



**Environmental Defense Fund Comments on
Draft Risk Evaluation for C.I. Pigment Violet 29
(Anthra[2,1,9-def:6,5,10-d'e'f']diisoquinoline- 1,3,8,10(2H,9H)-tetrone)
Docket ID: EPA-HQ-OPPT-2018-0604
Submitted Monday, January 14, 2019**

Environmental Defense Fund (EDF) appreciates the opportunity to provide comments to the Environmental Protection Agency (EPA) on the draft risk evaluation for C.I. Pigment Violet 29 (Anthra[2,1,9-def:6,5,10-d'e'f']diisoquinoline- 1,3,8,10(2H,9H)-tetrone) (hereafter PV29) being prepared under section 6(b)(4) of the Toxic Substances Control Act (TSCA) as amended by the Lautenberg Act, enacted on June 22, 2016.¹

Executive Summary

Under TSCA § 6(b)(4)(A), EPA must determine whether PV29 “presents an unreasonable risk of injury to health or the environment, without consideration of costs or other nonrisk factors, including an unreasonable risk to a potentially exposed or susceptible subpopulation identified as relevant to the risk evaluation by the Administrator, under the conditions of use.” In reaching that determination, TSCA §§ 26(h) and (k) require that EPA use the best available science and consider all reasonably available information. Under its own regulations, EPA has defined “reasonably available information” to include information that EPA “can reasonably generate, obtain, and synthesize for use in risk evaluations.” 40 C.F.R. § 702.33.

In its draft risk evaluation, EPA concludes that PV29 does not present an unreasonable risk. As detailed in our comments below, EPA’s draft risk evaluation cannot support that conclusion because EPA lacks sufficient information to characterize the hazards, exposures, and risks presented by PV29. In addition, the draft risk evaluation contains numerous logical flaws and unwarranted assumptions, rendering its final conclusion unsupported by substantial evidence, as required under TSCA. The resulting draft risk evaluation fails to consider reasonably available information or to use the best available science.

¹ All further citations to the draft risk evaluation for PV29 consist of only a page number in parentheses.

EPA's draft risk evaluation fails to acknowledge and address serious limitations and uncertainties associated with several of its characterizations of PV29's physical-chemical and environmental fate properties that it relies on to conclude low risk. EPA relies heavily on a single, poorly documented value for water solubility while failing to account for other available data on water solubility. EPA fails to address the implications of the very high persistence of PV29 in the environment. EPA also lacks any measured data that directly assess the potential for PV29 to bioaccumulate in humans or other organisms; instead EPA relies upon modeled values derived using an estimation program lacking sufficient data on similar chemicals. Finally, EPA does not address the proposed classification by members of the European Union of PV29 as a suspected very persistent, very bioaccumulative and toxic chemical that would, if confirmed, designate PV29 as a "substance of very high concern" (SVHC) under the EU's REACH Regulation.

The draft risk evaluation lacks crucial information on the conditions of use of PV29. TSCA defines "conditions of use" to mean "the circumstances, as determined by the Administrator, under which a chemical substance is intended, known, or reasonably foreseen to be manufactured, processed, distributed in commerce, used, or disposed of." EPA has ignored reasonably foreseeable uses and uses where available evidence establishes the use is occurring or has recently occurred. In particular, EPA ignored the presence of PV29 in products made using PV29 as an intermediate even though the evidence in the record establishes that PV29 often remains present in such products.

The draft risk evaluation lacks crucial information on exposure to PV29, and its cursory exposure analysis contains numerous flaws and unsupported assumptions. EPA lacks any actual data characterizing environmental, consumer, and general population exposures. EPA also has no actual data on the levels of PV29 released to or present in air, soil, sediment, surface water, people, other organisms, or products containing or made from the chemical. EPA simply dismisses consumer and general population exposures since they "are expected to be exposed at concentrations lower than worker exposures," but EPA provides no evidence to support that expectation. For occupational inhalation exposures, EPA relies on a single value for a workplace air concentration reported in a private personal communication from a manufacturer of PV29; EPA has not provided any detail about this value and appears to lack any supporting information necessary to assess the accuracy or certainty of the value. For occupational dermal exposures, EPA relies on modeled data using default assumptions contrary to the available evidence; EPA only analyzes exposure to the solid form of PV29, ignoring its existence in solution. EPA's basis for dismissing worker exposures by the oral route is unsupported. For inhalation, dermal, and oral routes of exposure, EPA lacks any data on absorption of PV29 but assumes low absorption solely based on its alleged low solubility. EPA's series of rationales for

dismissing the significance of worker exposures are weak and based on little actual data or analysis. EPA also ignores all occupational exposures by downstream processors and users based on the false assumption that exposures would invariably be lower since they handle a smaller overall quantity of PV29 than the manufacturer. EPA assumes without evidence that engineering controls and personal protective equipment – described in Safety Data Sheets (SDSs) that it has not made public and in unsubstantiated industry statements – are universally used in all workplaces handling PV29. EPA also fails to acknowledge and address the real-world limitations of these measures.

The draft risk evaluation lacks crucial information on environmental hazards and human health hazards. EPA has no information on chronic aquatic toxicity, terrestrial toxicity, or toxicity to sediment-dwelling organisms. Instead, EPA relies on three acute aquatic toxicity studies to draw the sweeping conclusion that PV29 presents no environmental hazard of any kind. For human health hazard, EPA relies on studies, most of which examined only acute lethal effects and none of which assessed chronic toxicity. EPA relies on a study of reproductive and developmental toxicity where EPA's own guidance asserts that it "will not provide evidence for definite claims of no effects." EPA relies on two acute toxicity studies to conclude PV29 presents no inhalation toxicity, despite the fact that the chemical's manufacturer that conducted the studies dismissed them as "not reliable" because they used an "unsuitable test system." EPA also concludes that PV29 is not carcinogenic on the basis of insufficient information and unsupported assumptions. EPA dismisses the potential for increased adverse effects on susceptible subpopulations based on studies that failed to look for such effects.

EPA's attempt to characterize risk contains numerous flaws and lacks empirical support. EPA provides only a "quantitative screening-level assessment of occupational exposure," but it is wholly inadequate. First, EPA uses the suspect and undocumented workplace exposure estimate privately provided to EPA by the chemical's manufacturer. Second, EPA calculates a potential dose rate based on a NIOSH inhalation exposure rate that is over 40 years old. Third, EPA assumes that a lower fraction of PV29 is dermally absorbed than the source it cites as support recommends based on the chemical's properties. Fourth, EPA fails to include all necessary uncertainty factors—such as for extrapolating from acute to chronic toxicity values and for database deficiencies—in calculating its benchmark margins of exposure for worker inhalation and dermal exposures. Even adding a single additional uncertainty factor would result in a benchmark value exceeding EPA's margin of exposure calculated for worker dermal exposure. The excessive extent of uncertainty associated with the limited hazard evidence base for PV29—let alone data deficiencies with regard to exposure—means EPA has absolutely no basis to conclude that PV29 does not present unreasonable risk. Finally, EPA failed to account for multiple routes of exposure to PV29 in its characterization of workplace risk. Meanwhile,

EPA failed to analyze risk to consumers, the general public, and relevant subpopulations on grounds that are largely cursory and reflect an approach to sentinel exposure assessment that violates both scientific norms and EPA's own regulation.

EPA has also completely failed to analyze a residual of PV29: naphthalimide. EPA provides no explanation for this failure.

Meanwhile, EPA has inconsistently and selectively applied its approach to systematic review, which has not been subject to any peer review and deviates from established, authoritative approaches to systematic review developed by experts. EPA failed to develop an upfront systematic review protocol for PV29. EPA's numerical scoring approach was neither transparent nor appropriately accounted for actual study flaws. EPA failed to adequately describe its approach to data integration. And EPA heavily relied upon unsubstantiated industry correspondence to inform its exposure analysis, but EPA refused to review and instead exempted this correspondence under its systematic review approach.

EPA's draft risk evaluation also violated several procedural and substantive requirements of TSCA. EPA failed to make the 24 health and safety studies underlying its analysis public, in violation of TSCA § 14(b)(2) and public-notice-and-comment requirements. EPA's cursory dismissal of various exposure pathways also violated the requirements of TSCA. EPA failed to consider reasonably available information. EPA also has not complied with TSCA § 6(b)(4)(F) or its risk evaluation rule in preparing the draft risk evaluation.

Ultimately, EPA needs much more information to prepare a scientifically and legally valid risk evaluation of PV29. In our comments, EDF identifies the crucial data gaps barring EPA from reaching a conclusion about PV29's risk. See Section 12.B. Having failed to do fill these gaps, EPA should immediately move to obtain the necessary information and to prepare an adequate risk evaluation.

* * *

TABLE OF CONTENTS

Executive Summary.....	1
Introduction	10
1. EPA must comply with TSCA § 14 and reopen the comment period to allow public review and comment on information that TSCA requires be public.....	11
A. EPA must make public the full studies underlying the draft risk evaluation and reopen the comment period to allow public comment on the basis for the risk evaluation.	11
B. EPA has failed to provide or develop even summaries of four of the scientific studies on which it relies.	15
C. More broadly, EPA needs to implement the requirements of TSCA § 14 when reviewing materials for the risk evaluation, and EPA should now comply and allow for public comment on the materials that should be publicly available.....	16
2. EPA’s draft fails to address serious limitations and uncertainties associated with several PV29 physical-chemical properties and environmental fate characteristics on which EPA relies to conclude low hazard.	17
A. EPA’s heavy reliance on a single, highly uncertain value for PV29’s water solubility casts major doubt on EPA’s hazard, exposure, and risk conclusions.	17
<i>i. EPA’s use of a single, poorly documented value does not accurately reflect the available data on PV29’s water solubility.....</i>	<i>17</i>
<i>ii. EPA’s extension of its unsupported assertion about PV29’s toxicity to encompass chronic toxicity distorts the extent of available data and is counter to authoritative guidance on toxicity testing of such substances.</i>	<i>19</i>
B. EPA downplays the very high level of persistence in the environment of PV29 in environment.....	20
C. EPA relies on incomplete and uncertain data to conclude that PV29 does not bioaccumulate.....	21
D. Under REACH, European authorities have identified PV29 as a suspected PBT and vPvB, and intend to subject it to a substance evaluation on that basis.....	23
E. EPA altered its prior characterization questioning the reliability of estimates derived using EPI Suite.....	24
3. EPA’s draft risk evaluation lacks sufficient information to evaluate potential uses, exposures, ecological and human health hazards, and risks.....	24

A.	EPA lacks critical information on uses of PV29 and has inappropriately eliminated numerous uses or related exposures from its risk evaluation.	26
	<i>i. Uses other than as an intermediate, including import.</i>	26
	<i>ii. Other uses that are reasonably foreseen absent compelling evidence to the contrary.</i>	29
	<i>iii. Use as an intermediate.</i>	30
B.	EPA lacks critical exposure information for PV29.	33
	<i>i. Environmental, consumer, and general population exposures.</i>	34
	<i>ii. Occupational exposures.</i>	36
	<i>a. Inhalation exposures.</i>	37
	<i>b. Dermal exposures.</i>	40
	<i>c. Worker exposures at downstream processing and use sites.</i>	42
C.	EPA’s draft risk evaluation lacks sufficient information to evaluate potential ecological hazards and risks.	43
	<i>i. Data from acute aquatic toxicity studies cannot substitute for studies of chronic aquatic toxicity.</i>	44
	<i>ii. EPA’s citing of the results of a Canadian screening exercise does not support EPA’s assertion that PV29 presents low aquatic hazard.</i>	46
	<i>iii. Data from a single acute Daphnia magna study (OECD-202) cannot be used as a proxy to evaluate potential hazards to all sediment-dwelling invertebrates.</i>	50
	<i>iv. EPA lacks any information on potential terrestrial toxicity of PV29.</i>	51
	<i>v. EPA employs completely circular arguments to dismiss any potential ecological risk.</i>	52
D.	EPA’s draft risk evaluation lacks sufficient information to evaluate potential human health hazards and risks.	54
	<i>i. The evidence base for PV29 for evaluating potential human health hazards is inadequate.</i>	54
	<i>ii. EPA’s conclusion that PV29 is not carcinogenic is based on insufficient information.</i>	57
4.	EPA’s exposure assessments and assumptions are deeply flawed.	59
	A. EPA’s occupational exposure assessment is replete with problems.	59

i.	<i>EPA restricts its occupational exposure analysis to the site of manufacture, failing to account for worker exposures at downstream processing and use sites.</i>	59
ii.	<i>EPA’s series of rationales for dismissing the significance of worker exposures are weak and based on little actual data or analysis.</i>	60
a.	<i>Inhalation and dermal exposures.</i>	60
b.	<i>Oral exposures.</i>	62
iii.	<i>EPA relies on Safety Data Sheets (SDSs) and unsubstantiated industry statements to discount potentially relevant routes of exposure and does not provide access to the referenced SDSs.</i>	64
iv.	<i>EPA discounts exposure based on use of PPE, failing to acknowledge its real-world limitations.</i>	68
B.	<i>EPA’s rationale for dismissing consumer and general population exposures does not even qualify as cursory.</i>	68
C.	<i>EPA’s dismissal of any concerns about exposures of vulnerable subpopulations distorts the law’s definition and fails to meet TSCA’s requirements.</i>	69
D.	<i>EPA’s rationale for adopting a sentinel over aggregate exposure assessment approach is inadequate and also distorts the meaning of sentinel exposure assessment.</i>	70
5.	<i>EPA’s draft risk evaluation contains serious deficiencies with respect to characterizing potential hazards and risks to human health.</i>	72
A.	<i>EPA’s calculation of the potential dose rate (PDR) uses a NIOSH inhalation exposure rate that is over 40 years old and an air concentration for PV29 dust that lacks any empirical basis.</i>	72
B.	<i>EPA fails to include all necessary uncertainty factors in calculating the benchmark margins of exposure for worker inhalation and dermal exposures.</i>	73
C.	<i>EPA has failed to consider multiple routes of exposure to PV29 in its characterization of workplace risk.</i>	75
6.	<i>EPA has dropped all mention of a residual of PV29: naphthalimide.</i>	76
7.	<i>EPA’s application of systematic review in the PV29 risk evaluation is seriously flawed.</i>	76
A.	<i>EPA has failed to develop an upfront systematic review protocol for PV29.</i>	77
B.	<i>EPA’s numerical scoring approach is flawed and opaque.</i>	78

i.	<i>EPA’s application of its scoring approach is not sufficiently transparent.....</i>	79
ii.	<i>EPA’s scoring approach fails to adequately reflect study flaws.</i>	79
C.	EPA has failed to adequately describe its approach to the data integration phase of its review process.....	81
D.	EPA inappropriately relied on unsubstantiated industry correspondence to inform its conclusions about exposure likelihood for PV29.....	82
E.	Fundamental flaws associated with EPA’s review of PV29 demonstrate the need for external peer review of the TSCA systematic review document.....	84
8.	TSCA requires EPA to analyze whether a chemical substance, as a whole, presents an unreasonable risk, and EPA does not have discretion to ignore conditions of use, exposures, or hazards.	84
A.	The plain text, overall structure, purpose, and legislative history of TSCA indicate that EPA has to determine whether a chemical substance presents an unreasonable risk comprehensively, considering all of its hazards, exposures, and conditions of use.	85
i.	<i>The plain text requires EPA to consider all hazards, exposures, and conditions of use.....</i>	85
ii.	<i>TSCA’s overall structure requires EPA to consider all hazards, exposures, and conditions of use.</i>	87
B.	EPA’s own risk evaluation rule requires that EPA consider all relevant hazards and all exposures under the conditions of use within the risk evaluation.....	89
9.	EPA should not refuse to further analyze exposure pathways on a cursory basis, and in any event, EPA still needs to consider those exposures when evaluating the combined exposures.....	90
10.	Real-world exposures still occur through disposal pathways, and EPA’s cursory dismissal of these exposures has insufficient support.	91
11.	EPA needs to analyze potential exposures from distribution, as well as from known and reasonably foreseeable accidental exposures.....	92
12.	EPA must consider “reasonably available” information, and thus EPA must use its authorities under TSCA §§ 4 and 8 to obtain additional information.....	93
A.	Any information that EPA can obtain under the exercise of its authorities under §§ 8(d), 8(a), and 8(c) is “reasonably available information,” so EPA must exercise those authorities.....	94

B. EPA must identify any information gaps and use its authority under TSCA § 4 to the fullest extent possible to fill those gaps.....	96
C. Relying on voluntary requests for information will result in limited, biased, inaccurate, or incomplete information on the chemicals.	99
D. EPA cannot rationally rely on unvetted industry submissions, and to the extent EPA relies on voluntary submissions from industry, EPA must take numerous additional steps to increase their reliability and transparency.	102
13. EPA should identify people living near disposal sites, sources of contamination, and other conditions of use as potentially exposed or susceptible subpopulations.	102
14. EPA needs to accurately evaluate real-world occupational and consumer exposures.....	103
A. EPA needs to explain how it will incorporate consideration of engineering controls and personal protective equipment (PPE) into its analyses.....	103
B. Even where engineering controls and/or PPE are used to some extent, EPA should always evaluate exposures scenarios without engineering controls and PPE in order to assess exposures and risks to those subpopulations not subject to such controls.....	104
C. EPA should never rely on PPE as a basis to assume low or no exposure, given the major real-world limitations of these measures.	104
15. EPA has not complied with TSCA § 6(b)(4)(F) or its risk evaluation rule in preparing the draft risk evaluation.....	106

Introduction

EDF previously provided comments on the TSCA review and scoping for the first 10 chemicals to undergo risk evaluations under amended TSCA, including PV29, on EPA's scope document for PV29, and on EPA's problem formulation for PV29.² In those comments, EDF identified a variety of legal violations and other problems with EPA's approach to this risk evaluation. Unfortunately, those same violations and problems remain in the draft risk evaluation, along with new ones. EDF incorporates these earlier comments and reiterates those points here as well, and EDF attaches those comments here.

Throughout our current comments, EDF criticizes aspects of EPA's analyses used to decide it will not conduct further analysis and its rush to judgment that PV29 does not present unreasonable risk. These concerns, addressed below, include (but are not limited to):

- equating a lack of information to mean there is no or low exposure;
- equating a lack of information to mean there is no or low hazard;
- questionable characterization of models or assumptions as conservative;
- assertions of low exposure, hazard, or risk based on EPA "expectations" that are insufficiently justified or documented;
- dismissal of serious data gaps with no plan to fill them; and
- reliance on unverified and very limited information sources to make sweeping conclusions.

EPA's analyses are arbitrary and capricious as well as inconsistent with TSCA's requirements that EPA use reasonably available information and comply with TSCA § 26(h), including using the best available science. EPA should fix all of these problems in its final risk evaluation.

² EDF Comments on Ten Problem Formulations under the Toxic Substances Control Act, <https://www.regulations.gov/document?D=EPA-HQ-OPPT-2016-0725-0061>; EDF Comments on Ten Scopes under the Toxic Substances Control Act, <https://www.regulations.gov/document?D=EPA-HQ-OPPT-2016-0725-0041>; EDF Comments on TSCA Review and Scoping for First 10 Chemicals under the Lautenberg Act, <https://www.regulations.gov/document?D=EPA-HQ-OPPT-2016-0725-0015>.

1. EPA must comply with TSCA § 14 and reopen the comment period to allow public review and comment on information that TSCA requires be public.

A. EPA must make public the full studies underlying the draft risk evaluation and reopen the comment period to allow public comment on the basis for the risk evaluation.

EPA is withholding from the public 24 studies that form the basis for its draft risk evaluation on PV29. Failure to release these studies violates section 14 of the Toxic Substances Control Act (TSCA), reflects a troubling lack of transparency, and violates the right of interested parties to review and submit comments on the science EPA cites to support its risk evaluation and to participate meaningfully in the peer review process. We request that the 24 studies be placed in the docket for the draft risk evaluation without delay, and we request that EPA reopen the comment period to allow comment on these materials underpinning the draft risk evaluation. Notably, EPA has not made a *single* underlying study available for public review or comment; we are aware of no precedent of a court upholding a public comment period where the agency withheld *every* study underlying its analysis.

The 24 studies, conducted by PV29's manufacturers, address the chemical's physical and chemical properties, environmental fate, human health effects, and toxicity to aquatic organisms. (pp. 39-43). According to the draft risk evaluation, 20 of the studies were submitted to the European Chemicals Agency (ECHA) in support of registration under the European Union (EU) REACH Regulation. The other four studies were not provided to ECHA but were apparently submitted to EPA by an unnamed data owner. EPA has made available the "robust summaries" prepared by the data owners for the 20 studies submitted to ECHA, but has not made even summaries of the other four studies available and has withheld all 24 studies based on "a claim of business confidentiality by the data owners."

Under section 14(b)(2), the law's restrictions on disclosure of confidential business information (CBI) do not apply to "any health and safety study which is submitted under this Act" for a chemical substance which "has been offered for commercial distribution." 15 U.S.C. § 2613(b)(2). The absence of CBI protection extends to both the study itself and "any data reported to, or otherwise obtained by, the Administrator from" the study. *Id.*

TSCA defines "health and safety study" to mean "any study of any effect of a chemical substance or mixture on health or the environment or on both, including underlying information and epidemiological studies, studies of occupational exposure to a chemical substance or mixture, toxicological, clinical, and ecological studies of a chemical substance or mixture, and any test performed pursuant to this Act." *Id.* § 2602(8). EPA regulations at 40 C.F.R. § 716.3 state that "[i]t is intended that the term health and safety study be interpreted

broadly” and encompass “[a]ny data that bear on the effects of a chemical substance on health or the environment.” The regulations are explicit that tests to determine the chemical and physical properties and fate and transport behavior of a substance fall within the definition, along with studies of a chemical’s human health effects and ecotoxicity. 40 C.F.R. § 720.3(k).

Thus, the 24 studies on PV29 are “health and safety studies” that cannot receive CBI protection under TSCA. Moreover, EPA’s obligation to disclose these studies cannot be satisfied merely by releasing “robust summaries” but requires public access to the full studies.

EPA has not described the claim(s) of confidentiality which it believes justifies withholding the 24 studies, but with respect to chemical substances, the only portion of a health and safety study or underlying information that can be treated as CBI under section 14(b)(2) is information “that discloses processes used in the manufacture or processing of a chemical substance.” The 24 studies likely contain little, if any, information meeting this description, and in the unlikely event any of the studies contain legitimate and substantiated CBI of this type, it can be redacted while all health and safety information is disclosed as provided for in section 14(b)(1).

It is possible that the data owners are basing their CBI claims on their “proprietary interest” in the studies under REACH. However, EPA could only honor these CBI claims if they have a basis in section 14 of TSCA. Nothing in section 14 allows EPA to avoid its unconditional obligation to disclose health and safety studies because of property right claims under European Union (EU) law.

EPA has suggested that public access to the 24 studies is unnecessary because it “has confirmed that the results of these full study reports are consistent with the corresponding robust summaries available in ECHA.” (p. 8). However, this puts the public in the untenable position of accepting EPA’s findings on faith. Without access to the full studies, the public cannot form its own judgments about the quality of the studies and the proper interpretation of the results. Thus, the public cannot meaningfully comment on whether EPA’s reliance on the studies is justified and whether they in fact support the Agency’s conclusion that PV29 does not present any unreasonable risk of harmful effects on health and the environment. EPA’s withholding of the studies effectively shuts the public out of the comment process because the 24 studies comprise the *sole* scientific basis for EPA’s determination that PV29 is not hazardous to humans or aquatic species.

As EDF has explained in prior comments, there are numerous reasons that it is important that the public have access to full studies and the underlying information, not simply robust or other

study summaries.³ Without access to full studies, the public is largely unable to assess and comment on the quality of the studies used by the agency, including the extent to which the requirements of section 26(h) and 26(i) are met. Even the best study summaries are incomplete descriptions that do not allow for an independent examination of study quality and conclusions reached by authors. Common examples of such conclusions include, “findings were not statistically significant,” “findings are within the range of historical controls,” and “effects observed were non-linear [and therefore biologically questionable or irrelevant].” Divorced from the details of the actual design and results of a study, it is impossible to evaluate the appropriateness of such conclusions. Moreover, systematic review practices require access to full studies, as details of study design and results are necessary elements of consistently determining study quality and ultimately evidence integration.

