority chemical substances.[41] However, each of the Draft Scopes fail to satisfy the substantive requirements of TSCA and the EPA implementing regulations for these risk evaluations, including identifying the hazards, exposures, conditions of use, the potentially exposed or susceptible subpopulations, and the information and scientific approaches that EPA plans to use in the risk evaluation. *See* 15 U.S.C. § 2605(b)(4)(D); 40 C.F.R. § 702.41(c).

Instead of publishing satisfactory Draft Scopes, EPA admits the inadequacies of the Draft Scopes and asserts that the missing information will be included in forthcoming systematic review documentation and other supplemental documents. By failing to provide the required information with the issuance of the Draft Scopes, EPA violates TSCA and the EPA

[41] *See* 85 Fed. Reg. 22,733.

implementing regulations and deprives the public of the opportunity to provide a full and meaningful review and comment on the Draft Scopes for each of the seven chemical substances. *See* 40 C.F.R. § 702.41(c)(7)(iii). TSCA rightfully does not provide for a disjointed, piecemeal approach to scoping risk evaluations. Instead, the law and implementing regulations require that the public be provided an opportunity to review and comment on thorough and complete presentations of the hazards, exposures, conditions of use, and the potentially exposed or susceptible subpopulations, and the information and scientific approaches that EPA plans to use in the risk evaluations. If EPA intends to use systematic review documentation or other supplemental documents to address the manifold gaps in the current Draft Scopes, TSCA and the EPA implementing regulations dictate that this documentation must be included in—not later be presented separate from—the Draft Scopes. Accordingly, such documentation must be issued jointly with the revised Draft Scopes for public review and comment.

The Draft Scopes contain parallel deficiencies and the following examples from the Draft scope for formaldehyde are illustrative:

- As to the potentially exposed or susceptible subpopulations that EPA plans to evaluate (15 U.S.C. § 2605(b)(4)(D); 40 C.F.R. § 702.41(c)(2)), EPA fails to identify the subpopulations:
    - "In developing exposure scenarios, EPA plans to analyze reasonably available information to ascertain whether some human receptor groups may be exposed via exposure pathways that may be distinct to a particular subpopulation or life stage (e.g., children's crawling, mouthing or hand-to-mouth behaviors) and whether some human receptor groups may have higher exposure via identified pathways of exposure due to unique characteristics (e.g., activities, duration or location of exposure) when compared with the general population (U.S. EPA, 2006a). Likewise, *EPA plans to evaluate reasonably available human health hazard information to ascertain whether some human receptor groups may have greater susceptibility than the general population to the chemical's hazard(s).*" [42]
- As to the hazards to health and the environment that EPA plans to evaluate (15 U.S.C. § 2605(b)(4)(D); 40 C.F.R. § 702.41(c)(2)), EPA fails to provide a complete list:
    - "*EPA is in the process of identifying additional reasonably available information* through systematic review methods and public comments, *which may update the list of potential environmental hazards associated with formaldehyde exposure*. If necessary, EPA plans to update the list of potential hazards in the final scope document of the formaldehyde."[43]
    - "*EPA is in the process of identifying additional reasonably available information* through systematic review methods and public input, *which may update the list of*

[42] *See* EPA, *Draft Scope of the Risk Evaluation for Formaldehyde*, p. 36 (Apr. 2020) (emphasis added), *available at* https://www.regulations.gov/document?D=EPA-HQ-OPPT-2018-0438-0029.

[43] *See id.* at 35.

potential human health hazards under the scope of the risk evaluation. If necessary, EPA plans to update the list of potential hazards in the final scope document of the formaldehyde risk evaluation."[44]

- As to the reasonably available information and science approaches that EPA plans to use (40 C.F.R. § 702.41(c)(3)), EPA fails to provide this information:
    - "EPA plans to seek public comments on the systematic review methods supporting the risk evaluation for formaldehyde *upon publication of the supplemental documentation* of those methods."[45]
    - "The details about the [inclusion/exclusion] criteria are not part of this document but *will be provided in a supplemental document* that EPA anticipates releasing prior to the finalization of the scope document."[46]
- As to the conceptual model that describes relationships between the chemical substance, the conditions of use within the scope of the evaluation and human and environmental receptors, and identifies human and ecological health hazards the EPA plans to evaluate for the exposure scenarios EPA plans to evaluate (40 C.F.R. § 702.41(c)(4)), EPA states that it will adjust this information:
    - "EPA plans to focus the risk evaluation for formaldehyde on the following exposures, hazards and receptors, however, EPA also plans to consider comments received on this draft scope *and other reasonably available information when finalizing this scope document, and to adjust the exposure pathways, exposure routes and hazards included in the scope document as needed*."[47]
- As to the analysis plan that identifies the approaches, methods, and/or metrics that EPA plans to use to assess exposures, effects, and risk (40 C.F.R. § 702.41(c)(5)), EPA refuses to provide details: "*The details will be provided in a supplemental document* that EPA anticipates releasing for public comment prior to the finalization of the scope document."[48] EPA also specifically states:
    - As to physical/chemical properties and environmental fate:
        - EPA plans to "[r]eview reasonably available measured or estimated p-chem and environmental fate endpoint data collected using systematic review procedures and, where reasonably available, environmental assessments conducted by other regulatory agencies" but that "[a]ll sources cited in EPA's analysis will be evaluated according to the