EPA should make such information public and easily searchable through online portals such as the Health and Environmental Research Online (HERO) database. EDF incorporates and reiterates the numerous points made in support of public access to the full studies here. *Id.*

EPA’s indication that it will allow members of the Scientific Advisory Committee on Chemicals (SACC) to review the 24 studies but deny access to the public only compounds this lack of transparency. An essential element of peer review under EPA’s Peer Review Handbook is a process to provide public input to the reviewers. This will be impossible if the public lacks access to the 24 studies. Moreover, by treating portions of the peer review process as CBI, EPA will deny the public full access to the peer reviewers’ deliberations, conclusions, and recommendations on a central element of the PV29 evaluation, further blocking meaningful public participation in the review process. It also will constrain the peer reviewers’ ability to engage in a robust debate and discussion during the peer review process.

EPA’s withholding of these studies also violates the requirements of public notice and comment codified in TSCA § 6(b)(4)(H). 15 U.S.C. § 2605(b)(4)(H). By requiring notice-and-comment at the draft risk evaluation stage, Congress meant to ensure a *meaningful* notice-and-comment opportunity as embodied by the procedural requirements of the Administrative Procedure Act (APA). “Under APA notice and comment requirements, ‘[a]mong the information that must be revealed for public evaluation are the “technical studies and data” upon which the agency relies [in its rulemaking].’” *Am. Radio Relay League, Inc. v. FCC*, 524 F.3d 227, 236 (D.C. Cir. 2008) (quoting *Chamber of Commerce v. SEC*, 443 F.3d 890, 899 (D.C. Cir. 2006)). “[T]he court explained long ago that ‘[i]n order to allow for useful criticism, it is especially important for the agency to identify and make available technical studies and data that it has employed in

³ See, e.g., EDF Comments on Procedures for Chemical Risk Evaluation under the Amended Toxic Substances Control Act at p. 37, <https://www.regulations.gov/document?D=EPA-HQ-OPPT-2016-0654-0074>.

reaching the decisions to propose particular rules.” *Id.* (quoting *Conn. Light & Power Co. v. Nuclear Regulatory Comm’n*, 673 F.2d 525, 530 (D.C. Cir. 1982)). “It would appear to be a fairly obvious proposition that studies upon which an agency relies in promulgating a rule must be made available during the rulemaking in order to afford interested persons meaningful notice and an opportunity for comment.” *Id.* at 237.

In *American Radio Relay League*, the D.C. Circuit found that an agency could not fulfill its notice-and-comment obligations by providing redacted versions of underlying studies, and the Court ruled that the agency had to provide the full studies for public comment. *Am. Radio Relay League, Inc. v. FCC*, 524 F.3d 227, 238 (D.C. Cir. 2008). As the Court explained, no authority suggests that an agency may “rely on the studies in a rulemaking but hide from the public parts of the studies that may contain contrary evidence, inconvenient qualifications, or relevant explanations of the methodology employed.” *Id.* at 239. Here, the study summaries do not provide the detailed information or explanations of the methodologies employed necessary to analyze the studies or adequately assess their results or limitations. Only access to the full studies will allow a meaningful opportunity to comment.

Indeed, even on the limited record currently available, the public can identify discrepancies between how EPA weighed the studies and the analyses by those who provided the studies. For example, examining the “robust summaries” for the studies of acute inhalation toxicity, BASF described the “adequacy of the study” as “disregarded due to major methodological deficiencies” and the reliability as “not reliable.” But EPA still ranked these studies as of “medium” quality. Thus, EPA’s analysis cannot be reconciled, on its face, with the available summaries of the studies. The full studies are necessary to assess the weight appropriately given to the studies.

For these reasons, EPA must place the 24 studies in the docket for the PV29 risk evaluation without delay and reopen the comment period to allow public comment on these materials underlying the draft risk evaluation.

In addition, it bears noting that EPA falsely characterizes the origin of the summaries of 20 of these studies as produced by the European Chemicals Agency (ECHA), when the summaries were actually produced by the manufacturer(s) who submitted the studies. In the draft risk evaluation, EPA states that the studies submitted to the European Chemicals Agency (ECHA) were “summarized by [(ECHA)].” (pp. 5, 6). This statement is flatly false and thus arbitrary and capricious. Under REACH, Registrants, not ECHA, develop the summaries that are then made

available in the registration “dossiers” for REACH chemicals.⁴ Thus, these studies and summaries were submitted by the manufacturer(s) to ECHA for inclusion in the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) registration dossiers; the studies and summaries have not been independently evaluated by ECHA or other government authorities in the EU. In citing information available through ECHA, EPA must clearly distinguish between industry data that have not been evaluated, industry data that have been evaluated by ECHA or other government authorities in the EU, and information that ECHA has itself developed or provided. At a minimum, EPA should not falsely state that the summaries were prepared by ECHA when they were, in fact, prepared by the manufacturer(s).

B. EPA has failed to provide or develop even summaries of four of the scientific studies on which it relies.

EPA indicates it has obtained full study reports for 24 individual scientific studies “from the data owners.” (p. 6). As explained above, EPA’s decision to withhold these studies is contrary to TSCA requirements and at odds with the goals of transparency and building confidence and trust in its risk evaluation process. For 20 of these 24 studies, EPA has directed reviewers to “robust summaries” that are publicly available through the website of the European Chemicals Agency (ECHA). However, not even summaries of the other four studies are available. They were not provided to ECHA, nor has EPA or the data owner bothered to provide summaries of these studies. Hence, the public has even less to examine in the case of these studies than it does for the other 20 studies. The four studies lacking even industry-prepared summaries are these:

- OECD Guideline 209: Activated Sludge, Respiration Inhibition Test (which assesses biodegradability)
- OECD Guideline 401: Acute Oral Toxicity with Rats
- OECD Guideline 404: Acute Dermal Irritation/Corrosion
- OECD Guideline 405: Acute Eye Irritation/Corrosion

See the references on page 20 to the first study and on page 26 to the other three. Moreover, while a few details of the latter three studies are provided in the draft risk evaluation’s Appendix D, EPA provides nothing at all for the first of these four studies; it is not included in Appendix B. Our inquiry to EPA as to why an entry for this study was not included went unanswered.

⁴ See ECHA, *How to report robust study summaries: Practical Guide* 3 p. 7 (Nov. 2012), https://echa.europa.eu/documents/10162/13643/pg_report_robust_study_summaries_en.pdf/1e8302c3-98b7-4a50-aa22-f6f02ca54352.

EPA's failure to provide even summaries of these studies fatally undermines any attempt by the public to try to comment meaningfully on EPA's reliance on these studies. EPA has violated TSCA § 14 and the notice-and-comment requirements of TSCA.

C. More broadly, EPA needs to implement the requirements of TSCA § 14 when reviewing materials for the risk evaluation, and EPA should now comply and allow for public comment on the materials that should be publicly available.

As explained above, EPA must disclose the 24 studies as health and safety studies under TSCA. But more broadly, in preparing this draft risk evaluation, EPA should have complied with its affirmative obligations under TSCA § 14. Based on the current record, it appears EPA has completely failed to meet those affirmative obligations. EPA must now cure those violations, disclose information that should be disclosed under TSCA § 14, and provide a public comment period based on the information that should be public under TSCA § 14.

As explained above in section 1.A, information from health and safety studies should be disclosed as a matter of law under TSCA § 14(b)(2) because it cannot be claimed confidential under TSCA § 14. In addition, for materials that can be subject to a confidentiality claim, EPA has an affirmative obligation to review at least 25% of non-chemical identity confidentiality claims under TSCA, 15 U.S.C. § 2613(g), and EPA has stated that it is implementing that obligation by "review[ing] every fourth submission received that contains non-chemical identity [confidential business information (CBI)] claims."⁵ Thus, on balance, EPA should have reviewed all confidentiality claims asserted in at least approximately one-fourth of the information submissions it received. Those claims must be substantiated at the time of submission. EPA must complete reviews of confidentiality claims within 90 days of receipt of the claims, and if EPA denies a claim, EPA must disclose the information that had been claimed confidential 30 days after notifying the claimant of the denial, absent a challenge to the denial in district court. 15 U.S.C. § 2613(g)(1)(A), (g)(2)(B). But there is no evidence that EPA has reviewed a *single* confidentiality claim received for information used in the draft risk evaluation.

In developing this draft risk evaluation, a large fraction of the information EPA relied upon constituted health and safety studies or information from such studies. All such information not subject to the narrow exception for process information needed to be made public. 15 U.S.C. § 2613(b)(2).

⁵ EPA REVIEW AND DETERMINATION OF CBI CLAIMS UNDER TSCA, <https://www.epa.gov/tsca-cbi/epa-review-and-determination-cbi-claims-under-tsca> (last visited Jan. 14, 2019).

For example, EPA often relied upon information submitted by BASF, Sun Chemical Corporation, or CPMA. *See, e.g.*, (p. 10) (citing these sources). Many of the submissions consist of information from health and safety studies or other health and safety information that must be disclosed. For example, EPA relied on a communication from Sun Chemical Corporation for the statement that: “an approximate maximum workplace air concentration of 0.5 mg/m³ would be expected over a 12 hour shift.” (p. 22) (citing Mott, 2017a). The underlying information in the submission qualifies as “any information reported to, or otherwise obtained by, [EPA] from a health and safety study,” 15 U.S.C. § 2613(b)(2)(B), because such studies include “studies of occupational exposure to a chemical substance,” *id.* § 2602(8). Similarly, EPA relies on a communication from Sun Chemical Corporation for the statement that: “it is estimated that 0.6 lb/day of [PV29] is being discharged.” (p. 21) (citing Mott, 2017b). Once again, the underlying information in the submission qualifies as “any information reported to, or otherwise obtained by, [EPA] from a health and safety study.” 15 U.S.C. § 2613(b)(2)(B), because such studies include “[a]ny data that bear on the effects of a chemical substance on health or the environment.” 40 C.F.R. § 720.3(k). EPA must disclose these submissions under TSCA.

Many additional examples are present in the draft risk evaluation; EPA appears to have taken no steps to comply with its obligations to disclose information under TSCA § 14. EPA must cure those violations by disclosing the information that constitutes health and safety information under TSCA § 14(b)(2). At a minimum, this information includes materials in BASF 2013, BASF 2017, Mott 2017a, Mott 2017b, and Sun Chemical 2017.

2. EPA’s draft fails to address serious limitations and uncertainties associated with several PV29 physical-chemical properties and environmental fate characteristics on which EPA relies to conclude low hazard.

A. EPA’s heavy reliance on a single, highly uncertain value for PV29’s water solubility casts major doubt on EPA’s hazard, exposure, and risk conclusions.

i. EPA’s use of a single, poorly documented value does not accurately reflect the available data on PV29’s water solubility.

EPA’s draft risk evaluation repeatedly invokes PV29’s low water solubility as a primary basis for concluding the chemical poses little hazard, exposure potential, or risk. The draft refers *more than 20 times* to the chemical’s low water solubility as justification for its often-sweeping conclusions that the chemical poses no concern. Given how much of EPA’s analysis hinges on the value it has assigned for this physical-chemical property, it warrants intense scrutiny. That scrutiny reveals that this value simply cannot bear the weight EPA has assigned to it.

EPA relies on a single experimental value – 0.01 milligrams per liter (mg/L) – reported in 2013 by one of the chemical’s manufacturers in the registration dossier it submitted to the European Chemicals Agency (ECHA). EPA has not made the study itself available, so only a summary prepared by the manufacturer is accessible by the public. There are a number of reasons to question the validity of or level of confidence that should be placed in that lone value, which EPA has entirely failed to mention, let alone address.

First, the summary of that study includes an important caveat in its fine print: “Study was performed without considering the pH value.”⁶ EPA makes no mention of this fact about the study on which it relies. Yet pH (the relative acidity or alkalinity of a solution) can dramatically affect the water solubility of a substance. In 2018, the Organization for Economic Co-operation and Development’s (OECD) Chemicals Committee issued its “Guidance Document on Aqueous-Phase Aquatic Toxicity Testing of Difficult Test Chemicals.”⁷ On page 25, the OECD stated: “it is noted that the pH of the distilled water [the medium in which water solubility is typically measured] may be different than that of the test solution [the medium in which, for example, a substance’s toxicity is tested] and that differences in those pHs may significantly affect the solubility.”

Second, EPA itself has cited different values for the water solubility of PV29. In its 2017 scope document for PV29,⁸ EPA listed its water solubility as 0.169 mg/L, a value derived using estimation models EPA relies on for other PV29 properties. Yet the decision to discard that earlier value, which is 16.9 times higher than the value EPA now chooses to rely on, is not mentioned, let alone explained, by EPA in its draft risk evaluation.

Third, summaries of the various environmental fate or toxicity studies included in the ECHA dossier for PV29 reported higher solubility values for PV29:

- A 1988 study that reported testing of PV29’s acute toxicity to freshwater fish, which used OECD Test Guideline #203 and indicated it complied with Good

⁶ PV29 Water Solubility Study Summary (2011), <https://echa.europa.eu/registration-dossier/-/registered-dossier/10330/4/9/?documentUUID=a7731d6e-6a80-4ce6-9513-035bf3314462> (located in section of summary titled “Any other information on results incl. tables”).

⁷ OECD, *Guidance Document on Aqueous-Phase Aquatic Toxicity Testing of Difficult Test Chemicals* (Jul. 2018), [http://www.oecd.org/officialdocuments/publicdisplaydocumentpdf/?cote=env/jm/mono\(2000\)6/rev1&doclanguage=en](http://www.oecd.org/officialdocuments/publicdisplaydocumentpdf/?cote=env/jm/mono(2000)6/rev1&doclanguage=en) (hereinafter “OECD 2018 Guidance”).

⁸ U.S. EPA, *Scope of the Risk Evaluation for Pigment Violet 29 (Anthra[2,1,9-def:6,5,10-d'e'f']diisoquinoline-1,3,8,10(2H,9H)-tetrone)* p. 16 (June 2017), https://www.epa.gov/sites/production/files/2017-06/documents/pv29_scope_06-22-17.pdf (hereinafter “PV29 Scope”).

Laboratory Practices (GLP),⁹ listed the chemical's solubility in the test solution as 670 mg/L – 67,000 times higher than the value EPA relies on.

- A 1999 study measuring PV29's biodegradability, which used OECD Test Guideline #301F and was GLP-compliant,¹⁰ reported the chemical's solubility in the test solution as "<500 mg/L," or up to 50,000 times higher than the value EPA relies on.

It is arbitrary and capricious for EPA to rely heavily on one measured value for water solubility (based on a study which concededly failed to account for pH) while ignoring other potential values for water solubility cited by EPA or observed in other studies. EPA also must address the discrepancy between its estimated value of water solubility and the various measured values, and EPA must address how it can rely on estimated values elsewhere while discounting them here.

ii. EPA's extension of its unsupported assertion about PV29's toxicity to encompass chronic toxicity distorts the extent of available data and is counter to authoritative guidance on toxicity testing of such substances.

As a general matter, measured solubility values for relatively poorly soluble substances are highly uncertain.¹¹ In particular, even where no effect is observed in *acute* aquatic toxicity studies up to the apparent limit of water solubility of a substance, that cannot be used to conclude there are no *chronic* toxic effects in aquatic species.

This is clearly stated in OECD's 2018 Guidance:

It is important to note that an absence of acute toxic effects at the saturation concentration cannot be used as the basis for predicting no chronic toxicity at saturation or at lower concentrations. Where test chemicals are predicted to have no acute toxic effects at saturation, it is recommended to consult the relevant regulatory authorities. Some regulatory authorities may prefer to omit acute toxicity tests and proceed straight to chronic toxicity testing.¹²

⁹ See BASF, PV29 Acute Toxicity to Fish Study Summary (1988),

<https://echa.europa.eu/registration-dossier/-/registered-dossier/10330/6/2/2/?documentUUID=cbecdba9-978c-4328-882f-4a8983018043>.

¹⁰ See BASF, PV29 Biodegradation Study Summary (1999), <https://echa.europa.eu/registration-dossier/-/registered-dossier/10330/5/3/2/?documentUUID=91ec6123-e4e1-4e78-8113-9d96c278a022>.

¹¹ OECD 2018 Guidance, p. 25.

¹² OECD 2018 Guidance, p. 53.

Yet EPA draws just such a no-effect conclusion without hesitation. It has not identified any chronic aquatic toxicity studies of PV29 at all. Yet in its risk determination for PV29, EPA asserts: “No effects were observed in environmental hazard testing with aquatic species up to the limit of solubility of the chemical, and it is not expected that aquatic exposures can reach concentrations where adverse effects can be seen.” (p. 32). Even assuming this is an accurate statement of the findings of the acute aquatic toxicity studies EPA possesses, it cannot possibly apply to chronic aquatic toxicity, a fact EPA fails to mention. It is arbitrary and capricious for EPA to infer no chronic effect based solely on acute toxicity data. EPA’s unqualified statement then serves as the basis for a further unwarranted leap to EPA’s risk determination that PV29 “does not present an unreasonable risk of injury to *** *the environment*.” EPA cannot make an accurate prediction about effects to the environment, as a whole, based solely on acute aquatic toxicity, both because it ignores chronic hazards and because the environment also includes other components such as sediment, land, and air, not just the aquatic environment.

To repeat: EPA draws this sweeping conclusion in the absence of any chronic data and in direct contravention of authoritative scientific guidance that makes clear no such conclusion can be drawn. EPA’s conclusion is contrary to the best available science and is arbitrary and capricious. In addition, as explained more below, EPA has authority to require testing for chronic hazard, and EPA’s failure to obtain this reasonably available information violates EPA’s duties under TSCA.

The deficiencies in EPA’s evidence base and assessment of ecological effects is further discussed in section 3.C. below.

B. EPA downplays the very high level of persistence in the environment of PV29 in environment.

In the Executive Summary of the draft risk evaluation, EPA repeatedly cites those physical-chemical and environmental fate properties of PV29, such as low water solubility and bioaccumulation potential, that it relies on to conclude the chemical presents little or no risk. See (pp. 5, 6). Yet the Executive Summary makes no mention at all of another key characteristic of PV29: The very high persistence of the chemical in the environment.

Not until page 19 of the draft risk evaluation is there any mention of this key parameter that is directly relevant to both the hazard and exposure potential of PV29. The mention on page 19 is the only reference to PV29’s high persistence in the entire draft risk evaluation. EPA never explains why this characteristic of PV29 can be disregarded.

It should be noted that the PBT assessment summary provided by BASF to ECHA in its registration dossier for PV29 – which is the source cited by EPA on page 19 – clearly states that

the substance is, not only persistent, but “very persistent” (vP).¹³ PV29’s very persistent characteristic increases the possibility that it presents an unreasonable risk, and EPA fails to address this aspect of the problem in its draft risk evaluation.

EPA’s total failure to grapple with the implications of this PV29 characteristic suggests a strong desire on its part to avoid acknowledging potential concerns while touting other properties it views as exculpatory. This is hardly the way to build trust or confidence in the objectivity of EPA’s risk evaluation.

C. EPA relies on incomplete and uncertain data to conclude that PV29 does not bioaccumulate.

EPA lacks any measured data that directly assess the potential for PV29 to bioaccumulate in humans or other organisms. Such data would include experimental measurements of the substance’s Bioconcentration Factor (BCF) or Bioaccumulation Factor (BAF). EPA has neither. Instead, EPA relies on model estimates of the BCF and BAF derived using its EPI Suite, which EPA presents in Table 3-1 on page 19 of the draft risk evaluation. No further details as to their estimation are provided – other than footnote “b” in that table, which states:

There are limited pigment data in the EPI Suite™ training set which is an uncertainty regarding the fate characterization. Despite the limitation in the dataset, similarities with other organic classes indicates [*sic*] that these predicted fate properties can be estimated by substructure fragments.

Estimation models are only as good as the “training set” – the extent and quality of the data that goes into them – and EPA signals here that there is reason to question the validity of its estimated BCF and BAF values. It then, without providing any detail at all, asserts “similarities with other organic classes” – which it does not identify – can be relied on to overcome the training set deficiencies. In the absence of far greater detail, these assertions simply cannot be trusted, especially when they pertain to such an important property of PV29. This is particularly so because other authorities note that estimation models for bioaccumulation “tend to have high uncertainties.”¹⁴ Given the limitations of these models and EPA’s ability –

¹³ PV29 PBT ASSESSMENT, <https://echa.europa.eu/registration-dossier/-/registered-dossier/10330/2/3/?documentUUId=7bdcdc6c-f96e-4adc-b499-dc7704398813> (last visited Jan. 14, 2019).

¹⁴ ECHA, *How to bring your registration dossier in compliance with REACH Tips and Hints - Part 5: Bioaccumulation II* p. 8 (Feb. 2014), https://echa.europa.eu/documents/10162/13628/06_bioaccumulation_webinar_en.pdf/4a723708-59a8-4312-95c6-dcbfeba64f2b.

but unwillingness – to require testing to address these crucial endpoints, EPA has failed to rely on reasonably available information or the best available science.

The registration dossier for this chemical submitted to ECHA also lacks any measured (or estimated) BCF and BAF values. It does, however, cite a measured value (though not even a summary of the corresponding study is provided) for a different parameter that the registrant asserts demonstrates the chemical does not bioaccumulate. That value, for the chemical’s “octanol-water partition coefficient” – referred to interchangeably as either “log K_{ow} ” or “log P_{ow} ” – is cited as 0.85, and on that basis the registrant concludes PV29 does not bioaccumulate.

In its draft risk evaluation, however, EPA argues that this value was derived using “unacceptable methods” and cannot be used. (p. 8). Indeed, EPA asserts that this parameter cannot be measured at all for PV29, though EPA does not cite to evidence supporting this conclusion. Instead, it uses another estimate: EPI Suite’s predicted log K_{ow} value of 3.76 – which reflects a ratio of solubility in octanol vs. water that is orders of magnitude higher than the measured value reported to ECHA.

This brings us back to EPA’s derivation of its estimates for BCF and BAF. According to EPA’s documentation for its EPI Suite model,¹⁵ these values are estimated using either of two methods:

BCFBAF™: Formerly called BCFWIN™, this program estimates fish bioconcentration factor and its logarithm using two different methods. The first is the traditional regression *based on log KOW* plus any applicable correction factors, and is analogous to the WSKOWWIN™ method. The second is the Arnot-Gobas method, which calculates BCF from mechanistic first principles.

Because it has failed to provide any detail at all, EPA does not indicate which method it used to derive its BAF and BCF values. But if it used the first method, then it would likely have relied on its estimated value for log K_{ow} . This sounds remarkably circular and hence suspect: EPA may have used an estimated value for log K_{ow} , which differs dramatically from the experimental value EPA rejected, to derive yet more estimated values for BAF and BCF.

Even assuming that EPA’s estimate for log K_{ow} is accurate, it is far from clear that this value – and BCF and BAF values derived based on it – supports EPA’s assertion that PV29 has low bioaccumulation potential. While ECHA generally regards a log $K_{ow} \leq 4.5$ to be indicative of

¹⁵ EPI SUITE™-ESTIMATION PROGRAM INTERFACE, <https://www.epa.gov/tsca-screening-tools/epi-suite-estimation-program-interface#models> (last visited Jan. 14, 2019) (emphasis added).

low bioaccumulation potential,¹⁶ ECHA generally requires more measured data on bioaccumulation if a substance's log K_{ow} exceeds 3, as here.¹⁷ In addition, none of these approaches account for potential for bioaccumulation directly from air, which can be a concern for certain substances with log K_{ow} exceeding 2,¹⁸ and is relevant to assessing risk to air-breathing organisms such as terrestrial or avian species – aspects of environmental risk that EPA utterly fails to account for.

In sum, EPA has provided no data and scant analysis to support its bald assertion that PV29 has low bioaccumulation potential. It has not required the development of any measured data to assess this critical endpoint, and relies on model estimates that introduce considerable uncertainty. EPA has fallen far short of what would be needed to conclude PV29 has low bioaccumulation potential. EPA has failed to generate reasonably available information that could have provided measured data of this endpoint, and EPA has also failed to establish that it has relied on the best available science given that EPA could easily have required testing to fill this crucial data gap. In addition, EPA's descriptions of its approach to estimating these values are so limited and vague that the reader cannot reasonably discern EPA's actual approach to deriving these values.

D. Under REACH, European authorities have identified PV29 as a suspected PBT and vPvB, and intend to subject it to a substance evaluation on that basis.

In marked contrast to EPA's assertion of a clean bill of health for PV29, at least two member countries of the European Union have identified PV29 as a suspected "substance of very high concern" (SVHC) under the REACH Regulation. Specifically, PV29 is listed as a "suspected PBT/vPvB" and is proposed to undergo a substance evaluation in 2021.¹⁹

¹⁶ See ECHA, *Guidance on Information Requirements and Chemical Safety Assessment Chapter R.11: PBT/vPvB assessment* p. 82 (June 2017), https://echa.europa.eu/documents/10162/13632/information_requirements_r11_en.pdf/a8cc_e23f-a65a-46d2-ac68-92fee1f9e54f.

¹⁷ See ECHA, *How to bring your registration dossier in compliance with REACH Tips and Hints - Part 5: Bioaccumulation II* pp. 4, 6 (Feb. 2014), https://echa.europa.eu/documents/10162/13628/06_bioaccumulation_webinar_en.pdf/4a723708-59a8-4312-95c6-dcbfeba64f2b.

¹⁸ See ECHA, *Guidance on Information Requirements and Chemical Safety Assessment Part C: PBT/vPvB assessment* p. 14 (June 2017), https://echa.europa.eu/documents/10162/13643/information_requirements_part_c_en.pdf.

¹⁹ ECHA, *Draft Community Rolling Action Plan (CoRAP) update for years 2019-2021* p. 22 (Oct. 2018), https://echa.europa.eu/documents/10162/13628/corap_list_2019-2021_en.pdf/3be44b84-5d72-01fe-f8d7-3a5a9c27951e. "PBT" stands for persistent, bioaccumulative and toxic; and "vPvB" stands for very persistent and very bioaccumulative.

EDF has not yet been able to obtain more detail on the basis for this listing of PV29, but it stands in direct contrast and contradiction to EPA's assertion that PV29 is not bioaccumulative or toxic. EPA's risk evaluation must address these concerns.

E. EPA altered its prior characterization questioning the reliability of estimates derived using EPI Suite.

EPA changed a footnote related to its use of EPISuite between the problem formulation and draft risk evaluation for PV29.

The footnote in the problem formulation states: "There are limited pigment data in the EPI Suite training set, *therefore values should be used with caution.*"²⁰ The footnote in the draft risk evaluation was changed to read: "There are limited pigment data in the EPI Suite™ training set which is an uncertainty regarding the fate characterization. Despite the limitation in the dataset, similarities with other organic classes indicates that these predicted fate properties can be estimated by substructure fragments." (p. 19, tbl. 3-1).

EPA's description of the appropriateness of EPI Suite for estimating PV29's physical chemical and environmental fate properties changed dramatically and without explanation. EPA should clarify and explain the change and address the appropriateness of using EPI Suite estimates in evaluating PV29's risks. Moreover, the original characterization openly acknowledges that there are limited pigment data in the EPI Suite training set, a fact that EPA still acknowledges. Therefore, its conclusion that "values should be used with caution" would appear to hold true. EPA must justify its decision to rely on EPI Suite despite these facts, and in particular, EPA must justify its decision to forego requiring testing for these endpoints.

3. EPA's draft risk evaluation lacks sufficient information to evaluate potential uses, exposures, ecological and human health hazards, and risks.

EPA's draft risk evaluation inaccurately asserts that the agency considered "all reasonably available data," (p. 5), and that the information on PV29 was sufficient for it to determine the

Substances meeting either of these designations are deemed to be "substances of very high concern" (SVHCs) under the REACH Regulation. Commission Regulation 1907/2006, Registration, Evaluation, Authorisation and Restriction of Chemicals, title VII, 2006 O.J. (L 396), <http://data.europa.eu/eli/reg/2006/1907/2018-03-01>.

²⁰ U.S. EPA, *Problem Formulation of the Risk Evaluation for C.I. Pigment Violet 29 (Anthra[2,1,9-def:6,5,10-d'e'f']diisoquinoline-1,3,8,10(2H,9H)-etrone)* p. 22, tbl. 2-4 (May 2018), https://www.epa.gov/sites/production/files/2018-06/documents/pv29_problem_formulation_5-31-18.pdf (emphasis added) (hereinafter "PV29 Problem Formulation").

chemical “does not present an unreasonable risk of injury to human health or the environment, without considering costs or other non-risk factors, including no unreasonable risk to potentially exposed and susceptible subpopulations identified as relevant, under the conditions of use.” As these comments document, however, the many glaring data gaps are so large as to preclude EPA from making a “no unreasonable risk” determination for PV29. EPA’s own definition of “reasonably available information” includes “information that EPA possesses or can *reasonably generate, obtain, and synthesize* for use in risk evaluations.” 40 C.F.R. § 702.33. Yet, despite the major gaps and EPA’s enhanced authority under the Lautenberg Act to require the development and submission of information, EPA has taken no steps whatsoever to use these authorities over the more than two years since PV29 was first identified as one of the first 10 substances to undergo risk evaluations.

EPA itself appears to recognize the thin support for many of its specific conclusions. The draft risk evaluation repeatedly uses qualifiers for specific conclusions, which are then dropped when it announces its risk determination. EPA has failed to explain how it can justify dropping these qualifications given the extreme data gaps in this administrative record.

Overall, based on our count, the draft includes 49 instances of EPA using the term “expected” (or “not expected”) in front of its conclusions regarding hazard, exposure, or risk. EPA similarly uses other terms such as “likely” or “not likely” to qualify many statements. These usages are perhaps inadvertently frank reflections of the dearth of data and analysis EPA has presented across this entire document. In any event, EPA has not explained how it can justify a “no unreasonable risk” determination when it lacks so much data necessary to prepare an adequate risk evaluation.

A few of many examples:

- “Qualitative and quantitative considerations of physical chemical data, environmental fate data, manufacturing, and use information indicates that exposures of [PV29] *are expected to be limited* for the conditions of use of [PV29].” (p. 5) (emphasis added).
- “Due to its physical properties, *it is expected to bind strongly* to soil organic matter and migration through soil to groundwater is *likely to be minimal*. If released to water, hydrolysis is *expected to be negligible*. Based on its estimated Henry’s Law Constant, [PV29] is *not expected to volatilize from water*. If released to air, it is *unlikely to undergo direct photolysis* and is *expected to be in the solid phase (i.e. particulates)*.” (p. 19) (emphases added).

- “Physical-chemical (see Table 2-1) and fate (see Table 3-1) properties as well as engineering controls limiting manufacturing releases (as discussed below), *are expected to result in limited exposure* to air, water and sediment, groundwater via biosolids, and landfill leaching.” (p. 20) (emphasis added).

Below we discuss some of the many serious deficiencies in the information and analysis EPA has provided that render its “no unreasonable risk” determination unjustified. Additional deficiencies are raised in subsequent sections of these comments critiquing EPA’s hazard, exposure and risk assessments for PV29.

A. EPA lacks critical information on uses of PV29 and has inappropriately eliminated numerous uses or related exposures from its risk evaluation.

i. Uses other than as an intermediate, including import.

In the draft risk evaluation, EPA has summarily dismissed a wide range of uses of PV29 it had earlier identified at the scoping and problem formulation stages for this chemical. EPA has done so “due to the agency’s *inability to prove that they are actually conditions of use,*” indicating that “no further evidence was found during the problem formulation and risk evaluation to support the *actual use* of [PV29] for these uses.” (p. 11) (emphases added). Thus, EPA erroneously suggests that its analysis should be limited to “actual use” of PV29. (p. 11, n. 2).

Beyond these assertions, EPA has given no indication as to what it actually did to reach this determination, including the basis on which it decided that the evidence of these uses it had earlier cited was not or is no longer valid. EPA also excluded “import” of PV29 from analysis because EPA did not find evidence of actual import. EPA’s removal of these conditions of use entirely from the risk evaluation for PV29 violates the legal standard for identifying “conditions of use,” ignores available evidence supporting their inclusion, and fails to provide a reasoned explanation for the exclusion of these conditions of use.

First, in implying that the standard it must meet to include a use is to *prove* that the use is known to be occurring, EPA has rewritten TSCA’s standard, which requires that EPA evaluate a chemical’s risk under its “conditions of use,” 15 U.S.C. § 2605(b)(4)(A), which is defined to include the circumstances “under which a chemical substance is *intended, known, or reasonably foreseen* to be *** used.” 15 U.S.C. § 2602(4) (emphasis added). Where there is evidence indicating a use of a chemical is reasonably foreseen to be occurring or to be able to occur, EPA must consider it in its risk evaluation of that chemical. EPA’s imposition upon itself of a burden

of proving a use is actually occurring in order to include it in a risk evaluation violates its mandate under TSCA.

Limiting the analysis to “actual use” essentially limits conditions of use to “known” conditions of use, and it impermissibly reads “reasonably foreseen” out of the definition. Congress included “reasonably foreseen” circumstances within TSCA with the express goal of ensuring that EPA swept more broadly than known (or intended) uses; EPA cannot evade that duty by limiting its analysis to conditions of use with evidence of current, ongoing use—such an interpretation would effectively limit EPA’s analysis to “known” uses. EPA cannot exclude the “other” conditions of use if they are “reasonably foreseen” circumstances.

Reasonably foreseen is a term of art with a long history in the law; it is well established under the law that “[a] natural and probable consequence is a foreseeable consequence. But to be reasonably foreseeable [t]he consequence need not have been a strong probability; a possible consequence which might reasonably have been contemplated is enough.” *People v. Medina*, 209 P.3d 105, 110 (Cal. 2009) (internal citations and quotation marks omitted).

EPA has provided no analysis explaining why “import” and the “other” uses are not reasonably foreseen, especially given that EPA’s initial research suggested that they are conditions of use. “Import,” in particular, seems reasonably foreseen. Given that the chemical has a domestic market and is successfully sold to downstream processors and users, it is reasonably foreseeable that persons might import the substance at some point in the future. EPA has provided no basis for assuming that no one will import PV29 in the future.

Second, for at least several of the uses EPA has eliminated, there is readily accessible evidence of their *current* use. In February 2017, EPA published “preliminary information” on uses of PV29.²¹ That document provides citations to a number of websites and Safety Data Sheets for some of the “other uses” that EPA included in its Problem Formulation for PV29 but now summarily dismisses. For instance:

- For “laboratory chemicals, light-harvesting materials, transistors, molecular switches, solar cells, optoelectronic devices,” (included as uses on p. 17 of the PV29 Problem Formulation), the source is a still-active product page for PV29²² that states:

²¹ See U.S. EPA, *Preliminary Information on Manufacturing, Processing, Distribution, Use, and Disposal of PV29* (Feb. 2017), <https://www.regulations.gov/document?D=EPA-HQ-OPPT-2016-0725-0004> (hereinafter “PV29 Preliminary Information”).

²² ALFA AESAR BY THERMOS FISHER SCIENTIFIC, <https://www.alfa.com/en/catalog/044098/> (last visited Jan. 4, 2019).

[PV29] is used extensively as an industrial pigment. It is used as a tunable laser dye, light-harvesting material, transistor, molecular switched solar cell, and optoelectronic device.

The page carries a 2019 copyright and allows the user to directly order the material online. The attached Safety Data Sheet for the product lists the “identified use” of the chemical as “scientific research and development.”²³ It is not clear what “further evidence” would be necessary to support identifying this use as a “known use,” let alone a reasonably foreseen condition of use.

- EPA had also previously identified “polyester fibers” as a condition of use in the “other uses” subcategory. The 2017 preliminary information document cites a number of product pages that identify use of the chemical in dyeing yarns and fiber. One product page states that the chemical is “[r]ecommended for mass-dyeing of polypropylene yarns and fibers.”²⁴ The page carries a 2019 copyright.
- One of Sun Chemical’s webpages for “perrindo violet” (its trade name for PV29) advertises the product for use in “even the most demanding paper applications.”²⁵ Sun Chemical advertises this product for use in automotive, fiber, film, industrial, injection molding, inkjet, nonwoven, packaging, paper, powder coatings, publications, rigid packaging, and toner.²⁶ These webpages carry 2019 copyrights. It is unclear what “further evidence” of the use of PV29 in these applications EPA would need and why it has been unable to find these readily accessible sources.

The reasonably available information reveals that PV29 is known or reasonably foreseen to be used in these circumstances, so EPA must include these conditions of use in the risk evaluation. Moreover, for the remaining excluded conditions of use, EPA has failed to provide a reasoned explanation for their exclusion, and in particular, EPA has failed to explain why the prior evidence originally leading to their identification does not support their inclusion. EPA’s analysis fails to grapple with this important aspect of the problem and is arbitrary and capricious.

²³ See Alfa Aesar, Safety Data Sheet, <https://www.alfa.com/en/content/msds/USA/44098.pdf>.

²⁴ LUPROFIL VIOLET 50-1105 C4, <https://polymer-additives.specialchem.com/product/p-basf-luprofil-violet-50-1105-c4> (last edited Dec. 18, 2017) (Luprofil is trade name for BASF’s “perylene violet based pigment”).

²⁵ PERRINDO FOR PAPER, <https://www.sunchemical.com/product/perrindo-for-paper/> (last visited Jan. 13, 2019).

²⁶ See HIGH PERFORMANCE PIGMENT, <https://www.sunchemical.com/attributes/product-group-pigment/hpp/page/4/> (last visited Jan. 13, 2019). While some of these uses appear to fall under use categories that EPA has not or may not have removed from the risk evaluation, others appear to have been removed, so we include the full list here to ensure none are overlooked.

ii. Other uses that are reasonably foreseen absent compelling evidence to the contrary.

More broadly, EPA appears to have evidence that PV29 is currently used *internationally* for many of the “other” conditions of use that EPA is now disregarding.²⁷ If PV29 is actually used for these purposes internationally, then EPA should also analyze those conditions of use because these are circumstances “under which a chemical substance is *** known *** to be manufactured, processed, distributed in commerce, used, or disposed of.” 15 U.S.C. § 2602(4). In addition, it is reasonably foreseeable that persons might use PV29 in those same circumstances in the United States if persons already use PV29 for those purposes abroad. If EPA is excluding these conditions of use because they only occur abroad, then EPA should try to justify that choice. Alternatively, if EPA believes that its original information identifying these circumstances was erroneous or incomplete, then EPA should set forth its analysis establishing that these conditions of use are not reasonably foreseen. But as it is, the record evidence suggests that these circumstances are conditions of use and EPA’s cursory dismissal of these conditions of use does not establish that they are not.

In particular, if any of these circumstances are known to have occurred in the past, then they are certainly reasonably foreseen conditions of use, absent compelling evidence that they will not resume. As argued further in section 8 of the comments, EPA must consider all conditions of use when preparing a risk evaluation under TSCA § 6, including so-called legacy uses, associated disposals, and legacy disposals. EDF has previously articulated these arguments and incorporates the arguments here.²⁸

Past conditions of use that are not currently ongoing are still “known” to have occurred in the past, and these conditions of use are definitely “reasonably foreseen.” 15 U.S.C. § 2602(4). While there may well be circumstances in which a use that is not currently occurring could be said to be not “reasonably foreseen” at this time, the term surely cannot be read in such a way that only uses that are known to be current are “reasonably foreseen” as that would read it out of existence and collapse the inquiry to one where a use must be “known” to be considered “reasonably foreseen.”

Numerous courts have recognized that circumstances are reasonably foreseen when similar circumstances have occurred in the past. *See, e.g., McKown v. Simon Prop. Grp., Inc.*, 344 P.3d

²⁷ *See, e.g.*, PV29 Preliminary Information, p. 12.

²⁸ EDF Comments on Ten Scopes under the Toxic Substances Control Act, pp. 4-11 (Sept. 2017), <https://www.regulations.gov/document?D=EPA-HQ-OPPT-2016-0725-0041>; *see also* EDF Comments on Ten Problem Formulations under the Toxic Substances Control Act, app. A, <https://www.regulations.gov/document?D=EPA-HQ-OPPT-2016-0725-0061>.

661, 663 (Wash. 2015); *Burns v. Penn Cent. Co.*, 519 F.2d 512, 515 (2d Cir. 1975). The fact that these conditions of use occurred in the past establishes that they are reasonably foreseen.

It is hard to see how the mere cessation of use, particularly if it ceased recently, is by itself sufficient to render the use not “reasonably foreseen.” The concept of “reasonably foreseen” wraps in uses that have never before existed if there is a logical rationale for thinking that such a use could occur; if a use has actually occurred, but merely halted, it is clearly not speculation that the chemical substance being evaluated could be used in that way; it is only a question of how likely it is that the chemical could be used that way again. EPA, however, does not appear to have undertaken such analyses.

As EPA itself acknowledged in its recently proposed significant new use rule for certain uses of asbestos, absent a regulation governing the resumption of an old condition of use, “the importing or processing of” a chemical for a past use that is no longer ongoing “may begin at any time.” 83 Fed. Reg. at 26,927. Thus, the condition of use is reasonably foreseen absent a legal ban on it. Even if a chemical is no longer used for a particular condition of use, persons may resume past uses in response to economic, regulatory, or other changes. For example, in the problem formulation for 1-BP, EPA states that few dry cleaners still use 1-BP as a dry cleaning solvent, but EPA also acknowledges that it is reasonably foreseen that such use may increase in response to increasing regulation of perchloroethylene for that use. See Problem Formulation for 1-BP at p. 20. Similarly, other past conditions of use that have been phased out may resume in response to economic changes and regulatory shifts. *If* PV29 had a particular condition of use in the past, EPA should analyze that condition of use absent compelling evidence that the use will not resume in the future.

iii. Use as an intermediate.

EPA asserts without any direct evidence that PV29’s use as an intermediate does not result in any environmental releases and exposures:

The EPA determined that 90 percent of the production volume is *used on site* as a chemical intermediate. As a result, *only 10 percent of the total production volume (~60,000 lbs) is used in a way that could result in environmental releases and exposures.* (p. 20) (emphasis added).

This problem is exacerbated by EPA description of the nature of PV29’s use as an intermediate: “During the use as a chemical intermediate, [PV29] is *consumed during the reaction.*” (p. 20) (emphasis added).

EPA uses the term “site-limited intermediate” when describing this main use of PV29: “Approximately 90 percent of the domestic production volume of [PV29] in 2015 (~530,000 lbs) was processed as a *site-limited intermediate for the manufacture of other perylene pigments.*” (p. 9) (emphasis added).

In making these assertions EPA is ignoring numerous factors that could lead to environmental releases or exposures, and as a result has failed to use its authorities to collect or require the development of information that it could have used to characterize those releases or exposures.

EPA’s assertions regarding PV29’s use as an intermediate raise several unaddressed relevant considerations.

First, EPA makes no mention of the potential for PV29 to remain present in the products generated from its use as an intermediate, whether site-limited or otherwise. PV29’s presence in such final products arises in either of two ways, neither of which EPA addresses or presents any data about:

- Less-than-complete reaction of PV29 in the manufacture of the other chemicals could leave a residual level in the final product(s); EPA presents no evidence that PV29 is completely “consumed in the reaction.” Our review of information submitted to EPA by industry sources indicates that such residuals do remain. For example, a comment submitted to EPA in 2017 from the American Coatings Association (ACA)²⁹ has a section titled “Residuals and Trace Levels.” ACA claims PV29 is “only present at trace levels,” but provides no supporting data and in fact acknowledges that companies do not measure or report such levels because doing so “is an expensive, time consuming and labor intensive process.”
- PV29’s use as a site-limited intermediate also encompasses a second activity: its *intentional* addition to other pigments to adjust their color. Based on information on page 10 of the draft risk evaluation, use of the chemical as a site-limited intermediate involves two activities: “An intermediate to *create or adjust color* of other perylene pigments.” Table 2-2 on page 13 also describes this use as “[c]reation [of] or adjustment to other perylene pigments.” The 2017 ACA comment to EPA notes that PV29 may be present “[n]ot as an impurity, but may come in with other perylene pigments. Perylene pigment manufacturers sometimes use PV29 to adjust the color of a

²⁹ See American Coatings Association (ACA) Comment on the Designation of PV29 for TSCA Risk Evaluation (Mar. 15, 2017), <https://www.regulations.gov/document?D=EPA-HQ-OPPT-2016-0725-0008> (hereinafter “ACA Comment”).

batch of pigment.” Yet EPA has presented no data on the levels of such intentionally added PV29 in the products resulting from its use as a site-limited intermediate and has not analyzed the associated potential for environmental releases and exposures.

Second, information provided by EPA leaves open the question of whether the intermediate use of PV29 is restricted to a single site or may involve more than one site. This is important, because if the use as an intermediate takes place at more than one site, then activities associated with its storage, transport and transfer entail greater risk of release and exposure than if those activities occur at only a single site.

Information EPA cites from the industry’s main trade association, the Color Pigments Manufacturers Association (CPMA)³⁰ seems to suggest that these activities take place only at Sun Chemical’s U.S. manufacturing facility:

- “[T] the majority of its [PV29’s] production is consumed as a site limited chemical substance, at one facility known to be manufacturing this color pigment.”³¹
- “Sun Chemical manufactures the substance principally as in intermediate for manufacturing other pigments, principally C.I. Pigment Red 179 (CAS 5521-31-3) and C.I. Pigment Red 224 (CAS 128-69-8), at the Goose Creek facility. Over the years, depending upon changes in color styling and other marketing demands, 85-90% of the manufactured [PV29] has been consumed on site.”³²

However, the 2017 ACA comment describes uses of PV29 by *two* companies (neither identified). While the uses are only broadly described, it appears they could encompass PV29’s use to “adjust” other pigments’ color:

Company A:

Product	Market	Percentage by Weight
Pigment dispersions in waterborne and solventborne systems	Industrial	8-16%
Waterborne and solventborne basecoats	Industrial	1-5%

³⁰ See Color Pigments Manufacturers Association (CPMA) Comment on the Designation of PV29 for TSCA Risk Evaluation (Mar. 13, 2017), <https://www.regulations.gov/document?D=EPA-HQ-OPPT-2016-0725-0006> (hereinafter “CPMA Comment”).

³¹ CPMA Comment, p. 3.

³² CPMA Comment, p. 5.

Not an impurity, but may come in with other perylene pigments. Perylene pigment manufacturers sometimes use PV29 to adjust the color of a batch of pigment.	Industrial	<0.1%
---	------------	-------

Company B:

Product	Market	Percentage by Weight
Colorant in solvent borne coating	Industrial	Up to 16%

Whether or not these uses fall under EPA’s use of the term site-limited intermediate, they clearly entail the transfer of PV29 between more than one site, which presents the potential for environmental releases or exposures that EPA has not examined and for which it appears to have obtained no actual data.

Thus, the evidence in the record indicates that PV29’s use as an intermediate does result in PV29’s presence in end products either as a residual or as an intentional addition. Those uses can result in exposure, and EPA’s contrary conclusion is contradicted by the evidence in the record. As a result, EPA’s failure to analyze the exposures and risks arising from PV29’s use as an intermediate is arbitrary and capricious and fails to account for reasonably available information.

B. EPA lacks critical exposure information for PV29.

Remarkably few data exist on potential exposures to PV29, and EPA took no steps at all to use its authority to require the submission or development of any more exposure data. Based on the draft risk evaluation, EPA has no actual data on the levels of PV29 released to or present in air, soil, sediment, surface water, people, other organisms, workplaces or products containing or made from the chemical. It lacks any data from, and hasn’t used its authorities to require, monitoring in workplaces or any environmental media.