[44] *See id.*

[45] *See id. at* 14.

[46] *See id.* at 20.

[47] *See id.* at 11.

[48] *See id.* at 12.

procedures *described in the systematic review documentation that EPA plans to publish* prior to finalizing the scope document."[49]

- "During risk evaluation, EPA plans to evaluate and integrate the physical/chemical and environmental fate evidence identified in the literature inventory using the methods *described in the systematic review documentation that EPA plans to publish* prior to finalizing the scope document."[50]

- As to exposures:

  - EPA plans to "[r]eview reasonably available published literature and other reasonably available information on processes and activities associated with the other conditions of use to analyze the types of releases and wastes generated . . . *using the evaluation strategy in the systematic review documentation that EPA plans to publish* prior to finalizing the scope document."[51]

  - EPA plans to "[e]valuate the weight of the scientific evidence of environmental release data . . . *using the methods described in the systematic review documentation that EPA plans to publish* prior to finalizing the scope document."[52]

  - EPA plans to "[e]valuate the weight of the scientific evidence of occupational exposure data . . . *using the methods described in the systematic review documentation that EPA plans to publish* prior to finalizing the scope document."[53]

- As to hazards (effects):

  - "EPA plans to evaluate environmental hazard data using the environmental toxicity data quality criteria *outlined in the systematic review documentation that EPA plans to publish* prior to finalizing the scope document."[54]

  - "During risk evaluation, EPA plans to evaluate and integrate the environmental hazard evidence identified in the literature inventory *using the methods described in the systematic review documentation that EPA*

[49] *See id.* at 46.

[50] *See id.*

[51] *See id.* at 47.

[52] *See id.* at 49.

[53] *See id.* at 53.

[54] *See id.* at 58.

plans to publish prior to finalizing the scope document."[55]

- EPA plans to "[r]eview reasonably available human health hazard data from alternative test methods" but "*plans to publish the systematic review documentation* prior to finalizing the scope document."[56]

- "EPA plans to identify human health hazards from acute and chronic exposures by evaluating the human and animal data that meet the systematic review data quality criteria described *in the systematic review documentation that EPA plans to publish* prior to finalizing the scope document."[57]

- "During risk evaluation, EPA plans to evaluate and integrate the human health hazard evidence identified in the literature inventory under acute and chronic exposure conditions using the methods *described in the systematic review documentation that EPA plans to publish* prior to finalizing the scope document." [58]

Thus, EPA has issued Draft Scopes lacking the substance required by TSCA at this stage of the process and depriving the public the opportunity to meaningfully review and comment on them.

D. Conclusion

As discussed above, the Draft Scopes do not satisfy the requirements of TSCA and EPA's implementing regulations at 40 C.F.R. Part 702, Subpart B. As a consequence, any risk evaluations and, as dictated, risk management actions developed from these Draft Scopes would also fail to satisfy those legal requirements. Left uncorrected, the deficiencies in the Draft Scopes will derail the risk evaluation and risk management of these initial high-priority chemical substances, and fail to protect human health and the environment.

To preserve the integrity of the safety evaluations for these chemical substances, EPA must withdraw the current Draft Scopes and issue revised Draft Scopes that fully satisfy the requirements of TSCA and EPA's implementing regulations. Further, if EPA intends to use "systematic review" or other supplemental documentation to address the manifold gaps in the current Draft Scopes, TSCA and the EPA implementing regulations dictate that this documentation be included in the newly issued revised Draft Scopes. EPA must also provide the public with the opportunity for meaningful review and comment on the revised Draft Scopes required by law rather than piecemeal public participation as the agency attempts to fill-in the missing elements.

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[55] *See id.* at 59.

[56] *See id.*

[57] *See id.* at 60.

[58] *See id.* at 61.

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