To some extent EPA acknowledges these data deficiencies, including as sources of uncertainty in its risk evaluation:

- “[T]he lack of environmental monitoring data means that the limited predicted environmental concentrations cannot be verified empirically.” (p. 27).

- “[E]nvironmental monitoring data were not available to verify the conclusions of limited environmental exposures.” (p. 27).
- “[T]here is some uncertainty as monitoring data were not identified to verify the conclusions of low exposure via water and air.” (p. 31).

EPA’s decision to proceed with no data on these exposures, despite its power to require the generation of this information, violates EPA’s duty to rely on reasonably available information and to comply with TSCA § 26(h), including the duty to use the best available science. In addition, as result of these data gaps, EPA’s conclusions generally lack the substantial evidence required to support EPA’s factual findings.

i. Environmental, consumer, and general population exposures.

EPA lacks any actual data characterizing environmental, consumer, and general population exposures. Instead it claims that releases can be expected to be low based on the chemical manufacturer’s assertions that they are, which EPA has made no attempt to confirm or analyze. EPA asserts that exposures can be expected to be low based on the chemical’s physical-chemical properties and its wholly unsubstantiated claim that consumers and the general population “are *expected* to be exposed at concentrations lower than worker exposures.” (p. 32) (emphasis added). This assertion entirely ignores the fact that the concentration might well be higher in a consumer product (e.g., an artist paint) and that the physical form of the chemical, the nature of activities potentially leading to exposure, the controls in or not in place, and myriad other factors are likely to differ greatly from those at the site of manufacture, which is the only setting EPA has analyzed at all. Among other things, by EPA’s own account, the manufacturing facility includes numerous systems designed to capture PV29, *see, e.g.*, (p. 23), and many of these measures would or may not be present in other settings. Hence, EPA’s expectations that concentrations would invariably be lower than those to which workers are exposed are undermined by EPA’s other statements. EPA’s reasoning is thus incoherent.

As already noted, EPA has no actual data on the levels of PV29 released to or present in air, soil, sediment, surface water, people, other organisms, or products containing or made from the chemical. It lacks any data from, and has not used its authorities to require, any monitoring or other measurement of the chemical’s presence in any products, wastes, air or water releases, or environmental media.

The only “data” EPA presents in its entire discussion of potential environmental, consumer and general population exposures is this assertion:

Ultimately, of the NPDES-permitted TSS discharges for this sole domestic manufacturing facility, it is estimated that 0.6 lb/day of [PV29] is being discharged (<0.1 percent of produced [PV29]) (Mott, 2017b). (p. 21).

EPA obtained this estimate through a personal communication from an employee of Sun Chemical, the only U.S. manufacturer of PV29 that reported manufacture under EPA's Chemical Data Reporting (CDR) rule in 2016 and 2012.³³ To state the obvious, Sun Chemical has a strong interest in having EPA find its chemical safe.^{34,35} All the public has to go on is the statement just cited and a reference in the draft risk evaluation indicating that Sun Chemical's Robert C. Mott personally communicated this value to EPA on September 25, 2017. EPA has not even made the content of the personal communication public, nor has it provided or alluded to any *actual* data provided by Mott to support his statement. EPA cites this value, but acknowledges it is not directly measured at all but is at best a "guesstimate" of what fraction of a value for total suspended solids (TSS) is comprised of PV29. Even the data for TSS are not provided.

Moreover, it appears that, in order to rely on this information, EPA had to exempt it from being scrutinized using its own TSCA Systematic Review approach. On page 18 of the draft risk evaluation, EPA states that its systematic review approach "is not well suited for the review" of such "correspondences with industry *** used to inform the likelihood of exposure," and "[a]s a result, formal data quality evaluation of these references according to the *Application of Systematic Review in TSCA Risk Evaluations* (U.S. EPA, 2018a) was not conducted." EPA's

³³ EPA states this on page 9 of the draft risk evaluation. CDR reporting is limited to sites that manufacture 25,000 or more pounds per reporting year of a chemical, however, so it does not capture any additional companies or sites manufacturing less than that amount.

³⁴ See section 12.C. and D. of these comments for discussion of the limitations of information EPA receives through voluntary means.

³⁵ Notably, Sun Chemical's NPDES-permitted, daily maximum release amount for total suspended solids (TSS) is 3,331 lbs/day. NPDES PERMIT LIMITS AND MONITORING REQUIREMENTS FOR SUN CHEMICAL BUSHY PARK FACILITY, GOOSE CREEK, SC, https://echo.epa.gov/trends/loading-tool/reports/permit-limits?permit_id=SC0003441&year=2018 (last visited Jan. 10, 2019). Assuming *arguendo* that Mott's estimate of 0.6 lbs/day as the amount of PV29 present in the facility's TSS release is accurate, this would mean that the release of PV29 makes up only 0.02% of the allowable daily release of TSS from the facility. Moreover, a brief examination of Sun Chemical's effluent charts shows that on October 31, 2018 the daily release of TSS was 380 lbs (which is an amount generally representative of the values provided for 2018), and based on Mott's estimate, PV29 would still make up only 0.16% of the daily release. EFFLUENT CHARTS FOR SUN CHEMICAL BUSHY PARK FACILITY, GOOSE CREEK, SC, <https://echo.epa.gov/effluent-charts#SC0003441> (last visited Jan. 14, 2018) (select "All Outfalls" and "TSS"). Considering the NPDES permitted and reported levels of TSS, does EPA still consider Mott's estimate of PV29 release to the environment to be reasonable?

decision to selectively exclude certain sources of information from its Systematic Review approach results in inconsistent and arbitrary decision-making. In addition, EPA's own Risk Evaluation Rule requires that EPA use a systematic review approach when weighing evidence, 40 C.F.R. § 702.33, thus excluding certain evidence from that approach violates EPA's own risk evaluation rule. Nonetheless, EDF has serious concerns with EPA's TSCA systematic review approach; see section 7 below.

EPA appears to have relied exclusively (or nearly so) on this same source to draw all of its conclusions on the extent of environmental releases and exposures, including:

- “approximately 1-2 percent of the [manufacturing?] volume is potentially released to air, landfill and surface water” (p. 20);
- “air releases directly to the environment from manufacturing are expected to be limited based on the use of dust handling systems by the manufacturer” (p. 21);
- 1-2 percent of the [manufacturing?] volume of PV29 may enter surface water (p. 21);
- “destruction removal efficiencies for incinerators are expected to be >99 percent” (p. 21); and
- “environmental exposures are likely to be limited for [PV29]. As a result, no further analysis was necessary for environmental releases and environmental exposure” (p. 21).

EPA thus lacks substantial evidence to support its conclusions about environmental, consumer, and general population exposures. By proceeding without any measured data or other reliable information about these exposures, despite the ability to require reporting of such information, EPA has failed to rely on reasonably available information. EPA has also failed to comply with the requirements of TSCA § 26(h), including the obligation to use the best available science.

ii. Occupational exposures.

With respect to occupational exposures, EPA says it “conducted a quantitative screening-level assessment of occupational exposure using a high-end estimate of inhalation and dermal exposure.” (p. 5). In this subsection we identify numerous deficiencies in the data EPA used and assumptions it made for this exposure assessment. In sum, EPA lacks substantial evidence on occupational exposures from the inhalation and dermal routes, and EPA has no evidence about exposures to downstream processors and users. EPA relies excessively on voluntarily submitted information that is not publicly accessible, and may be unreliable as it appears to be accompanied by no supporting or explanatory information confirming its accuracy. EPA's analyses contain numerous unwarranted assumptions that render its reasoning arbitrary, and

by failing to require any reporting or tests of occupational exposure despite the clear authority to obtain that information, EPA has failed to consider reasonably available information or use the best available science.

In assessing dermal exposures to workers, EPA appears to have relied on modeling (p. 23), even though EPA itself acknowledges that measured workplace exposure data is preferred over modeled estimates.³⁶ EPA has identified a hierarchy of information sources when assessing exposure, ranked from most to least preferred in the following order:

1. Measured personal exposure monitoring data for the chemical.
2. "Indirectly" measured area exposure concentration monitoring data.
3. Measured data for a "surrogate" chemical with similar "exposure-affecting" properties and used in the same (or very similar) process.
4. Modeled exposure estimates:
 - Simulated exposure estimates (e.g., mass balance model) for the chemical.
 - Regulated limits as an estimated "upper bound" of exposure.
 - "Rule-of-thumb" exposure estimates, or those developed using analogous points of reference and engineering judgment.³⁷

EPA also states "[t]his order of preference is expected to apply generally to most cases of worker exposure assessment."³⁸ Yet, despite EPA's clearly stated preference for measured exposure monitoring data, EPA has made no attempt to attain workplace monitoring data for dermal exposure; nor has it explained why resorting to modeling when it could have required measured data to be developed is sufficient for this risk evaluation.

a. Inhalation exposures.

EPA asserts that, for the inhalation assessment, it obtained and used workplace "air monitoring data." The nature of these "data" warrants scrutiny. EPA obtained them through a personal communication from an employee of Sun Chemical, the only U.S. manufacturer of PV29 that reported manufacture under EPA's Chemical Data Reporting (CDR) rule in 2016 and 2012,³⁹ who claims, according to EPA, that "an approximate maximum workplace air concentration of 0.5 mg/m³ [milligrams per cubic meter] would be expected over a 12 hour shift" at a PV29

³⁶ U.S. EPA, *ChemSTEER USER Guide: Chemical Screening Tool for Exposures and Environmental Releases* p. 251 (2013), https://www.epa.gov/sites/production/files/2015-05/documents/user_guide.pdf (hereinafter "ChemSTEER Guide").

³⁷ *Id.*

³⁸ *Id.*

³⁹ EPA states this on page 9 of the draft risk evaluation. CDR reporting is limited to sites that manufacture 25,000 or more pounds per reporting year of a chemical, however, so it does not capture any additional companies or sites manufacturing less than that amount.

manufacturing facility. (p. 22). To state the obvious, Sun Chemical is an entity with a strong interest in having EPA find its chemical safe.⁴⁰ All the public has to go on is the statement just cited and a reference in the risk evaluation indicating that Sun Chemical’s Robert C. Mott personally communicated this value to EPA on September 25, 2017. EPA has not even made the content of the personal communication public, nor has it provided or alluded to any *actual* data provided by Mott to support his statement. EPA cites this value, but then acknowledges it does not know what this workplace air value actually represents, noting the personal communication was not clear: “It is not clear if the monitoring data were for [PV29] or for total dust.” (p. 22). Agencies have correctly rejected industry submissions when they lack sufficient annotations and analysis of the submitted data. *See, e.g., American Iron & Steel Inst. v. OSHA*, 939 F.2d 975, 985 (D.C. Cir. 1991).

Moreover, it appears that, in order to rely on this information, EPA had to exempt it from being scrutinized using its own TSCA Systematic Review approach. On page 18 of the draft risk evaluation, EPA states that its systematic review approach “is not well suited for the review” of such “correspondences with industry *** used to inform the likelihood of exposure,” and “[a]s a result, formal data quality evaluation of these references according to the *Application of Systematic Review in TSCA Risk Evaluations* (U.S. EPA, 2018a) was not conducted.” As explained above, this selective exemption from systematic review is both arbitrary and violates 40 C.F.R. § 702.33.

EPA also assumes without explanation or justification that workers could potentially inhale PV29 only in dust form. Yet the chemical is also produced in high-concentration solution form:

- “[PV29] is manufactured as a solid and *in solution* ***. It is handled and processed as a dry powder *and formulation* during all conditions of use.” (p. 20) (emphases added).
- “Workers at the manufacturing site handle large volumes of [PV29] at *nearly 100 percent concentration*.” (p. 22) (emphasis added).

EPA has not analyzed inhalation exposures to the chemical in solution at high concentration, nor has it provided any basis to conclude that such exposures would be a) lower than or b) exclusive of inhalation exposures to the chemical in solid form. Various activities involving the chemical in solution could readily yield mists or aerosols (or possibly even vapors, despite the chemical low vapor pressure at room temperature) that could be inhaled.

⁴⁰ See section 13.C. and D. of these comments for discussion of the limitations of information EPA receives through voluntary means.

The industry's main trade association, the Color Pigments Manufacturers Association (CPMA), submitted a comment to EPA in 2017 noting use of PV29 in downstream applications involving high heat (which could generate vapors) or spraying (which could generate mists or aerosols).⁴¹ In describing applications it estimated as comprising about 58% of total sales of PV29, CPMA stated (emphases added):

OEM and refinish paint: ~58%; these sales are primarily to paint manufacturers for use in automotive paints, both for original equipment manufacture (in which the paint is *baked onto the metal* by the car manufacturer) and for refinish (where the *paint is sprayed on by auto body shops*). [PV29] is a high-performance pigment and is one of the few pigments in its color range that *can withstand the high heat involved in OEM application*. It is highly light-fast, and so will not fade after years of direct sun exposure.⁴²

The chemical's known uses in products such as inks and artists' paints could also entail activities generating mists, aerosols, or vapors. Yet EPA fails to mention, let alone analyze, the potential for inhalation of any form other than powder or dust, and appears to have no data at all to characterize such exposures.

Finally, EPA acknowledges it has no actual data on inhalation absorption of PV29:

[PV29] is presented with limited data sets and one of the factors that is *missing is the absorption potential*. Despite the *lack of an absorption test*, the EPA was able to describe potential absorption of [PV29] based on physical-chemical properties, which indicate that [PV29] is classified as poorly absorbed by all routes of exposure (low solubility, low vapor pressure), which led the EPA to consider a default assumption of 10 percent absorption from dermal exposure and 100 percent absorption from inhalation. (p. 30) (emphases added).

Astoundingly, EPA relies wholly on physical-chemical properties to definitively conclude that "[PV29] is classified as poorly absorbed by all routes of exposure." (p. 30). It should be noted that, in the absence of any actual absorption data, EPA's assumption of 100% absorption could likely have lent some conservatism – but only if EPA had applied it consistently, across the multiple potential exposures, and to all physical forms of the chemical that could be inhaled.

⁴¹ CPMA Comment, p. 5.

⁴² *Id.*

b. Dermal exposures.

With respect to dermal exposure of workers, EPA presented only a single scenario that it claims represents the “theoretical maximum exposure.” (p. 23). There is no basis for this characterization. Certain aspects of the scenario do appear to be conservative: EPA used a “high” default for the amount of solid material contacting skin and assumed no use of gloves. However, nothing in EPA’s cited source, its ChemSTEER user guide, describes these assumptions as comprising a “theoretical maximum exposure.” Other aspects of EPA’s modeling assumptions do not appear to be conservative at all:

- Only a single exposure event per worker is assumed per day.⁴³
- Only a single worker is assumed to be exposed per day.⁴⁴
- Yet the range of activities to which the model applies would clearly have the potential to involve multiple exposures per day or exposure of multiple workers.⁴⁵

EPA’s apparent use of these default values appears to be at odds with other data EPA has regarding the number of workers potential exposed to PV29 at Sun Chemical’s facility. The ChemSTEER model’s user guide and other sources call on users to modify the default values where they are data available to more accurately estimate dermal exposure.⁴⁶ EPA’s 2016 CDR data reported by Sun Chemical for this facility indicate that between 25 and 50 workers are likely exposed to the chemical substance during manufacturing.⁴⁷ Also, the 2016 CDR data reported by Sun Chemical indicate that between 100 and 500 workers are likely exposed to the chemical substance during industrial processing.⁴⁸ EPA has not explained why it did not use these reported data from the company instead of the ChemSTEER defaults noted above.

⁴³ ChemSTEER Guide, p. 342.

⁴⁴ *Id.*

⁴⁵ *Id.* at p. 341.

⁴⁶ *Id.* at p. 342 (the user “may elect to change any parameter”); Pamela R.D. Williams, et al., *An Overview of Exposure Assessment Models Used by the US Environmental Protection Agency* at 107 (2010),

<https://pdfs.semanticscholar.org/61ad/1b7ee18f3b3f77ec3ed36c38803049a49750.pdf> (“[T]he default values in these models can be modified, and *should be changed* if other values are deemed more suitable for the specific exposure scenario being evaluated.”) (emphasis added).

⁴⁷ Chemical Data Reporting for Pigment Violet 29 (2016),

<https://chemview.epa.gov/chemview/?tf=0&ch=81-33-4&su=2-5-6-7&as=3-10-9-8&ac=1-15-16&ma=4-11-1981377&tds=0&tdl=10&tas1=1&tas2=asc&tas3=undefined&tss=&modal=template&modalId=19354179&modalSrc=4&modalDetailId=34729751&modalCdr=19354179>.

⁴⁸ *Id.*

EPA's dermal exposure analysis assumed exposure would only be to PV29 in solid form. Yet the material is also produced in the form of a high-concentration solution:

- “[PV29] is manufactured as a solid and in solution ***. It is handled and processed as a dry powder and formulation during all conditions of use.” (p. 20).
- “Workers at the manufacturing site handle large volumes of [PV29] at nearly 100 percent concentration.” (p. 22).

EPA has not analyzed dermal exposures to the chemical in solution at high concentration, nor has it provided any basis to conclude that such exposures would be a) lower than or b) exclusive of dermal exposures to the chemical in solid form.

Finally, EPA acknowledges it has no actual data on dermal absorption of PV29:

[PV29] is presented with limited data sets and one of the factors that is *missing is the absorption potential*. Despite the *lack of an absorption test*, the EPA was able to describe potential absorption of [PV29] based on physical-chemical properties, which indicate that [PV29] is classified as poorly absorbed by all routes of exposure (low solubility, low vapor pressure), which led the EPA to consider a default assumption of 10 percent absorption from dermal exposure and 100 percent absorption from inhalation. (p. 30) (emphases added).

Astoundingly, EPA relies wholly on physical-chemical properties to definitively conclude that “[PV29] is classified as poorly absorbed by all routes of exposure.” (p. 30). In its risk calculations, EPA used a default assumption of 10% dermal absorption. EPA cites as support a document from ECHA. (p. 30, n. 10). However that document actually supports a default assumption of 100% dermal absorption. ECHA states:

[i]nitially, basic physicochemical information should be taken into account, i.e. molecular mass and lipophilicity (log P). Following, a default value of 100% skin absorption is generally used unless molecular mass is above 500 and log P is outside the range [-1, 4], in which case a value of 10% skin absorption is chosen (de Heer et al., 1999).⁴⁹

In this case, EPA reports that PV29's molecular weight is 390.35 and estimates its log P (also called log K_{ow}) as 3.76. (p. 9, tbl. 2-1). Hence, both parameters fall within the stated range that warrants a default assumption of 100% dermal absorption, not 10%.

⁴⁹ ECHA, *Guidance on Information Requirements and Chemical Safety Assessment Chapter R.7c: Endpoint specific guidance* p. 186 (June 2017), https://echa.europa.eu/documents/10162/13632/information_requirements_r7c_en.pdf.

c. Worker exposures at downstream processing and use sites.

EPA's draft risk evaluation has not provided and EPA does not appear to possess any data on potential exposures to workers at downstream processing and use sites, nor even information on how many sites are involved or how many workers are potential exposed.

Our re-review of EPA's earlier documents on PV29 turned up only two far-from-adequate statements relevant to these questions:

- The preliminary information document states: "For the 2012 CDR period, four firms reported processing PV29."⁵⁰
- The problem formulation references, without citing any source, "the twenty downstream industrial facilities that process [PV29] into plastics, paints and coatings."⁵¹

Hence, EPA does not appear to have data that could be used to characterize either the number or extent of worker exposures at such facilities. Bizarrely, the only "analysis" EPA has presented in the draft risk evaluation that is relevant to worker exposure potential at such sites is its justification for not analyzing environmental releases and environmental exposures from downstream processing and use sites: "Because per site volumes handled by downstream users are likely to be much less than the manufacturer (i.e., less than 5 percent each), it is expected that potential [PV29] discharges per site to water and its related sediment, infiltration to groundwater via land application of biosolids, other landfill leaching, and air emissions will be proportionally lower." (p. 21). The reference to "5 percent" presumably reflects the problem formulation's undocumented reference to the existence of "twenty downstream industrial facilities that process" PV29.

It is nonsensical to assume without any actual data that one can simply divide the (unquantified) level of exposure at PV29's single manufacturing facility by the number of downstream sites to draw any conclusions whatsoever about exposure potential at the latter sites. The form of the material, the nature of activities potentially leading to exposure, the controls in or not in place, and myriad other factors must be assumed to vary significantly. It is quite possible for occupational exposure at a downstream site to significantly exceed exposure at the manufacturing site given the potentially different activities and controls that might be in place. EPA has pointed to no evidence supporting its contrary assumption.

⁵⁰ PV29 Preliminary Information, p. 5.

⁵¹ PV29 Problem Formulation, p. 23.

C. EPA’s draft risk evaluation lacks sufficient information to evaluate potential ecological hazards and risks.

Information on potential ecological hazards in EPA’s draft risk evaluation is limited to three guideline acute aquatic studies using the following methods: OECD-221 Lemna sp. Growth Inhibition Test,^{52,53} Growth Inhibition Test,⁵⁴ OECD-202 Daphnia sp. Acute Immobilisation Test,⁵⁵ and OECD-203 fish, Acute Toxicity Test.⁵⁶

EPA cannot fully and sufficiently evaluate the potential ecotoxicity of PV29 on the basis of these three studies alone. In particular, these guideline studies are all short-term acute toxicity tests and are limited to a handful of types of aquatic organisms. EPA has not identified 1) any chronic ecological toxicity studies, 2) any study of toxicity to sediment-dwelling organisms, or 3) any studies of toxicity to terrestrial or avian organisms. Indeed, EPA notes in the draft risk evaluation:

[T]here are no data that characterize the hazard of [PV29] to aquatic species following chronic exposure, nor are there toxicity testing with terrestrial species data available to characterize the hazards of [PV29], so there is some uncertainty regarding the environmental risk following acute exposure to sediment-dwelling invertebrates, chronic exposure to aquatic species, and exposure to terrestrial species. In addition, the lack of environmental monitoring data means that the limited predicted environmental concentrations cannot be verified empirically.⁵⁷ (p. 27).

The consequence of such drastically limited ecotoxicity information is not “some uncertainty,” but rather uncertainty so significant that EPA cannot possibly sufficiently evaluate the

⁵² OECD, *Test No. 221: Lemna sp. Growth Inhibition Test* (2006), https://www.oecd-ilibrary.org/environment/test-no-221-lemna-sp-growth-inhabitation-test_9789264016194-en.

⁵³ Note EPA’s draft risk evaluation incorrectly identifies this guideline study (OECD-221) as OECD-201 in Appendix C-1.

⁵⁴ OECD, *Test No. 201: Freshwater Alga and Cyanobacteria, Growth Inhibition Test* (2011), https://www.oecd-ilibrary.org/environment/test-no-201-alga-growth-inhibition-test_9789264069923-en.

⁵⁵ OECD, *Test No. 202: Daphnia sp. Acute Immobilisation Test* (2004), https://www.oecd-ilibrary.org/environment/test-no-202-daphnia-sp-acute-immobilisation-test_9789264069947-en.

⁵⁶ OECD, *Test No. 203: Fish, Acute Toxicity Test* (1992), https://www.oecd-ilibrary.org/environment/test-no-203-fish-acute-toxicity-test_9789264069961-en.

⁵⁷ See also discussion of limited environmental exposure and monitoring information in section 3.B.i.

ecological hazards and risks of PV29 resulting from its known releases, the magnitude of which remain unquantified and are “characterized” solely on the basis of a private personal communication with a conflicted industry source.⁵⁸ While EPA asserts that the lack of hazard identified in the three acute, aquatic guideline studies is sufficient to conclude that PV29 “demonstrates a low hazard to environmental receptors,” (p. 26), EPA’s assertion is unfounded and deeply problematic. EPA’s ultimate conclusion that PV29 presents a low hazard lacks substantial evidence in the record and does not reflect the best available science, because EPA lacks *any* data on chronic hazard, hazard to sediment-dwelling organisms, or hazard to terrestrial or avian organisms. In addition, given that EPA could have reasonably required the generation of this information during this risk evaluation, EPA has failed to consider reasonably available information about these hazards.

i. Data from acute aquatic toxicity studies cannot substitute for studies of chronic aquatic toxicity.

EPA should not assume that data from acute aquatic studies can sufficiently address potential chronic aquatic effects for the same chemical. Acute aquatic toxicity tests and chronic aquatic toxicity tests are designed to measure different toxicological effects. Acute aquatic toxicity studies typically measure a limited set of effects (e.g., lethality) over a very short period of exposure, whereas chronic aquatic toxicity studies are designed to measure delayed, sub-lethal effects (e.g., hatching, growth, and survival)⁵⁹ following longer periods of exposure.⁶⁰ EPA guidelines to develop numerical national water quality criteria for the protection of aquatic organisms require data from acute and chronic aquatic toxicity tests.⁶¹ Moreover, many chemicals have been shown to exhibit significantly different aquatic acute and chronic toxicity values, and these values can differ widely across species for the same chemical.^{62,63} For example, Ahlers 2006 notes:

⁵⁸ See section 12.C. of these comments for more concerning such conflicts of interest.

⁵⁹ AQUATIC TOXICITY, <https://ec.europa.eu/jrc/en/eurl/ecvam/alternative-methods-toxicity-testing/validated-test-methods/aquatic-toxicity> (last visited Jan. 13, 2019).

⁶⁰ Am. Soc’y for Testing & Materials (ASTM), *Standard Guide for Conducting Acute, Chronic, and Life-Cycle Aquatic Toxicity Tests with Polychaetous Annelid* (2000), https://www.waterboards.ca.gov/water_issues/programs/tmdl/docs/303d_policydocs/151.pdf

⁶¹ U.S. EPA, *Guidelines for Deriving Numerical National Water Quality Criteria for the Protection Of Aquatic Organisms and Their Uses* (1985), <https://www.epa.gov/sites/production/files/2016-02/documents/guidelines-water-quality-criteria.pdf>.

⁶² Jan Ahlers, et al., *Acute to chronic ratios in aquatic toxicity--variation across trophic levels and relationship with chemical structure*, 25:11 ENVTL. TOXICOLOGY & CHEMISTRY 2937-45 (Nov. 2006), <https://www.ncbi.nlm.nih.gov/pubmed/17089717/> (“For fish, daphnids, and algae, acute to chronic ratios (ACRs) have been determined from experimental data regarding new and existing

The evaluation revealed that acute data have only limited predictive value for long-term effects in aquatic ecosystems. The ACR correlates neither with acute toxicity nor with base-line toxicity as modeled through log Kow, and no ACR correlation is found across trophic levels. Whereas narcosis (and, in particular, nonpolar narcosis) appears to be a useful predictor for low ACRs, a nonnarcotic MOA is not a good indicator of high ACR. At the same time, compounds containing at least one SA [structural alert] have a substantially increased probability for a high ACR. Accordingly, a scheme combining both MOA and SA knowledge may be the best current model to discriminate, in the context of priority setting, between low and high ACRs when chronic data are lacking. The overall result is that at present, a conservative prediction of long-term toxicity can be achieved only through life-cycle tests.⁶⁴

As discussed in section 2.D., at least two member countries of the European Union (EU) have identified PV29 as a suspected “substance of very high concern” (SVHC) under the REACH Regulation. Specifically, PV29 is listed as “suspected PBT/vPvB.”⁶⁵ Under the REACH regulation,

chemicals. Only test results in accord with the European Union Technical Guidance Document (TGD) and validated by authorities were considered. Whereas the median ACRs of 10.5 (fish), 7.0 (daphnids), and 5.4 (algae) are well below the ACR safety factor of 100 as implied by the TGD, *individual ACRs vary considerably and go up to 4400. The results suggest that a safety factor of 100 is not protective for all chemicals and trophic levels.* Neither a correlation between ACR and baseline toxicity as modeled through the logarithmic octanol-water partition coefficient nor an ACR correlation across trophic levels exists. Narcosis is associated with a preference for a low ACR; nevertheless, low ACRs are frequently obtained for nonnarcotics. Analysis of chemical structures led to the derivation of structural alerts to identify compounds with a significantly increased potential for a high ACR, which may prove to be useful in setting test priorities. *At present, however, life-cycle tests are the only way to conservatively predict long-term toxicity.*” (emphases added).

⁶³ See Martin May, et al., *Evaluation of acute-to-chronic ratios of fish and Daphnia to predict acceptable no-effect levels*, 28:1 ENVTL. SCIENCES EUROPE 16 (2016), <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5044967/>.

⁶⁴ Jan Ahlers, et al., *Acute to chronic ratios in aquatic toxicity--variation across trophic levels and relationship with chemical structure*, 25:11 ENVTL. TOXICOLOGY & CHEMISTRY 2937-45 (Nov. 2006), <https://www.ncbi.nlm.nih.gov/pubmed/17089717/>.

⁶⁵ ECHA, *Guidance on Information Requirements and Chemical Safety Assessment Chapter R.11: PBT/vPvB assessment* p. 82 (June 2017), https://echa.europa.eu/documents/10162/13632/information_requirements_r11_en.pdf/a8cc e23f-a65a-46d2-ac68-92fee1f9e54f.

substances assessed as a PBT or vPvB require further action including long-term toxicity testing.⁶⁶

Among other testing, PV29 should be subject to long-term aquatic toxicity testing given its clearly persistence, the lack of evidence that it is not bioaccumulative, and concerns from at least two EU member countries that PV29 may be a PBT or vPvB.

EPA ultimately concludes in the draft risk evaluation that PV29 “*** is *unlikely* to present an unreasonable risk to environmental receptors from chronic exposures.” (p. 28) (emphasis added). Not only is this an unscientific and unreasonable conclusion, it is also does not meet the risk determination standard under TSCA section 6, see 15 U.S.C. § 2605(b)(4)(A), which requires that EPA determine whether a substance does or does not present unreasonable risk, not whether risk is likely or unlikely.

ii. EPA’s citing of the results of a Canadian screening exercise does not support EPA’s assertion that PV29 presents low aquatic hazard.

In seeking to find support for its conclusion, EPA cites the results of a screening process that the government of Canada applied to PV29 in 2006. On page 11 of the draft risk evaluation, EPA states: “[t]he conclusion of Canada’s screening indicated that because of low toxicity and low solubility, [PV29]’s hazard potential is low (Environment Canada, 2006).” And on page 25: “[t]his is consistent with the Canadian Ecological Risk Classification for [PV29], which did not present additional information, where it was determined that [PV29] did not meet the criteria for categorization as a prioritized substance for further evaluation and the potential hazard is low (Environment Canada, 2006).” Upon examination, Environment Canada’s screening process does not support these particular statements or a finding of no unreasonable risk. Given the limited nature of Environment Canada’s screening, EPA cannot rely on the screening to support a finding of no unreasonable risk.

We examined the source EPA cited to determine if it supported EPA’s conclusions, and we found it did not support them. That link goes to an entry in EPA’s HERO database, which in turn links to a general page on Environment Canada’s website titled “Domestic substances list: categorization of existing substances.” Using the substance search function on that page brought us to a PV29-specific page: <https://pollution-waste.canada.ca/substances->

⁶⁶ Commission Regulation 1907/2006, Registration, Evaluation, Authorisation and Restriction of Chemicals, annex XIII, sec. 2.1. & sec. 3.2.3, 2006 O.J. (L 396), <http://data.europa.eu/eli/reg/2006/1907/2018-03-01>; see also *id.* at annex I, sec. 4.1 (requiring that the PBT and vPvB assessment conducted as part of the chemical safety assessment required under Article 14, be done in accordance with annex XIII).

[search/Substance/DisplaySubstanceDetails?Id=81-33-4](#). This page indicates that Environment Canada had indeed concluded that PV29 “[d]id not meet the criteria under subsection 73(1) of the Canadian Environmental Protection Act, 1999 (CEPA).” However, it gave no indication as to the basis for that decision and provided no direct support for EPA’s assertions of “low toxicity and low solubility” and that “the potential hazard is low.”

On December 11, 2018, EDF inquired with the EPA contact person listed for the PV29 draft risk evaluation, noting EPA’s referenced citation did not indicate the basis for Environment Canada’s determination and seeking further information about how that source supported EPA’s conclusions. Unfortunately, despite our several attempts to get more clarifying information, we did not receive a substantive response from EPA.

We therefore conducted further research on our own to clarify what Environment Canada did and did not determine and on what basis.

First, here is some important background. The 1999 amendments to the Canadian Environmental Protection Act (CEPA) required Health Canada to sort through 23,000 substances on the Domestic Substances List (DSL) to identify (“categorize in”) chemicals meeting certain criteria indicative of potential risk, and to do so in just seven years (1999 to 2006).⁶⁷ Unlike prioritization under TSCA, Canada’s categorization exercise was intended only to identify chemicals of potentially high concern, *not* to also identify chemicals of low concern. In addition, Canadian officials made do with whatever information they already had or could develop rapidly through predictive models.⁶⁸

Many chemicals reviewed by Canada were not “categorized in” because the available information was too uncertain or lacking altogether. No attempts were made to fill data gaps through testing. As a result, despite what EPA asserts, chemicals that Canada found not to meet the categorization criteria *cannot* be characterized as affirmatively low-concern. Given that TSCA now gives EPA strong information generation authorities, EPA is not compelled to make do with whatever data, however limited, it already has. In addition, EPA has an affirmative obligation to consider reasonably available information, including information that EPA can require be generated. Moreover, TSCA requires EPA to conduct a full risk evaluation of PV29, not a mere screening exercise to determine whether it meets certain pre-set criteria of

⁶⁷ See Canadian Environmental Protection Act, S.C. 1999, c. 33, pt. 5 Controlling Toxic Substances, <https://www.canada.ca/en/environment-climate-change/services/canadian-environmental-protection-act-registry/publications/canadian-environmental-protection-act-1999/part-5.html>.

⁶⁸ See Richard Denison, *O Canada!*, EDF HEALTH BLOG (Jul. 24, 2009), <http://blogs.edf.org/health/2009/07/24/o-canada/>.

concern. Canada's DSL categorization in no way meets TSCA's requirements for a full risk evaluation.

EDF contacted Environment Canada to better discern the data it used with respect to aquatic toxicity in making its categorization decision for PV29. On December 20, 2018, Environment Canada provided us with a 2006 document titled "Ecological Categorization Criteria and Process for Substances on the Domestic Substances List."⁶⁹ That document states (boldface in original): **"Environment Canada prefers to use acute toxicity studies over chronic toxicity studies because more studies and QSAR models are available for acute endpoints.** This makes it easier to directly compare the properties of a large number of substances." While that approach might make some sense for a screening exercise applied to thousands of chemicals and where the authority to fill data gaps is lacking, it is hardly an excuse for EPA to rely exclusively on conclusions drawn from acute toxicity studies when conducting a full risk evaluation of PV29.

That document also indicated that Environment Canada used the following cut-off for its acute aquatic toxicity criterion: If a chemical's $LC_{50}(EC_{50}) \leq 1 \text{ mg/L}$,⁷⁰ then it is deemed to meet the categorization criterion of being "inherently toxic to aquatic species (iT)."

Finally, EDF located Environment Canada's specific DSL categorization results for PV29, using an OECD chemicals data portal.⁷¹ That webpage indicates that Environment Canada's "pivotal" toxicity value was its predicted acute toxicity to fathead minnows, with the LC50 value being 0.115 mg/L.⁷² This value is nearly 10-fold *lower* than Environment Canada's cut-off of 1 mg/L.

⁶⁹ This document does not appear to be available online any longer. EDF is happy to make it available upon request.

⁷⁰ Environment Canada's document states: "LC50 represents the concentration of a substance in water causing death in 50% of the experimental organisms in the water. EC50 represents the concentration of a substance in water inducing toxic effects on 50% of the experimental organisms." LC stands for lethal concentration and EC for effects concentration.

⁷¹ See CATEGORIZATION RESULTS FROM THE CANADIAN DOMESTIC SUBSTANCE LIST, <https://canadachemicals.oecd.org/ChemicalDetails.aspx?ChemicalID=e1470396-fb0b-4c24-977e-813a67a9d834> (last visited Jan. 14, 2019).

⁷² In EPA's May 2018 problem formulation for PV29, EPA indicates that it had earlier assigned PV29 a high hazard score when placing it on its 2012 TSCA Work Plan, "based on a predicted, modeled fish acute LC50 value of 4.6 mg/l" reported by Environment Canada. PV29 Problem Formulation, p. 40. But Environment Canada, in the source cited by EPA, clearly indicates the "pivotal" value it used in categorization was the far lower – hence, more toxic – value of 0.115 mg/l.

Pivotal value for iT (mg/l)	0.115
Toxicity to fathead minnow (LC50 in mg/l) as predicted by Topkat v6.1	0.115

It should be noted that Environment Canada’s “pivotal” value of 0.115 mg/L for PV29’s acute aquatic toxicity is lower than the water solubility estimate of 0.169 mg/L EPA provided in its PV29 scope document.⁷³ Even assuming *arguendo* that EPA’s assertions with respect to PV29’s poor water solubility are accurate, this means that PV29 could reach levels of solubility in water sufficient to kill 50% or more of fathead minnows exposed to it – not to mention exerting other non-lethal aquatic effects.

Of further note is that Environment Canada’s specific DSL categorization results for PV29 include only *acute* toxicity values for aquatic toxicity, confirming that Environment Canada did not have or generate any chronic aquatic toxicity data for the chemical. Given that the value cited by Environment Canada is well below its cut-off value for identifying a substance as “inherently toxic to aquatic species (iT),” EDF looked for but could not find any explanation from Environment Canada for why, despite these data, it determined that PV29 did not meet the iT categorization criterion.

However, a statement in the draft risk evaluation hints at an explanation. On pages 10-11, EPA states:

[t]his determination for [PV29] and seven other similar pigments were made using a combination of QSAR modeling and hazard data for analogous pigments with low solubility (Pigment Red 149; CAS RN 4948-15-6). The conclusion of Canada’s screening indicated that because of low toxicity and low solubility, [PV29]’s hazard potential is low (Environment Canada, 2006).

If this is the explanation, it is wholly inadequate: Neither EPA nor the Environment Canada source EPA has cited have provided any predicted or measured data for the similar pigments, and searching Environment Canada’s website and the Canadian data via the OECD chemicals portal for Pigment Red 149 did not yield such data either. In addition, this explanation does not address why the “pivotal” modeled value for toxicity should be disregarded when it indicates a potential unreasonable risk.

⁷³ PV29 Scope, p. 16.

EPA has failed to explain, or provide a link to a source that explains, why this pivotal toxicity value can be ignored, and given its implications for toxicity, ignoring this value while otherwise relying on Environment Canada's analysis is arbitrary and capricious.

As noted earlier, EDF found that EPA's cited source does not directly support its specific assertion that Environment Canada found "because of low toxicity and low solubility, [PV29]'s hazard potential is low." EDF asked EPA to clarify or provide the information. Unfortunately, EPA declined to do so.

One other possible explanation of Environment Canada's categorization decision is that it, like EPA, presumed that toxic levels would not be reached due to low solubility of PV29 or the other pigments. If so, our earlier discussion of the uncertainties in estimating water solubility for such substances fully applies here as well. In any event, as OECD notes, this line of argument cannot rule out that there are chronic effects at lower levels, and there is no indication that Environment Canada had any chronic toxicity data for the other pigments.

Environment Canada's screening process concededly did not address chronic aquatic toxicity, and its analysis acknowledges a modeled acute toxicity value that raises concerns. Given the different purpose and limited nature of Environment Canada's analysis and the lack of explanation for its conclusion, it would be arbitrary and capricious to rely on that screening process to support a finding of no unreasonable risk.

iii. Data from a single acute Daphnia magna study (OECD-202) cannot be used as a proxy to evaluate potential hazards to all sediment-dwelling invertebrates.

EPA acknowledges that it lacks information to evaluate potential hazards to sediment-dwelling organisms, but then indicates without any discussion or substantiation that there is no concern based on 1) the "weight of the evidence considering the limited potential for aquatic releases" and 2) lack of observed effects in all environmental hazard studies. (p. 27).

It is entirely unclear what EPA is referring to by "weight of the scientific evidence considering limited exposure for aquatic releases." EPA's draft risk evaluation includes no discussion of how it has applied a weight-of-evidence approach for any aspect of the evaluation. Moreover, as discussed in section 3.B.i., EPA relies heavily on personal communications with a representative from the sole reporting U.S. manufacturer of PV29, Sun Chemical, for information relating to its use, release, and disposal.

Despite EPA's acknowledgment that PV29 is likely to accumulate in sediment, (p. 27), and in the absence of hazard information for sediment-dwelling organisms, EPA asserts data on the water flea *Daphnia* can suffice because it is an invertebrate like some sediment-dwelling organisms.

The lack of observed effects in Daphnia is not sufficient to dismiss potential hazards to all sediment-dwelling invertebrates or other organisms.⁷⁴ As noted below, it is particularly questionable to rely on aquatic toxicity studies to assess toxicity to sediment-dwelling and other organisms for a chemical with low water solubility.

EPA concludes that PV29 “is *unlikely* to present an unreasonable risk to sediment-dwelling, aquatic invertebrates.” (p. 27) (emphasis added). Not only is this an unscientific and unreasonable conclusion, it also does not meet the risk determination standard under TSCA section 6, see 15 U.S.C. § 2605(b)(4)(A), which requires that EPA determine that a substance does or not present unreasonable risk, not whether risk is likely or unlikely.

iv. EPA lacks any information on potential terrestrial toxicity of PV29.

EPA has not identified any studies of potential terrestrial (including avian) toxicity for PV29, despite the fact that this substance is persistent and released into the environment including to landfills where it has potential to leach and contaminate soil. Again, the hazard database for potential ecological toxicity of PV29 is limited to three acute aquatic toxicity studies. This is wholly inadequate to characterize the potential toxicity PV29 poses to the range of ecological organisms that may be exposed to this substance, including terrestrial organisms.

⁷⁴ See Gary L. Phipps, et al., *Use of the aquatic oligochaete Lumbriculus variegatus for assessing the toxicity and bioaccumulation of sediment-associated contaminants*, 12:2 ENVTL. TOXICOLOGY & CHEMISTRY 269 (Feb. 1993), <https://setac.onlinelibrary.wiley.com/doi/abs/10.1002/etc.5620120210> (“An ideal test, or suite of tests, for contaminated sediments would have a number of attributes, including (a) ecological relevance (i.e., the organisms are, or represent, potentially important species in aquatic ecosystems), (b) ability to assess chronic end points such as reproductive effects, (c) incorporation of all relevant routes of exposure (i.e., exposure to interstitial water, ingestion of contaminated particles), (d) tolerance of a wide range of physical sediment characteristics (e.g., particle size), and (e) ability to assess bioaccumulation of sediment-associated contaminants. Also, any species recommended for standard tests should be easily cultured and handled in the laboratory. *Many different organisms and test end points have been proposed for assessing contaminated sediments [3]. However, the majority of these tests do not conform to all of the above criteria. For example, many researchers use upper-water-column test species, such as cladocerans [which includes Daphnia] and fishes, to assess the toxicity of contaminated sediments; however, these organisms are not relevant if species of concern are benthic, particularly in terms of adequately addressing all possible routes of exposure.*”) (emphases added); see also U.S. EPA, *Methods for Measuring the Toxicity and Bioaccumulation of Sediment-associated Contaminants with Freshwater Invertebrates* (Mar. 2000), <https://permanent.access.gpo.gov/lps45981/ZyPDF.pdf>.

Indeed, a 2014 European Chemicals Agency (ECHA) report notes (emphasis added):

Limited information is available regarding the sensitivity of aquatic versus terrestrial organisms to chemical substances. Hazard criteria based on aquatic organisms is by some Authors in the scientific literature considered to provide a conservative classification. On the other hand for some substances higher toxicity has been observed for the terrestrial compartment. At the same time the aquatic and non-aquatic ecosystems differ with regards to mechanisms of toxicity and metabolism as well as exposure and uptake routes. *Especially for substances with low water solubility toxic effects may not be detectable through acute aquatic toxicity tests whereas prolonged aquatic exposure and/or tests with terrestrial organisms exposed through soil or food may result in toxic effects.*⁷⁵

Not only does ECHA make clear that toxicity to terrestrial organisms may differ from aquatic organisms, specifically noting that the toxicity to the former may be higher, but that for substances with low water solubility, as is the case for PV29, acute aquatic toxicity testing may be insufficient to evaluate toxicity to aquatic organisms resulting from prolonged exposure.

Similarly, the authors of a 2014 National Academies report, *A Framework to Guide Selection of Chemical Alternatives* state that “relative chemical hazards to terrestrial organisms do not necessarily follow the same patterns as that seen with aquatic organisms, necessitating separate testing and assessment schemes.”⁷⁶

The lack of any terrestrial toxicity data for PV29 is a major data gap and deficiency, leading to significant uncertainty in an evaluation of its potential ecological risks. Because EPA lacks *any* evidence on terrestrial toxicity, EPA’s conclusion that PV29 does not present a hazard to the environment is not based on substantial evidence and cannot be justified.

v. EPA employs completely circular arguments to dismiss any potential ecological risk.

EPA states:

⁷⁵ Nanna B. Hartmann, et al., *Review of available criteria for non-aquatic organisms within PBT/vPvB frameworks Part II: Toxicity assessment* p. 37 (Aug. 2014), <http://publications.jrc.ec.europa.eu/repository/bitstream/JRC90621/lbna26737enn.pdf>.

⁷⁶ NAT’L RESEARCH COUNCIL, *A FRAMEWORK TO GUIDE SELECTION OF CHEMICAL ALTERNATIVES* p. 83 (2014), <https://www.ncbi.nlm.nih.gov/books/NBK253965/>.

In the previous sections, the EPA determined that expected releases and subsequent environmental exposures are limited as a result of a qualitative consideration of available physical-chemical, environmental fate, manufacturing and release, and exposure information. While the agency has determined that there are sufficient data available to make this determination, environmental monitoring data were not available to verify the conclusions of limited environmental exposures. This lack of monitoring data is unlikely to impact the conclusions, as the low solubility of the chemical and lack of environmental hazard means that it would be unlikely for environmental concentrations to reach a level where adverse effects could be observed in environmental receptors. (p. 27).

EPA employs entirely circular arguments to dismiss potential risks of harm resulting from exposure to PV29. EPA acknowledges the inadequate hazard information for PV29 (three acute aquatic studies), but then dismisses any concern about this by asserting there is limited exposure potential for PV29. The agency then acknowledges the limited exposure information for PV29, but then dismisses any concern about this by citing the “lack of environmental hazard”—as determined by three acute aquatic toxicity studies, as well as its low solubility. EPA repeatedly employs this sort of circular argument throughout the draft risk evaluation to argue away any risk concerns. The resulting “analysis” lacks the necessary evidentiary support and reflects arbitrary reasoning.

* * *

In sum, EPA bases its sweeping conclusion that PV29 presents no environmental hazard or risk solely on acute aquatic toxicity data that, according to EPA’s Appendix C listings, examined only the single endpoint of mortality. Where other acute data, such as those developed by Environment Canada using prediction models, indicate acute toxicity, EPA dismisses those based on the chemical’s presumed low water solubility – an argument subject to the significant limitations noted in section 2.A. above that add considerable uncertainty even to a conclusion of no or low acute aquatic toxicity.

Yet EPA takes numerous huge leaps from there, first to assert no aquatic toxicity of any kind, then to assert no environmental hazard of any kind, and finally to assert no environmental risk.

EPA’s effort to invoke Environment Canada’s findings as support falls far short of what is needed, based as it is on a screening approach that was forced to rely on available data, however limited, and clearly only considered acute aquatic toxicity.

Having relied solely on acute aquatic toxicity data, EPA’s draft risk evaluation has failed even to establish that PV29 presents no acute aquatic hazard or risk, let alone that it presents no chronic aquatic hazard or risk or more broadly, no environmental hazard or risk. No evidence in the administrative record speaks to chronic aquatic toxicity or to non-aquatic environmental hazards, so EPA cannot rationally reach conclusions about those hazards or risks. EPA decisions under TSCA must be supported by substantial evidence, 15 U.S.C. § 2618(c)(1)(B)(II), and here EPA has no evidence supporting these conclusions.

D. EPA’s draft risk evaluation lacks sufficient information to evaluate potential human health hazards and risks.

i. The evidence base for PV29 for evaluating potential human health hazards is inadequate.

The evidence base for PV29 does not even fulfill the OECD Screening Information Data Set (SIDS)⁷⁷ —“the minimum amount of data that is required for making an initial hazard assessment of chemicals.”⁷⁸ The total extent of human health effects data identified in EPA’s draft risk evaluation is captured in the table below:

Target Organ/System	Study Type	Number of Studies
Mortality	OECD-401; Acute Oral	3
Mortality	Acute Inhalation Toxicity ⁷⁹	2
Mortality	Acute-Intraperitoneal Toxicity	2
Reproductive and Developmental	OECD-421; Reproduction and Developmental Toxicity screening test	1
Skin Irritation	OECD-404; Skin irritation: occlusive & Skin irritation: in vivo	2
Eye irritation	OECD-405; Eye irritation/Corrosion	2

⁷⁷ OECD, MANUAL FOR THE ASSESSMENT OF CHEMICALS, chp. 2 Data Gathering (Mar. 2012), <http://www.oecd.org/chemicalsafety/testing/49944183.pdf>.

⁷⁸ CHAPTER 2. DATA GATHERING AND TESTING: SIDS, THE SIDS PLAN AND THE SIDS DOSSIER, <http://www.oecd.org/chemicalsafety/risk-assessment/chapter2datagatheringandtestingsidsthesidsplanandthesidsdossier.htm> (last visited Jan. 14, 2019).

⁷⁹ See section 7.B.ii. below for a discussion of the disqualifying methodological problems with these studies and EPA’s failure to account for them.

Skin sensitization	OECD-429; Skin sensitization: mouse local lymphocyte assay (LLNA)	1
Genotoxicity	OECD-471; Genotoxicity – gene mutation (in vitro)	1
Genotoxicity	OECD-476; Genotoxicity – gene mutation (in vitro)	1

Almost all of the data are acute and much of it examines only lethality. Importantly, as with ecological toxicity (see section 3.C.), there are no chronic toxicity studies available to evaluate potential human toxicity.

Despite the inadequacy of the evidence base for evaluating potential human toxicity, EPA concludes:

These full study reports concluded that no adverse effects were observed for all routes of exposure (oral, dermal, inhalation), nor were dermal or eye irritation effects reported. As a result, the EPA concludes that [PV29] presents a low hazard to human health. *** No data was found on the metabolism of [PV29]; hence the metabolic fate is unknown. However, [PV29] is unlikely to be metabolized based on poor absorption.” (p. 25).

Essentially, EPA is claiming that the general absence of hazardous effects observed in the extremely limited amount and types of tests available means that PV29 isn’t hazardous at all. This is an absurd conclusion to draw, does not represent the best available science, and harkens back to the problems with the original TSCA that in the absence of data showing a hazard, EPA could not require the data necessary to fill data gaps, and that an absence of data indicating harm was equated to evidence of no harm. EPA’s argument that the absence of metabolic data is acceptable because of poor absorption is entirely inappropriate given the severe deficiencies in EPA’s absorption data and arguments (see sections 3.B.ii. and 4.A.ii.). Ultimately, EPA’s conclusion that PV29 presents a low hazard to human health lacks a sufficient evidentiary basis and reflects arbitrary reasoning, in which EPA draws conclusions from the available evidence that the evidence does not support. Moreover, by failing to use its information authorities to fill these data gaps, EPA has failed to consider reasonably available information in reaching this conclusion.

At the same time, EPA swiftly discounts evidence of hazard where it is observed in the evidence base:

Toxicity effects were observed in the intraperitoneal studies at high concentrations (LD50= 7000-9000 mg/kg-bw). However, the nature of this route of exposure is not relevant for [PV29] because the test material is injected directly into the intra-peritonium (body cavity) and [PV29] is poorly absorbed by all routes due to its low solubility. (p. 25).

Here again, EPA invokes its problematic low solubility argument. EPA cannot rely on a deeply flawed low solubility-low absorption argument to dismiss the observed effects in the two intraperitoneal studies (see sections 3.B.ii. and 4.A.ii.).

EPA relies on a screening reproduction and developmental toxicity study, OECD-421, for its human health risk calculation for workers (see section 4.B.-D. for discussion of deficiencies in EPA's exclusive focus on worker risks). The OECD-421 guideline study is not a rigorous assessment of potential reproductive or developmental toxicity. The OECD-421 guideline itself notes:

This test does not provide complete information on all aspects of reproduction and development. In particular, it offers only limited means of detecting post-natal manifestations of pre-natal exposure, or effects that may be induced during post-natal exposure. Due (amongst other reasons) to the relatively small numbers of animals in the dose groups, the selectivity of the end points, and the short duration of the study, *this method will not provide evidence for definite claims of no effects.*⁸⁰

Similarly, EPA's own Health Effects Test Guideline modeled after OECD-421, OPPTS 870.3550 Reproductive/Developmental Toxicity Screening Test, contains the same critical, qualifying language pertaining to the limitations of this guideline study:

This test does not provide complete information on all aspects of reproduction and development. In particular, it offers only limited means of detecting postnatal manifestations of prenatal exposure, or effects that may be induced

⁸⁰ OECD, *Test No. 421: Reproduction/Developmental Toxicity Screening Test*, <https://www.oecd-ilibrary.org/docserver/9789264264380-en.pdf?expires=1546544951&id=id&accname=guest&checksum=2C7FF0874B41A0E9082D0CF0248A7F3F> (emphasis added).

during postnatal exposure. *Due (amongst other reasons) to the relatively small numbers of animals in the dose groups, the selectivity of the end points, and the short duration of the study, this method will not provide evidence for definite claims of no effects.*⁸¹

EPA entirely fails to acknowledge its own and OECD's guidance stating clearly that the limits of this screening test are such that the agency cannot use the negative results from this study to conclude there are no reproduction or developmental effects. EPA then goes on to conclude, "As no effects were observed up to the limit-dose, further chronic toxicity testing is not needed." (p. 31). This is a gross perversion of toxicology—short-term studies cannot substitute for long-term evaluations of chronic effects. It also contradicts statements the agency makes a few sentences earlier: "This test [OECD-421] does not provide complete information on all aspects of reproduction and development, but rather provides a limited means of detecting post-natal manifestations of pre-natal exposure, or effects that may be induced during post-natal exposure." (p. 31).

ii. EPA's conclusion that PV29 is not carcinogenic is based on insufficient information.

EPA states:

While no suitable analogs were identified for [PV29] concerning genotoxicity, structural activity relationships (SAR) considerations and the expected poor absorption and uptake of [PV29], support the EPA's conclusion that [PV29] is unlikely to be a carcinogen. (p. 25).

AND

The absence of a chronic exposure carcinogenicity study resulted in some uncertainty regarding the carcinogenicity of [PV29]. Based on the available data, [PV29] is not reported to be a developmental neurotoxin. Despite the lack of this study, the carcinogenic potential of [PV29] was sufficiently assessed using available data, which included two short-term, genotoxicity studies and a consideration of the structural activity of the compound, which determined that [PV29] is not likely to be carcinogenic. (p. 31).

⁸¹ U.S. EPA, *Health Effects Test Guidelines OPPTS 870.3550 Reproduction/Developmental Toxicity Screening Test* p. 1 (Jul. 2000), <https://www.regulations.gov/document?D=EPA-HQ-OPPT-2009-0156-0015> (emphasis added).

EPA's rationale for deciding PV29 is not likely to be a carcinogen is highly flawed:

- EPA makes an *exposure* argument – expected poor absorption and uptake – to conclude a carcinogenic *hazard* does not exist. Whether or not PV29 has carcinogenic hazard potential is completely independent of the issue of exposure.
- EPA irrelevantly notes the absence of any reports of developmental neurotoxicity. This has nothing to do with concerns regarding carcinogenicity; and EPA doing so serves to highlight that EPA lacks adequate information regarding developmental neurotoxicity yet somehow erroneously believes the lack of *reports* of developmental neurotoxicity means that PV29 does not have this effect.
- The agency lacks any *in vivo* genotoxicity or clastogenicity studies or chronic studies of carcinogenicity.
- Genotoxicity is not the only mode of carcinogenicity. Other modes of carcinogenicity for which EPA has no relevant data whatsoever include, for example, oxidative stress and chronic inflammation.⁸²
- PV29 is a derivative of perylene—a polycyclic aromatic hydrocarbon (PAH). The carcinogenicity of PAHs is well-established.⁸³ An analysis of PV29 through ToxTree provides a structural alert for PV29 given its structural similarity to PAHs.⁸⁴ Notably, metabolic activation of PAHs is a key aspect of this class of substances' carcinogenic potential.⁸⁵ EPA lacks any information regarding the metabolism of PV29. (p. 25). EPA completely fails to analyze this structural alert or consider this evidence suggesting that PV29 may be a carcinogen.

EPA lacks substantial evidence supporting its finding that PV29 is unlikely to be a carcinogen, and reasonably available information suggests that PV29 may be a carcinogen. By failing to collect the information necessary to assess carcinogenicity—including but not limited to *in vivo* genotoxicity or clastogenicity studies—EPA has failed to consider reasonably available information necessary to accurately assess PV29's risks.

⁸² Smith MT, et al., *Key Characteristics of Carcinogens as a Basis for Organizing Data on Mechanisms of Carcinogenesis*, 124:6 ENVTL. HEALTH PERSPECTIVES 713-21 (June 2016), <https://www.ncbi.nlm.nih.gov/pubmed/26600562>.

⁸³ Agency for Toxic Substances & Disease Registry (ATSDR), *Case Studies in Environmental Medicine Toxicity of Polycyclic Aromatic Hydrocarbons (PAHs)* p. 34 (2009), <https://www.atsdr.cdc.gov/csem/csem.asp?csem=13&po=11>.

⁸⁴ TOXTREE - TOXIC HAZARD ESTIMATION BY DECISION TREE APPROACH, <http://toxtree.sourceforge.net/> (last visited Jan. 14, 2019).

⁸⁵ William M. Baird, et al., *Carcinogenic polycyclic aromatic hydrocarbon-DNA adducts and mechanism of action*, 45:2-3 ENVTL. & MOLECULAR MUTAGENESIS (Feb. 2005), <https://onlinelibrary.wiley.com/doi/abs/10.1002/em.20095>.

4. EPA’s exposure assessments and assumptions are deeply flawed.

A. EPA’s occupational exposure assessment is replete with problems.

i. EPA restricts its occupational exposure analysis to the site of manufacture, failing to account for worker exposures at downstream processing and use sites.

EPA’s only effort at a quantitative assessment of worker exposures to PV29 is limited to what EPA claims is “a high-end exposure analysis *** to represent a theoretical high-end exposure of [PV29] at a manufacturing site.” (p. 22) (emphasis added). There are numerous reasons to question the data and model assumptions EPA used to carry out this analysis, including the suspect nature of the workplace air concentration discussed earlier in section 3.B.ii.A.

While EPA acknowledges the potential for exposure to workers at downstream processing sites, (p. 22) (“Oral and inhalation exposures from downstream processors and users are possible”), the agency quickly discounts this possibility by asserting PPE will be used and oral absorption will be poor due to low water solubility. We have addressed the flaws in these assertions elsewhere in these comments (see discussion on water solubility in section 2.A.i., discussion of oral absorption in section 4.A.ii., and discussion of the limitations of reliance on PPE in section 14).

It is entirely inappropriate for EPA to ignore exposure of workers at processing and use sites given that EPA has provided no actual data on the extent of use or efficacy of engineering controls and PPE at such sites. (The only relevant resource provided is CPMA’s letter, which asserts – backed by no data – that customers processing paint and plastics are “understood” to handle dry powder using modern engineering controls.⁸⁶) In the case of workers processing PV29 for rubber products, there is absolutely no information provided to the public on use of engineering controls or PPE.

Moreover, EPA’s analysis is based on the unsupported assertion that worker exposures at the manufacturing site will necessarily be higher than all other worker exposures. EPA’s only rationale for this assertion is that “per site volumes handled by downstream users are likely to be much less than the manufacturer (i.e., less than 5 percent each),” (p. 20), the implication being that if a lower volume is present at a site, that automatically translates into lower exposure – without regard to the form of the material, the nature of activities potentially leading to exposure, the controls in or not in place, and myriad other factors that are likely to be highly variable. EPA provides no other basis for limiting its entire quantitative occupational exposure analysis to the site of manufacture.

⁸⁶ CPMA Comment, p. 6.

Notably, the draft risk evaluation appears to rely on the engineering controls allegedly in place at the manufacturing site, *see, e.g.*, (pp. 23, 24), which EPA expects would lower workplace air levels and air releases. EPA has no data establishing that similar engineering controls are in place at processing and use sites, so EPA has no basis for assuming that the reported air monitoring value for the manufacturing site constitutes a “high-end estimate.”

As previously noted in section 3.B.ii., EPA also assumed that workers would be exposed via inhalation and dermal routes only to the substance in solid (powder) form, ignoring the fact that the substance is also produced in high-concentration solution, which provides the potential for exposure to mists, aerosols, vapors and direct skin contact with liquids.

EPA’s complete failure to analyze exposure at processor and use sites ignores an important aspect of the problem and is thus arbitrary and capricious. EPA also has authority to obtain information on these exposures, and by failing to collect that information, EPA has failed to consider reasonably available information and to comply with TSCA § 26(h), including the duty to use the best available science.

ii. EPA’s series of rationales for dismissing the significance of worker exposures are weak and based on little actual data or analysis.

EPA then dismisses manufacturing and downstream worker exposures to PV29 using a series of weak or otherwise problematic arguments discussed below. The absence of empirical evidence supporting EPA’s conclusions means that EPA’s conclusions are not supported by substantial evidence, and once again, EPA has failed to consider reasonably available information and use the best available science which could have provided actual evidence on these exposures.

a. Inhalation and dermal exposures.

With regard to inhalation and dermal exposures, EPA states:

Workers may be exposed via inhalation and dermal routes during the handling of neat materials. However, absorption via inhalation pathways is expected to be low due to low water solubility and dermal absorption is estimated to be negligible for the neat material (because it is a solid of high molecular weight), and poor absorption in solution (based on high molecular weight and low solubility). (pp. 21-22).

This excerpt is poorly written and unclear, but EPA appears to be asserting that workers are not exposed to the neat substance via inhalation and dermal routes for reasons including low water solubility and high molecular weight.

A poorly soluble substance in water can be inhaled and cause adverse effects. Multiple studies reveal that inhalation of poorly soluble particles can lead to significant health impacts, including chronic pulmonary inflammation, pulmonary fibrosis, and lung tumors.^{87,88,89}

In addition, EPA is ignoring the multiple mechanisms by which chemicals, including poorly soluble substances, may be absorbed. As noted in a 2017 report by ECHA:

The major routes by which toxicants enter the body are via the lungs, the gastrointestinal tract (both being absorption surfaces by nature), and the skin. To be absorbed, substances must transverse across biological membranes. Mostly this occurs by passive diffusion. *** [A]bsorption may occur via facilitated diffusion, active transport or pinocytosis, processes that are more actively directed and therefore require energy).⁹⁰

Moreover, EPA has not considered the absorption of PV29 as present in formulations such as paints, coating, and inks. The presence of other constituents in a PV29 formulation can significantly alter the absorbability of PV29. The pharmaceutical industry employs many different approaches to increase the absorption of drugs with lower water solubility, including for example the use of surfactants.^{91,92} Surfactants are a common constituent of paints and coatings.⁹³

⁸⁷ Eileen D. Kuempel, et al., *Human and Animal Evidence Supports Lower Occupational Exposure Limits for Poorly-Soluble Respirable Particles*, 58:9 THE ANNALS OF OCCUPATIONAL HYGIENE 1205 (Nov. 2014), <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4618468/>.

⁸⁸ Oberdörster G., *Lung particle overload: implications for occupational exposures to particles*, 21:1 REGULATORY TOXICOLOGY & PHARMACOLOGY 123 (Feb. 1995), <https://www.ncbi.nlm.nih.gov/pubmed/7784625>.

⁸⁹ Mike Jayjock, *Inhaled Insoluble Particles are more than a Nuisance*, HUMAN HEALTH RISK ASSESSMENT TO CHEMICALS (June 22, 2014), <http://jayjock-associates.blogspot.com/2014/06/inhaled-insoluble-particles-are-more.html>.

⁹⁰ ECHA, *Guidance on Information Requirements and Chemical Safety Assessment Chapter R.7c: Endpoint specific guidance* p. 176 (June 2017), https://echa.europa.eu/documents/10162/13632/information_requirements_r7c_en.pdf.

⁹¹ Shweta Gupta, et al., *Formulation Strategies to Improve the Bioavailability of Poorly Absorbed Drugs with Special Emphasis on Self-Emulsifying Systems*, ISRN PHARM. (Dec. 2013), <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3888743/>.

EPA's argument that exposure via inhalation is expected to be negligible because of low water solubility is highly problematic and discordant with current scientific understanding. At a minimum, EPA should have obtained actual absorption information instead of simply assuming that low solubility will necessarily result in low absorption.

EPA additionally attempts to rely on industrial hygiene controls to dismiss worker exposures:

Engineering controls for [PV29], as stated directly in the SDS, include adequate ventilation, processing enclosure, and local exhaust ventilation or other engineering controls. Personal protective equipment (PPE) includes safety glasses with side-shields, dust goggle under certain circumstances, chemical resistant impervious gloves, and particulate respirators if needed (BASF, 2017; CPMA, 2017a; Sun Chemical, 2017). Oral and inhalation exposures from downstream processors and users are possible; however, occupational exposures from these downstream users are likely to be limited due to the expected use of PPE (per Safety Data Sheet for [PV29]) and poor oral absorption due to low water solubility (BASF, 2017; CPMA, 2017a; Sun Chemical, 2017). (p. 22).

The extent of information available on these controls is limited to safety data sheets from BASF and Sun Chemical and a comment from the Color Pigments Manufacturer Association (CPMA). There appear to be no empirical data to document the extent of use or effectiveness of any of these industrial hygiene controls. Additionally, EPA again invokes inadequate arguments around poor oral absorption due to low water solubility.

In subsection iii of this section and section 14 below, we further discuss why EPA's reliance on SDSs and PPE is insufficient to dismiss worker exposures.

b. Oral exposures.

Broadly with regard to oral exposure, EPA states:

⁹² Ketan T. Savjani, et al., *Drug Solubility: Importance and Enhancement Techniques*, ISRN PHARM. (Jul. 2012), <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3399483/>.

⁹³ DOW SURFACTANTS - INDUSTRIAL COATINGS AND PAINTS, <https://www.dow.com/surfactants/applications/paints/indust.htm> (last visited Jan. 14, 2019).

Oral ingestion is not a relevant pathway for workers manufacturing [PV29] since there is no foreseeable route of exposure. Standard workplace practices prohibit eating and smoking in manufacturing facilities. In addition, minimal incidental oral exposures are avoided by the use of personal protective equipment (PPE) that are discussed below (Mott, 2017a). In addition, oral absorption is poor due to low water solubility. (p. 22).

This argument assumes oral exposure would only occur if workers eat contaminated food or smoke. It also assumes without any documentation that there is 100% compliance with the no-eating-or-smoking policy. Research has revealed that incidental ingestion by workers from hand-to-mouth contact occurs in the workplace.⁹⁴

No information is provided on the type of PPE used and whether it is sufficiently protective; EPA simply asserts that the equipment will be used and will entirely eliminate incidental oral exposure. EPA needs to more closely assess the potential for oral exposure via pathways beyond ingestion of contaminated food. EPA again references low water solubility as a basis for poor oral absorption for workers. This is problematic for the reasons already discussed.

EPA also relies here on a personal communication from one employee of what EPA states is the only reporting U.S. manufacturer of the chemical, Sun Chemical (Mott 2017a). EPA appears to have no empirical data as to the extent of use or effectiveness of any of these controls. Moreover, the content of the Mott 2017a personal communication is not publicly available.⁹⁵ Nor is there any mention made of the inherent conflict of interest that this personal communicator has in minimizing any concerns over exposure to the chemical his company makes (see section 3.B.ii.a.). Yet EPA relies heavily on this conflicted source⁹⁶ to support its conclusions that workplace exposures are negligible.

EPA must immediately make public the details of the Mott 2017a, and all other personal communications relevant to the risk evaluation in the docket. EPA's reliance on these personal

⁹⁴ Melanie G. Ng, et al., *Inadvertent ingestion exposure: hand- and object-to-mouth behavior among workers*, 26 J. OF EXPOSURE SCIENCE & ENVTL. EPIDEMIOLOGY 9-16 (2016), <https://www.nature.com/articles/jes201471>.

⁹⁵ EDF's search of the PV29 problem formulation and risk evaluation dockets for Mott 2017a yielded nothing; the only related item is a document noting that a February 13, 2017 meeting was held between EPA and representatives of BASF, SOCMA, GL+PC, Avanti, CPMA, and Sun Chemical (Robert Mott). Stakeholder Meeting with CPMA – February 13, 2017, <https://www.regulations.gov/document?D=EPA-HQ-OPPT-2016-0725-0026>.

⁹⁶ See section 12.C. of these comments for more concerning such conflicts of interest.

communications to assert limited exposure to workers (and the environment) is highly questionable given the lack of information provided and the inappropriateness of evaluating risk only assuming universal use and efficacy of industrial hygiene controls

Finally, EPA asserts that PV29 will not leach from plastics or paints: “When [PV29] is encapsulated in plastics or paint resins, it is not expected to leach out (21 CFR 178.3297, (BASF, 1998)).” This conclusion appears to be completely drawn from information included in a food additives petition to FDA for PV29 which is not publicly available. It is also highly doubtful, given extensive lack of empirical data EPA has in its possession, that information submitted with the food additives petition contains measured data evaluating the leaching potential for PV29.

iii. EPA relies on Safety Data Sheets (SDSs) and unsubstantiated industry statements to discount potentially relevant routes of exposure and does not provide access to the referenced SDSs.

EPA repeatedly asserts that exposure is minimal due to engineering controls and personal protective equipment (PPE) specified in Safety Data Sheets (SDSs) for PV29. For example:

Engineering controls for [PV29], as stated directly in the SDS, include adequate ventilation, processing enclosure, and local exhaust ventilation or other engineering controls. Personal protective equipment (PPE) includes safety glasses with side-shields, dust goggle under certain circumstances, chemical resistant impervious gloves, and particulate respirators if needed (BASF, 2017; CPMA, 2017a; Sun Chemical, 2017). Oral and inhalation exposures from downstream processors and users are possible; however, occupational exposures from these downstream users are likely to be limited due to the expected use of PPE (per Safety Data Sheet for [PV29]) and poor oral absorption due to low water solubility (BASF, 2017; CPMA, 2017a; Sun Chemical, 2017). (p. 22).

EPA repeatedly cites three sources to support its statements: BASF, 2017; CPMA, 2017a; Sun Chemical, 2017. However, the HERO database entries for the BASF SDS (“Paliogen® Red Violet K 5011: Material Safety Data Sheet”)⁹⁷ and the Sun Chemical SDS (“Safety Data Sheet: Violet

⁹⁷ PALIOGEN® RED VIOLET K 5011: MATERIAL SAFETY DATA SHEET, https://hero.epa.gov/hero/index.cfm/reference/details/reference_id/4081884 (last visited Jan. 14, 2019).

29”)⁹⁸ do not provide links to the respective SDSs. Without access to the referenced SDSs, it is not possible for EDF and other commenters to assess the accuracy of EPA’s claims regarding engineering controls and PPE.

Notably, EPA’s description qualifies the extent of use of PPE with the phrase “if needed.” This qualification calls into question whether the SDSs even describe use of this PPE as actually required, as recommended or otherwise optional, or as only required in limited circumstances. It is entirely unclear whether or how these SDSs describe the use of this PPE.

Given EPA’s failures to provide the SDSs and the limited explanation provided by EPA, EDF attempted to locate the SDSs on its own.

We identified an SDS from BASF dated October 2018 for Paliogen Red Violet K 5411⁹⁹ by locating “Pigment Violet 29” on BASF’s SDS search database;¹⁰⁰ however, we cannot be certain that it is the correct SDS given that the HERO database references a 2017 document for “Paliogen® Red Violet K 5011.”¹⁰¹ While the SDS we identified does list types of PPE recommended for use, it does not mention ventilation engineering controls, except what is recommended *in its absence*: “Breathing must be protected when large quantities are decanted without local exhaust ventilation.”¹⁰² This clearly indicates the potential for the chemical to be handled in settings where such engineering controls are not used – directly undermining EPA’s assumption of universal use. Furthermore, this SDS is for a mixture that includes a component with an occupational exposure limit (Kaolin, CASRN: 1332-58-7); it is therefore unclear whether an SDS for the use of PV29 alone or in other formulations, if they exist, would include the same precautions.

⁹⁸ SAFETY DATA SHEET: VIOLET 29, https://hero.epa.gov/hero/index.cfm/reference/details/reference_id/4121201 (last visited Jan. 14, 2019).

⁹⁹ BASF, Safety Data Sheet (Dec. 2018), https://worldaccount.basf.com/wa/NAFTA~en_US/Catalog/Pigments/doc4/BASF/PRD/30048503/.pdf?asset_type=msds/pdf&language=EN&validArea=REG_EU&urn=urn:documentum:ProductBase_EU:09007af880396198.pdf.

¹⁰⁰ BASF NORTH AMERICAN PIGMENTS, https://worldaccount.basf.com/wa/NAFTA~en_US/Catalog/Pigments/pi/BASF/Brand/paliogen (last visited Jan. 14, 2019).

¹⁰¹ Paliogen® Red Violet K 5011: Material Safety Data Sheet, https://hero.epa.gov/hero/index.cfm/reference/details/reference_id/4081884 (last visited Jan. 14, 2019) (emphasis added).

¹⁰² BASF, Safety Data Sheet p. 4 (Dec. 2018), https://worldaccount.basf.com/wa/NAFTA~en_US/Catalog/Pigments/doc4/BASF/PRD/30048503/.pdf?asset_type=msds/pdf&language=EN&validArea=REG_EU&urn=urn:documentum:ProductBase_EU:09007af880396198.pdf.

We found that Sun Chemical’s PV29 SDS is not accessible to the public, as the company only makes SDSs available to registered customers.¹⁰³

However, even if EPA had provided the SDSs, as it should have, the mere presence of language in an SDS is completely insufficient to conclude that engineering controls are actually in place or that personal protective equipment is actually utilized, or that they are sufficiently effective and protective. While SDSs are required to be provided as a hazard communication tool, the only legal requirement under OSHA is that the employer provide the SDS to employees and train them how to access and understand them.^{104,105,106} For example, the 2012 OSHA Hazard Communications Standard explains:

While the current HCS [Hazard Communication Standard] and this final standard require the provision of information on recommended control measures, including respiratory protection, personal protective equipment, and engineering controls, *there is no requirement for employers to implement the recommended controls*. An employer should use all available information when designing an appropriate protective program, but *a recommendation on a safety data sheet by itself would not trigger the need to implement new controls*.¹⁰⁷

Any legal requirement that SDS recommendations be followed would come through a separate requirement such as where there is an OSHA exposure limit for the substance. For PV29, one of the thousands of chemicals for which OSHA has no standard, there is no OSHA obligation beyond OSHA’s rarely used general duty clause for employers to provide any protection for workers.

In fact, there is significant evidence that SDSs are frequently not understood or followed. For example, Nicol et al. (2008) conducted a systematic search of the literature and identified serious problems with the use of SDSs even as hazard communication tools: they are often

¹⁰³ Sun Chemical’s website states “[r]egistered customers with existing logon credentials can visit the current site for information on how to access 3E Protect.” Sun Chemical, *Sun Chemical Upgrades Its Safety Data Sheet Online Platform* (Dec. 11, 2017), <https://www.sunchemical.com/sun-chemical-upgrades-its-safety-data-sheet-online-platform/>.

3E Protect is their SDS and chemical management platform. *Id.*

¹⁰⁴ OSHA Hazard Communication Standard, 77 Fed. Reg. 17574, 17788 (Mar. 26, 2012) (codified at 29 C.F.R. § 1910.1200(g)), https://www.osha.gov/FedReg_osha_pdf/FED20120326.pdf.

¹⁰⁵ OSHA, *Inspection Procedures for the Hazard Communication Standard (HCS 2012)* pp. 55-56 (Jul. 2015), https://www.osha.gov/OshDoc/Directive_pdf/CPL_02-02-079.pdf.

¹⁰⁶ OSHA, *Field Operations Manual* p. 5-2 (Aug. 2016), https://www.osha.gov/OshDoc/Directive_pdf/CPL_02-00-160.pdf.

¹⁰⁷ 77 Fed. Reg. at 17693 (emphasis added).

inaccurate, incomplete, and too technical for workers to understand.¹⁰⁸ The 2012 OSHA Hazard Communication Standard corroborates these findings.¹⁰⁹ For example, the Standard reports that “several studies show that employees do not understand approximately one-third of the safety and health information listed on SDSs prepared in accordance with the current standard” and that “[s]tudies also report that roughly 40% of persons reviewing SDSs found them difficult to understand.”¹¹⁰

Given the limitations of SDSs and given EPA’s authority to require that manufacturers and processors develop and provide actual data on workplace exposures, EPA cannot reasonably rely on SDSs to assume workers are adequately protected.

The HERO database entry for “CPMA, 2017a” does provide a link to a comment submitted by the Color Pigments Manufacturers Association, Inc. to EPA in March 2017.¹¹¹ While EPA does not specify what aspect of that letter it is citing, EPA appears to be relying on the following statement in the letter:

Domestic exposures and releases. As approximately 85-90% of Sun’s production of [PV29] production is consumed onsite to make other pigments, there is no offsite exposure to this production. [PV29] is not subject to an OSHA permissible exposure level but is regulated simply as a nuisance particulate. Workers are provided with gloves and dust masks.

Customers are advised that the product is not known to possess any hazardous properties and is properly handled as a nuisance dust. During the processing of the products into paint and plastics, customers are understood to handle the dry powder using modern engineering controls, primarily due to the presence of other industrial chemicals and not the pigment.¹¹²

¹⁰⁸ Anne-Marie Nicol, et al., *Accuracy, comprehensibility, and use of material safety data sheets: A review*, 51:11 AM. J. OF INDUS. MED. 861-76 (Jul. 2008), <https://onlinelibrary.wiley.com/doi/abs/10.1002/ajim.20613>.

¹⁰⁹ 77 Fed. Reg. at 17593-95, 17603.

¹¹⁰ *Id.* at 17603; see also OSHA, *Inspection Procedures for the Hazard Communication Standard (HCS 2012)* (Jul. 2015), https://www.osha.gov/OshDoc/Directive_pdf/CPL_02-02-079.pdf.

¹¹¹ CPMA Comment, <https://www.regulations.gov/document?D=EPA-HQ-OPPT-2016-0725-0006>.

¹¹² CPMA Comment, p. 6.

CPMA provides no references or evidence to support these statements, some of which appear to be little more than conjecture (e.g., “customers are *understood to* handle dry powder using modern engineering control ***.”).¹¹³

Finally, EPA completely ignores oral ingestion as a pathway of exposure – eliciting the “standard workplace practices prohibit eating and smoking in manufacturing facilities” and asserting that any minimal incidental oral exposure would be avoided by the use of personal protective equipment. EPA’s only reference for this statement is a personal communication with Robert C. Mott with Sun Chemical Corporation. Details on the deficiencies in EPA’s assessment of oral exposures are provided in subsection ii.B. of this section.

iv. EPA discounts exposure based on use of PPE, failing to acknowledge its real-world limitations.

EPA hand-waves away the oral and dermal routes of exposure, at least in part by assuming that PPE is always utilized and effective:

- “[D]ermal absorption is estimated to be negligible for the neat material because it is a solid of high molecular weight, *use of PPE*, and due to poor absorption in solution based on low solubility.” (pp. 21-22) (emphasis added).
- “In addition, minimal incidental [*sic*] oral exposures are avoided by the use of personal protective equipment (PPE).” (p. 22).

However, given the major real-world limitations of PPE, EPA should not assume efficacy of these measures without empirical data. The extent of use and efficacy of PPE and the ability to predict and control individual behavior are variable and uncertain. See section 14 below for further detail on real world limitations of PPE.

Use of PPE should only be considered sufficient to exclude an exposure scenario if robust and reliable data are available to document actual use and efficacy across all relevant settings and over time. EPA has not identified any such data here.

Furthermore, there can be no expectation that consumers exposed to PV29, for example, when using an artistic paint, will wear any personal protective gear at all.

B. EPA’s rationale for dismissing consumer and general population exposures does not even qualify as cursory.

As a result of the lack of any actual data, EPA states it was able to conduct only a “*qualitative* assessment of potential environmental, consumer, and general population exposures.” (p. 5).

¹¹³ *Id.*

Beyond assertions of low exposure invoking the chemical's physical-chemical properties, EPA's qualitative exposure assessment is largely a set of assertions, with no actual analysis or data, that concludes with the claim that consumers and the general population "are *expected* to be exposed at concentrations lower than worker exposures." (p. 32) (emphasis added).

TSCA section 6(b)(4)(F)(iv) requires that, in conducting a risk evaluation, EPA "shall *** take into account, where relevant, the likely duration, intensity, frequency, and number of exposures under the conditions of use of the chemical substance." Duration, intensity, frequency, and number are all quantitative terms, and EPA has provided no data or analysis characterizing any of these parameters with respect to environmental, consumer, and general population exposures. As a result, EPA has failed to meet TSCA's requirements for risk evaluations.

The only remotely "quantitative" element in EPA's entire discussion of potential consumer and general population exposures is the manufacturer's asserted estimate for water discharges from its manufacturing facility. In section 3.B.i., we discuss why this value is wholly unreliable and insufficient.

In addition, EPA's conclusions about environmental, consumer, and general population exposures are not supported by substantial evidence because, as far as the draft risk evaluation explains, these exposures are based solely on EPA's "expectations" that exposure will be lower than workplace exposures. EPA has not pointed to any actual evidence or analysis supporting this conclusion. Moreover, by failing to exercise its information authorities to obtain information about these exposures, EPA has failed to consider reasonably available information or comply with TSCA § 26(h), including the duty to use the best available science.

C. EPA's dismissal of any concerns about exposures of vulnerable subpopulations distorts the law's definition and fails to meet TSCA's requirements.

EPA begins section 3.4.1 of the draft risk evaluation by faithfully citing TSCA's requirement that EPA evaluate risks to "potentially exposed or susceptible subpopulations," and then accurately transcribes the law's definition of that term. EPA then proceeds to ignore this mandate and distort the definition.

EPA states that "[I]n developing the risk evaluation, the EPA analyzed the reasonably available information to ascertain whether some human receptor groups may have greater exposure or susceptibility than the general population to the hazard posed by a chemical. The results of the available human health data, which reported no effects for all routes of exposure (oral, dermal, and inhalation), indicating that *there is no evidence of increased susceptibility for any single group relative to the general population.*" (p. 24) (emphasis added).

Elsewhere in these comments we discuss at length the inadequacies of the data EPA has relied on. What EPA fails to mention here is that all but one of the human health studies EPA has *did not look for increased susceptibility* of various subpopulations. The one study that it might be argued did consider this factor – a screening-level reproduction and developmental toxicity study using OECD Guideline 421 – *cannot* be used to conclude “no effect,” based on EPA’s own guidance, as well as authoritative international guidance on this very test (see section 3.D.i. of these comments for a discussion of why it cannot). One cannot rationally conclude that there is no greater susceptibility when studies examining susceptibility are lacking.

Astoundingly, EPA is willing to conclude that a lack of effects in inadequate studies translate into no “increased susceptibility for any single group relative to the general population,” which flies in the face of science-based decision-making and fails to meet TSCA’s mandate that EPA actually determine whether a chemical presents risk to potentially exposed or susceptible subpopulations.

EPA then resorts to an exposure argument: “[T]he exposure calculation for workers is based on full immersion and is *therefore protective of all other subpopulations*, such as children and pregnant women in the general population, which are not expected be exposed to [PV29] at similarly high levels.” (p. 24) (emphasis added).

This assertion – again made without any actual data or analysis – ignores the potential for increased susceptibility of certain subpopulations. Infants, children, pregnant women and the elderly are identified in TSCA as vulnerable subpopulations based mainly on their higher susceptibility, not higher exposure, so this argument even if it were supported is largely irrelevant. Even if EPA had demonstrated – which it has not – that a healthy adult worker does not face unreasonable risk from workplace exposures to PV29, and even if EPA had demonstrated – which it has not – that such workers always face greater exposure to PV29 than other subpopulations, EPA could not conclude that PV29 presents no unreasonable risk to those other subpopulations. EPA’s argument contravenes the very purpose of TSCA’s explicit provisions regarding risks to vulnerable subpopulations.

Given the absence of any reliable evidence addressing susceptibility, EPA’s conclusions about susceptible subpopulations are not supported by substantial evidence. In addition, by failing to use its information authorities to obtain information on susceptibility, EPA has violated its duties to consider reasonably available information and use the best available science.

D. EPA’s rationale for adopting a sentinel over aggregate exposure assessment approach is inadequate and also distorts the meaning of sentinel exposure assessment.

EPA asserts: “As a result of the *limited nature of all routes of exposure* resulting from the conditions of use of [PV29], a consideration of aggregate exposures of [PV29] was deemed not

to be appropriate for this risk evaluation.” (p. 24) (emphasis added). Instead, EPA states it develop[ed] a screening-level analysis of sentinel exposure (dermal and inhalation) to workers (the population with the *theoretical highest anticipated exposure*).” (p. 14) (emphasis added). This rationale is inconsistent with EPA’s own definitions of aggregate and sentinel exposure and does not reflect a science-based approach to exposure assessment. 40 C.F.R. § 702.33.

First, whether or not various routes of exposures are limited in nature or not is not a rational basis for selecting a sentinel approach. EPA needs to be able to demonstrate that in selecting a subset of exposures to be sentinels, it is accounting for all relevant exposures of individuals within the population or the environment. EPA’s assertion that it need only account for the highest anticipated exposure ignores the potential that multiple sources of exposure, even if each is “limited,” may expose the same entities and that the combination of those exposures may engender a risk greater than the risk from the highest exposure alone. A worker exposed to PV29 at work may also be exposed to the chemical at home, e.g., through exposure to consumer products containing it, or as a result of its presence in air, water, food, etc. EPA’s approach also ignores the potential that a lower exposure may result in greater risk to a member of a vulnerable subpopulation.

Indeed, EPA’s “screening-level analysis of sentinel exposure (dermal and inhalation) to workers” is inadequate even to assess the risk to a worker (even ignoring all other potential exposures that worker may experience). EPA did not consider or even mention the obvious and very real potential that a worker handling PV29 might be exposed by both inhalation and dermal routes.

EPA also misapplies the sentinel approach. EPA seems to believe the approach entails identifying the *single* highest exposure across all possible routes and subpopulations, that is, that it can select one sentinel exposure to represent all exposures.

Yet EPA’s own definition of “sentinel exposure” in its Risk Evaluation Rule does not support this approach. EPA defined the term to mean “the exposure to a single chemical substance that represents the plausible upper bound of exposure relative to all other exposures within a broad *category of similar or related exposures*.” 40 C.F.R. § 702.33 (emphasis added). A sentinel exposure can only stand in for those exposures that are sufficiently similar or related to be represented by the sentinel exposure for that category of exposures. Other sentinel exposures need to be identified for other categories of exposure that are less similar or related.

EPA’s worker exposure assessment looked only at manufacturing workers handling the chemical in a solid/powder form. How can that possibly represent downstream workers handling a solution of the chemical or using a commercial product containing it? How could it represent the exposure of an artist using a violet paint, or an auto body worker spray-painting a car after hammering out a dent? These exposures are not similar or related to exposures of

manufacturing workers handling the chemical in a solid/powder form. EPA has provided no reasoning or explanation for how its use of a single sentinel value here complies with its regulatory definition of sentinel exposure.

Only by identifying multiple sentinel exposures for various categories of exposure can EPA reasonably evaluate a chemical substance's overall risk, which is what TSCA mandates EPA to do. Like aggregate exposure assessment, a sentinel exposure assessment methodology can be used, when appropriate, for accounting for the full range of relevant exposures to an entity. The sentinel exposures for different categories can be combined to account for the full range of relevant exposures.

EPA's decision to conduct only a screening-level assessment of certain manufacturing worker exposures and then claim that it can serve as the sole sentinel exposure for all other human exposures – all other workers, consumers, the general population, and all vulnerable subpopulations – is scientifically corrupt and fails to meet TSCA's mandates.

5. EPA's draft risk evaluation contains serious deficiencies with respect to characterizing potential hazards and risks to human health.

As discussed in section 3.D., EPA has insufficient information to characterize hazards, exposures, and risks to human health, and its sweeping statements of no concern from exposure to PV29 are wholly inappropriate. Beyond the lack of information, EPA's human health risk characterization for PV29 has a number of serious deficiencies.

A. EPA's calculation of the potential dose rate (PDR) uses a NIOSH inhalation exposure rate that is over 40 years old and an air concentration for PV29 dust that lacks any empirical basis.

EPA calculates a potential dose rate value (PDR) of 7.5 mg/day using a default respiration rate of 1.25 m³/hour and a "manufacturer-provided" workplace dust concentration of 0.5 mg/m³. The default respiration rate of 1.25 m³/hour appears to date back to a 1976 National Institute of Occupational Health (NIOSH) document titled "A Guide to Industrial Respiratory Protection," making this default value over 40 years old.¹¹⁴ EPA provides no evidence that this value remains valid, and must provide empirical evidence to support the use of this value in the final risk evaluation. The "manufacturer-provided" workplace PV29 dust concentration of 0.5 mg/m³ is based on a personal communication with a single representative from the sole manufacturer of PV29 in the United States, Sun Chemical (Mott 2017a). As discussed in section 3.B.ii.a., EPA does not appear to have any measured data to support this value.

¹¹⁴ NIOSH, A GUIDE TO INDUSTRIAL RESPIRATORY PROTECTION (1976).

B. EPA fails to include all necessary uncertainty factors in calculating the benchmark margins of exposure for worker inhalation and dermal exposures.

EPA fails to include necessary uncertainty factors in its calculations of benchmark margins of exposure (BMOE) for risks to workers from inhalation and dermal exposure. The BMOE EPA derives is 100, resulting from the multiplication of two uncertainty factors—10 for interspecies variation (UF_S) and 10 for intraspecies variation (UF_H). However at a minimum, EPA should have included two additional uncertainty factors for: 1) “uncertainty in extrapolating from data obtained in a study with less-than-lifetime exposure to lifetime exposure (i.e., extrapolating from subchronic to chronic exposure);” and 2) “the uncertainty associated with extrapolation from animal data when the database is incomplete.”^{115,116}

In chemical risk assessment, uncertainty factors are default values applied in the characterization of chemical hazard and risk to account for uncertainties in the evidence base (e.g., using animal data to characterize effects in humans) and expected variability in the population (e.g., differences in underlying health conditions). As described in the National Academy of Sciences report, *Science and Decisions: Advancing Risk Assessment*:

[Uncertainty] factors are used to adjust for differences in individual human sensitivities, for humans’ generally greater sensitivity than test animals’ on a milligrams-per-kilogram basis, for the fact that chemicals typically induce harm at lower doses with longer exposures, and so on. At times, the factors have been termed safety factors, which is especially problematic given that they cover variability and uncertainty and are not meant as a guarantee of safety.¹¹⁷

With regard to the subchronic to chronic uncertainty factor, the EPA Risk Assessment Forum notes in its 2002 report, *A Review of the Reference Dose and Reference Concentration Processes*:

[D]uration adjustment currently in use is the application of a UF when only a subchronic duration study is available to develop a chronic reference value such

¹¹⁵ U.S. EPA Risk Assessment Forum, *A Review Of The Reference Dose And Reference Concentration Processes* p. 4-38 (Dec. 2002), <https://www.epa.gov/sites/production/files/2014-12/documents/rfd-final.pdf>.

¹¹⁶ REFERENCE DOSE (RFD): DESCRIPTION AND USE IN HEALTH RISK ASSESSMENTS, <https://www.epa.gov/iris/reference-dose-rfd-description-and-use-health-risk-assessments#1.4> (last visited Jan. 14, 2019).

¹¹⁷ NAT’L RESEARCH COUNCIL, *SCIENCE AND DECISIONS: ADVANCING RISK ASSESSMENT* at chp. 5, p. 132 (2009), <https://www.ncbi.nlm.nih.gov/pubmed/25009905>.

as the RfC or the RfD (U.S. EPA, 1994). A default value of 10 for this UF is applied to the NOAEL/LOAEL or BMDL/BMCL from the subchronic study on the assumption that effects from a given compound in a subchronic study occur at a 10-fold higher concentration than in a corresponding (but absent) chronic study.¹¹⁸

The OECD-421 study EPA uses to calculate margins of exposure for dermal and inhalation exposure to workers is of short duration, and is not a chronic study. In the absence of chronic data, EPA should apply an additional uncertainty factor of 10.

With regard to the database uncertainty factor, the same report notes:

The database UF is intended to account for the potential for deriving an underprotective RfD/RfC as a result of an incomplete characterization of the chemical's toxicity. In addition to identifying toxicity information that is lacking, review of existing data may also suggest that a lower reference value might result if additional data were available. Consequently, in deciding to apply this factor to account for deficiencies in the available data set and in identifying its magnitude, the assessor should consider both the data lacking and the data available for particular organ systems as well as life stages.¹¹⁹

The characterization of PV29's human health toxicity is clearly incomplete as discussed extensively in section 3.D. EPA should apply an additional uncertainty factor of 10 to account for PV29's woefully incomplete database.

Application of just one of these uncertainty factors exceeds EPA's margin of exposure calculation for worker dermal exposure. Applying both additional uncertainty factors would result in a benchmark margin of exposure of 10,000—a value that exceeds by nearly thirty-fold EPA's margin of exposure for worker dermal exposure. EPA cannot conclude that PV29 does not present an unreasonable risk to workers.

There are additional uncertainty factors that are relevant and could also reasonably be applied, including factors to account for the uncertainty in extrapolating from a LOAEL to NOAEL and for

¹¹⁸ U.S. EPA Risk Assessment Forum, *A Review Of The Reference Dose And Reference Concentration Processes* p. 4-45 (Dec. 2002), <https://www.epa.gov/sites/production/files/2014-12/documents/rfd-final.pdf>.

¹¹⁹ *Id.* at p. 4-44.

deficiencies in the database related to children’s health risks.^{120,121} Further uncertainty is introduced by EPA’s route-to-route extrapolation—its use of an oral toxicity study to characterize potential inhalation and dermal effects and risks.¹²² (pp. 29-30).

The excessive extent of uncertainty associated with the hazard evidence base for PV29—let alone data deficiencies with regard to exposure—means EPA has absolutely no basis to conclude that PV29 does not present unreasonable risk.

C. EPA has failed to consider multiple routes of exposure to PV29 in its characterization of workplace risk.

The margin of exposure for dermal exposure to workers (361) is only 3-4 times higher than EPA’s presumed BMOE (100) even without including the additional uncertainty factors just discussed or other adjustments needed to address concerns about EPA’s assumptions on dermal absorption (see sections 3.B.ii. and 4.A.ii.). It is important to reiterate that EPA assumed worker exposure would only occur to PV29 in the form of a dry powder. (pp. 23, 30). EPA did not include PV29 exposure to workers from formulations of PV29 (e.g., paints, inks, dyes) and ignored potential hand-to-mouth worker exposure based on a claimed prohibition on eating, drinking, and smoking in manufacturing facilities. (p. 22).

Even assuming 100% compliance with such prohibitions—and that all workers thoroughly wash before eating, drinking, or smoking—no other scenarios, including those where such prohibitions are not in place (e.g., consumer uses, including artists) or they may not be complied with (e.g., downstream processors and users), were considered because EPA simply assumed those exposures would be lower.

As discussed throughout these comments, EPA should accurately account for all routes and scenarios of exposure to PV29.

¹²⁰ *Id.*

¹²¹ U.S. EPA, *Consideration of the Fqpa Safety Factor and Other Uncertainty Factors in Cumulative Risk Assessment of Chemicals Sharing a Common Mechanism of Toxicity* (Feb. 2002), <https://www.epa.gov/sites/production/files/2015-07/documents/apps-10x-sf-for-cra.pdf>.

¹²² Rennen, MA, et al., *Oral-to-inhalation route extrapolation in occupational health risk assessment: a critical assessment*, 39:1 REG. TOXICOLOGY & PHARMACOLOGY 5-11 (2004), <https://www.ncbi.nlm.nih.gov/pubmed/14746775>.

6. EPA has dropped all mention of a residual of PV29: naphthalimide.

In the problem formulation, EPA identifies naphthalimide as a residual of PV29 as manufactured. EPA describes naphthalimide in the problem formulation as follows:

There are no known by-products or degradation products resulting from the manufacture of [PV29]. There is a residual amount of naphthalimide, the starting material used in the fusion, at approximately 1% (Sun Chemical, 2017a). Per robust study summary reports from the ECHA Database, the hazard profile of naphthalimide is low for human health and environmental receptors (ECHA, 2017a). Based on the minimal amount of naphthalimide released from manufacturing and low hazard, EPA will not conduct any further analysis of the naphthalimide residual associated with [PV29] production.¹²³

This is an entirely inadequate review of the potential risks associated with naphthalimide, based solely on industry information provided to and not evaluated by ECHA. It certainly does not comply with TSCA § 26(h) nor represent use of the best available science. Moreover, EPA has dropped all mention of naphthalimide in the draft risk evaluation. This is a significant, arguably deceitful, omission. By failing to adequately analyze naphthalimide, EPA has overlooked an important aspect of the problem and engaged in arbitrary and capricious analysis.

EPA must conduct a much more extensive review of the extent of presence and the potential risks of naphthalimide in PV29 before reaching a decision to do no further analysis. The implications of EPA's dismissal of any need to evaluate the naphthalimide residual are significant. EPA has indicated elsewhere that it will not analyze exposures and risks of chemicals only present incidentally (e.g., as an impurity or byproduct) (e.g., see 1,4-dioxane problem formulation¹²⁴) when preparing risk evaluations, suggesting that the appropriate time for such evaluation may be when the parent substance is undergoing risk evaluation. EDF strongly disagrees that EPA can disregard a chemical's presence as an impurity or byproduct when evaluating the chemical, and our concerns are only affirmed and increased by EPA's cursory dismissal of the naphthalimide residual associated with PV29.

7. EPA's application of systematic review in the PV29 risk evaluation is seriously flawed.

EPA's Risk Evaluation Rule requires that EPA use a systematic review approach when weighing evidence, 40 C.F.R. § 702.33, but EPA's approach to systematic review in the PV29 risk

¹²³ PV29 Problem Formulation, p. 14.

¹²⁴ U.S. EPA, *Problem Formulation of the Risk Evaluation for 1,4-Dioxane* (May 2018), <https://www.regulations.gov/document?D=EPA-HQ-OPPT-2016-0723-0064>.

evaluation violates numerous basic principles of systematic review. EPA thus violates its own regulation.

A. EPA has failed to develop an upfront systematic review protocol for PV29.

Violating a basic principle of systematic review, EPA failed to establish an upfront protocol for PV29. As EDF noted in our previous comments¹²⁵ on EPA's *Application of Systematic Review in TSCA Risk Evaluations*¹²⁶ document (hereafter TSCA systematic review document), EPA has acknowledged the importance of protocol development to the systematic review process. In the TSCA systematic review document, EPA states:

Protocol development is intended to *pre-specify* the criteria, approaches and/or methods for data collection, data evaluation and data integration. It is important to plan the systematic review approaches and methods *in advance* to reduce the risk of introducing bias into the risk evaluation process. (p. 19) (emphases added).

This statement aligns with authoritative sources on systematic review, including Cochrane and the National Academy of Sciences (NAS). The Cochrane Handbook states:

Publication of a protocol for a review prior to knowledge of the available studies reduces the impact of review authors' biases, promotes transparency of methods and processes, reduces the potential for duplication, and allows peer review of the planned methods (Light 1984).¹²⁷

Similarly, the 2014 NAS review of EPA's IRIS program states:

When the systematic review questions have been specified, a protocol for each review should be developed. A protocol makes the methods and the process of the review transparent, can provide the opportunity for peer review of the methods, and stands as a record of the review. The protocol also minimizes bias

¹²⁵ EDF Comments on Application of Systematic Review in TSCA Risk Evaluations p. 8, <https://www.regulations.gov/document?D=EPA-HQ-OPPT-2018-0210-0077>.

¹²⁶ U.S. EPA, *Application of Systematic Review in TSCA Risk Evaluations* (May 2018), https://www.epa.gov/sites/production/files/2018-06/documents/final_application_of_sr_in_tsca_05-31-18.pdf.

¹²⁷ The Cochrane Collaboration, *Cochrane Handbook for Systematic Reviews of Interventions* at pt. 1, chp. 2.1 (Mar. 2011), <http://handbook-5-1.cochrane.org/>.

in evidence identification by ensuring that inclusion of studies in the review does not depend on the findings of the studies.¹²⁸

Despite EPA's acknowledgment of the importance of upfront protocol development, the agency has not developed such a protocol for PV29. In the TSCA systematic review document, EPA states that – for the first 10 chemicals – “protocol development is staged in phases while conducting the assessment work,” pointing to a compressed timeline as justification for not producing a pre-established protocol. (p. 19). However, the draft risk evaluation for PV29 has been released without any indication that a protocol was in fact developed for this chemical as the assessment was conducted; no such protocol has been made publicly available.

EDF reiterates that EPA must develop pre-established protocols for each chemical undergoing risk evaluation and that insufficient time is not an acceptable justification for EPA's failure to develop protocols for the first 10 chemicals undergoing risk evaluation. Upfront protocol development is a fundamental feature of systematic review, which EPA by regulation has explicitly included in its definition of the weight of the scientific evidence. EPA must develop comprehensive protocols, make them publicly available, and subject them to public comment – prior to initiating subsequent steps of the risk evaluation process.

B. EPA's numerical scoring approach is flawed and opaque.

As described in detail in prior comments¹²⁹ on EPA's TSCA systematic review document (which we incorporate by reference here), the numerical scoring approach that EPA has adopted for individual study evaluation is entirely inconsistent with best practices in systematic review. These authoritative sources, including Cochrane and the National Academies' Institute of Medicine (IOM), explicitly advise against the use of scoring to evaluate studies, as this approach is not transparent and has been deemed unreliable by empirical evidence. EDF maintains that the numerical scoring approach that EPA has developed for its systematic review process is fundamentally inappropriate and urges EPA to do away with this strategy and replace it with an approach that reflects best practices in systematic review.

While the disparity between EPA's study evaluation approach and those recommended by leading systematic review experts provides ample reason for EPA to abandon its scoring

¹²⁸ Nat'l Research Council, *Review of EPA's Integrated Risk Information System (IRIS) Process* at chp. 3, p. 36 (2014), <https://www.ncbi.nlm.nih.gov/books/NBK230069/>.

¹²⁹ EDF Comments on Application of Systematic Review in TSCA Risk Evaluations pp. 12-17, <https://www.regulations.gov/document?D=EPA-HQ-OPPT-2018-0210-0077><https://www.regulations.gov/document?D=EPA-HQ-OPPT-2018-0210-0077>.

strategy in favor of empirically-supported best practices, the draft risk evaluation for PV29 further demonstrates the flaws of EPA’s current methodology.

i. EPA’s application of its scoring approach is not sufficiently transparent.

In its TSCA systematic review document, EPA’s example data evaluation scoring sheets include a “Reviewer’s comments” field for each study metric, which represents space for the reviewer to “Document concerns, uncertainties, limitations, and deficiencies and any additional comments that may highlight study strengths or important elements such as relevance.” EPA notes that “a reviewer is strongly encouraged to provide a comment for metrics categorized as *Medium* or *Low* to improve transparency.” (p. 35). However, the scoring sheets for PV29 do not contain reviewer comments or any justification for EPA’s metric score determinations.¹³⁰ EPA must make publicly available all reviewers’ comments as well as any other materials related to the score determinations for individual study metrics and overall study scores.

ii. EPA’s scoring approach fails to adequately reflect study flaws.

One of the key deficiencies of study evaluation strategies that assign overall scores to individual studies is that those overall scores can mask flaws that might otherwise cause a study’s conclusions to be questioned.¹³¹ This is occurring in EPA’s scoring approach, which averages together several study metric scores to produce an overall study score.

For example, EPA evaluated two BASF acute inhalation toxicity studies (BASF 1975a; BASF 1978a). The summaries BASF prepared for the dossier it submitted to ECHA for these two studies both indicate that the studies are “not reliable” because of use of an “unsuitable test system as the inhalation hazard test is insufficient for non-volatile substances.”¹³² EPA’s scoring

¹³⁰ U.S. EPA, *C.I. Pigment Violet 29 (81-33-4) Systematic Review: Supplemental File for the TSCA Risk Evaluation* (Dec. 2018), https://www.epa.gov/sites/production/files/2018-12/documents/12.04.18_update_-_22_draft_pv29_systematic_review_supplemental_file.pdf.

¹³¹ Greenland S. & O'Rourke K, *On the bias produced by quality scores in meta-analysis, and a hierarchical view of proposed solutions*, 2:4 *BIostatistics* 463-71 (2001), <https://www.ncbi.nlm.nih.gov/pubmed/12933636>.

¹³² BASF, Acute Inhalation Toxicity Study Summary (1976), <https://www.regulations.gov/contentStreamer?documentId=EPA-HQ-OPPT-2018-0604-0002&attachmentNumber=3&contentType=pdf>; BASF, Acute Inhalation Toxicity Study Summary (1978), <https://www.regulations.gov/contentStreamer?documentId=EPA-HQ-OPPT-2018-0604-0002&attachmentNumber=4&contentType=pdf>.

sheets¹³³ indicate that these studies were scored “low” for several metrics, including “Preparation and storage of test substance,” which for inhalation studies corresponds with a determination that “there is reason to question the validity of the method used for generating the test substance.”¹³⁴ A “low” score indicates that the study metric deficiency is likely to have a substantial effect on the study results. However, because many of the other study metrics were scored “high”, the overall study quality – which is the averaged across all study metrics – was assigned “medium.” Thus, the flaws that caused these two studies to be deemed “not reliable” in their summaries submitted to ECHA are simply averaged away in EPA’s scoring framework.

The example above suggests that similar flaws that could bias studies are not appropriately captured using EPA’s current methodology. It also suggests that EPA may be including critically deficient studies in its reviews. While the two BASF acute inhalation toxicity studies were scored “medium” under EPA’s TSCA systematic review study evaluation approach, it seems likely that these studies should in fact have been scored “unacceptable” and therefore excluded from the review altogether. In their summaries, these studies were deemed unreliable due to an “unsuitable test system.” This would also appear to correspond with a score of “unacceptable” for EPA’s “Preparation and storage of test substance” metric for animal toxicity studies, which states that “[f]or inhalation studies *** the method used is atypical or inappropriate” (p. 193); yet these studies were given scores of “low” for this metric.

The fact that these two studies were not eliminated from the review appears to be in conflict with EPA’s scoring methodology, but this discrepancy is particularly problematic because EPA then used these two studies to conclude that PV29 is not associated with acute or chronic inhalation toxicity. In section 4.2 of the draft risk evaluation, which reviews human health hazards, EPA “concludes that [PV29] presents a low hazard to human health across all routes of exposure.” (p. 25). EPA then lists the study types for which it received full study reports, stating that because these reports did not find adverse effects, PV29 presents low hazard to humans:

These full study reports concluded that no adverse effects were observed for all routes of exposure (oral, dermal, inhalation), nor were dermal or eye irritation effects reported. As a result, the EPA concludes that [PV29] presents a low hazard to human health. (p. 25).

¹³³ U.S. EPA, *C.I. Pigment Violet 29 (81-33-4) Systematic Review: Supplemental File for the TSCA Risk Evaluation* (Dec. 2018), https://www.epa.gov/sites/production/files/2018-12/documents/12.04.18_update_-_22_draft_pv29_systematic_review_supplemental_file.pdf.

¹³⁴ TSCA Systematic Review, p. 193.

Among the list of studies that EPA references in support of its conclusion, only two directly measure inhalation toxicity. Though EPA does not state this explicitly in section 4.2, it is clear in Table_Apx C-1, (p. 41, app. D), that these studies upon which EPA relied to conclude that inhalation of PV29 does not produce adverse effects are the two acute inhalation toxicity studies conducted – and dismissed due to their unreliable methods – by BASF.

The issue is further exacerbated by the fact that the full studies have not been made publicly available and that reviewers' comments documenting the rationale for the scores given to these studies by EPA were also not made public. Based on the available information, it appears that EPA has concluded that PV29 is not associated with inhalation toxicity based on two studies that were inadequately designed to test even for acute inhalation toxicity for this type of substance, as determined by the owners of these studies.

EPA itself has stated that the studies are consistent with their summaries that describe these studies as “unreliable.” (p. 8). There is an inherent inconsistency between EPA’s ranking of these studies as “medium” and EPA’s stated agreement with the data owner’s characterization of them as “unreliable.” EPA’s reasoning regarding these studies thus is arbitrary and capricious, with EPA adopting contradictory positions on the quality of these studies.

C. EPA has failed to adequately describe its approach to the data integration phase of its review process.

EPA has failed to provide a pre-established framework for its approach to data integration in the TSCA systematic review document and here again in the PV29 draft risk evaluation, despite the fact that EPA’s own definition of weight of the scientific evidence for TSCA risk evaluations states that a pre-established protocol should be used. Citing the risk evaluation rule in the TSCA systematic review document, EPA states:

Within the TSCA risk evaluation context, the weight of the scientific evidence is defined as “a systematic review method, applied in a manner suited to the nature of the evidence or decision, that uses a *pre-established protocol* to comprehensively, objectively, transparently, and consistently identify and evaluate each stream of evidence, including strengths, limitations, and relevance of each study and *to integrate evidence* as necessary and appropriate based upon strengths, limitations, and relevance.” (p. 18) (emphases added).

Without a pre-established framework for data integration, there is no way to transparently ensure that the data integration process is occurring consistently across all chemical risk

assessments; there is also a much greater risk of introducing reviewer bias into individual assessments when the protocol has not been pre-defined.

Additionally, EPA failed to develop a data integration protocol for PV29, despite stressing the importance of doing so in its TSCA systematic review document:

Protocol Development is intended to pre-specify the criteria, approaches and/or methods for data collection, data evaluation and data integration. It is important to plan the systematic review approaches and methods in advance to reduce the risk of introducing bias into the risk evaluation process. (p. 19).

EPA's description of its approach to data integration in its draft risk evaluation for PV29 is severely lacking. Especially given that EPA did not include details about data integration in its TSCA systematic review document, the agency should have provided information about the upfront approach that it followed to integrate evidence for PV29 in the draft risk evaluation. EPA itself acknowledged this, stating in its TSCA systematic review document that the agency "will provide further details about the data integration strategy along with the publication of the draft TSCA risk evaluations." (p. 27). However, EPA has not met this stated goal. Instead, the Data Integration section of the draft risk evaluation for PV29 simply states that "EPA analyzed and synthesized" available evidence, without specifying its strategy for data integration. The discussion of evidence integration that EPA provides also does not detail how individual study scores were used in this step of the review process for PV29. EPA needs to address data integration in the final risk evaluation for PV29.

The absence of a general framework for data integration and the lack of details regarding the approach taken and results of the data integration process for PV29 will be even more problematic for future risk evaluations where there is significantly more information that will need to be integrated. EPA should immediately describe its general approach to evidence integration, referring to established systematic review approaches, including the OHAT, Navigation Guide, and IRIS methods. EPA must detail its specific approach to evidence integration, including how individual study evaluation informs its conclusions, in protocols developed for each chemical undergoing risk evaluation.

D. EPA inappropriately relied on unsubstantiated industry correspondence to inform its conclusions about exposure likelihood for PV29.

The TSCA systematic review framework includes criteria for evaluating studies on exposures, including monitoring, survey-based, and epidemiological data, among other data types.

However, in this draft risk evaluation, EPA relies heavily on industry correspondences (Mott 2017a, Mott 2017b) to inform conclusions about the likelihood of exposure to PV29.

Several references initially identified as on-topic during a preliminary title and abstract screen were excluded after further screening based primarily on lack of information specific to [PV29], due to the limited nature of these references, but were utilized in the assessment. This included exposure and engineering citations, i.e., *correspondences with industry*, considered to be on-topic and *used to inform the likelihood of exposure*. (p. 18) (emphases added).

EPA then notes that these sources were not evaluated using its TSCA systematic review approach, stating that “formal data quality evaluation of these references according to the *Application of Systematic Review in TSCA Risk Evaluations* (U.S. EPA, 2018a) was not conducted.” (p. 18). EPA justifies this by saying that these sources do not fit within its current TSCA systematic review framework:

The nature of these documents is such that the current framework as outlined in the *Application of Systematic Review in TSCA Risk Evaluations* (U.S. EPA, 2018a) is not well suited for the review of these types of references. (p. 18).

EPA does not, however, explain whether or not this means that the TSCA systematic review framework should be modified, whether this type of information will be treated similarly in future assessments, or if personal communications should even be relied on at all. Instead, EPA states that these references were “individually addressed” without providing any details about what this means or why this approach is justified.

Given that industry correspondences were not evaluated under EPA’s TSCA systematic review framework, the conclusions about exposure to PV29 in this draft risk evaluation are determined to a very large extent by unsubstantiated and unreviewed personal communications, thereby undermining the purpose of using systematic review to minimize bias in chemical assessments. Moreover, EPA has violated its own Risk Evaluation Rule by giving weight to evidence *without* subjecting it to systematic review. See 40 C.F.R. § 702.33. If these personal communications cannot withstand systematic review, then it is arbitrary for EPA to rely on them so heavily (or at all) in its draft risk evaluation. Moreover, selectively applying systematic review when convenient and declining to apply it when inconvenient is the definition of arbitrary and capricious decision-making. EPA has provided no reasoned explanation for how it can weigh this information without systematic review.

EPA should not rely on anecdotal information sources to inform overall risk determinations. EPA should also prepare a final risk evaluation for PV29 that does not rely on these types of information sources. Instead, EPA should obtain reliable data and information that can withstand scrutiny under a legitimate systematic review approach.

E. Fundamental flaws associated with EPA’s review of PV29 demonstrate the need for external peer review of the TSCA systematic review document.

EPA has made a risk determination that is ostensibly based on what the agency calls a systematic review of the available evidence, but the reality is that its review process ignored or downplayed the unreliability of acute inhalation toxicity studies that were rejected by their own data owners, using these flawed studies to claim that PV29 is not associated with inhalation toxicity. Worse yet, EPA has relied heavily on anecdotal industry sources that were not even subject to its own deeply flawed review process to conclude that the likelihood of exposure to PV29 is minimal. These problems underscore the fundamental deficiencies of the approach laid out in EPA’s TSCA systematic review document – in particular the numerical scoring strategy EPA has used to evaluate individual study quality.

In order to prevent these shortcomings from plaguing future chemical risk evaluations, EPA should immediately initiate an external, independent peer review of its TSCA systematic review document from an authoritative scientific body and subsequently use this feedback to change its review process to align with best practices in systematic review. EDF believes the appropriate entity to undertake this peer review is the NAS.

8. TSCA requires EPA to analyze whether a chemical substance, as a whole, presents an unreasonable risk, and EPA does not have discretion to ignore conditions of use, exposures, or hazards.

In its prior scoping documents, EPA stated that it had authority to exclude conditions of use. In our comments on those documents, EDF explained that this approach is foreclosed under the statute, and EDF incorporates those arguments here.¹³⁵ In the problem formulations, EPA stated that it had authority to also exclude hazards and exposures under the condition of use. In our comments on those documents, EDF explained that this approach is foreclosed under the statute, and EDF incorporates those arguments here.¹³⁶

¹³⁵ EDF Comments on Ten Scopes under the Toxic Substances Control Act, pp. 4-11, <https://www.regulations.gov/document?D=EPA-HQ-OPPT-2016-0725-0041>.

¹³⁶ EDF Comments on Ten Problem Formulations under the Toxic Substances Control Act, pp.13-19, <https://www.regulations.gov/document?D=EPA-HQ-OPPT-2016-0725-0061>.

In the draft risk evaluation for PV29, EPA does not expressly rely on its so-called authority to exclude conditions of use, exposures, or hazards. But EPA does cursorily dismiss certain conditions of use, exposure pathways, and hazards based on remarkably limited evidence. *See, e.g.*, (p. 11 & n. 2) (excluding reasonably foreseeable conditions of use based on limited evidence); (pp. 14-17) (refusing to analyze certain exposure pathways in-depth); (p. 25) (dismissing various hazards on a cursory basis). In doing so, EPA violates its duty under the statutory language to consider all of the conditions of use, exposures, and hazards related to a chemical substance.

EPA should evaluate all of the reasonably available evidence of conditions of use, exposure, and hazard. As explained below in section 12, EPA should use its authorities to obtain reasonably available information to prepare the required analysis.

A. The plain text, overall structure, purpose, and legislative history of TSCA indicate that EPA has to determine whether a chemical substance presents an unreasonable risk comprehensively, considering all of its hazards, exposures, and conditions of use.

i. The plain text requires EPA to consider all hazards, exposures, and conditions of use.

Statutory interpretation should begin, as always, with the language of the statute. The plain language of the risk evaluation provision supports the interpretation that EPA must consider all hazards, exposures, and conditions of use as necessary “to determine whether a *chemical substance* presents an unreasonable risk.” 15 U.S.C. § 2605(b)(4)(A) (emphasis added). This directive expresses Congress’s clear intent that EPA evaluate the risks posed by “a chemical substance” as a whole. Congress consistently used the phrase “a chemical substance” to describe the object of priority designations and risk evaluations. 15 U.S.C. § 2605(b)(1)-(4), (i) (using the phrase 14 times). This language requires EPA to consider all hazards and exposures that contribute to the total risk presented by the chemical substance as a whole.

This whole-substance focus begins during prioritization. The definitions of high- and low-priority substances make clear that it is the “substance” that receives the designation, not selected conditions of use, exposures, or hazards. *See id.* § 2605(b)(1)(B). The provision requiring EPA to select the first ten chemicals also directed that the risk evaluations be “conducted on 10 chemical substances drawn from the 2014 update of the TSCA Work Plan,” making the object of these risk evaluations the chemical substances as a whole. *Id.* § 2605(b)(2)(A). As EPA reasoned in the Prioritization Rule, “[t]he statute is clear that EPA is to designate the priority of the ‘chemical substance’—not a condition of use for a chemical substance.” 82 Fed. Reg. 33,753, 33,755 (July 20, 2017) (citing 15 U.S.C. § 2605(b)(1)(A)). Similarly, EPA must prioritize the whole chemical, and EPA is not directed to prioritize only

certain hazards or exposures. Indeed, the prioritization process expressly “shall include a consideration of the hazard and exposure potential of a chemical substance,” without any basis for EPA to limit that consideration to only certain hazards or exposures. 15 U.S.C. § 2605(b)(1)(A).

EPA must also conduct risk evaluations on “a chemical substance” as a whole. For example, TSCA provides that “[u]pon designating a chemical substance as a high-priority substance, the Administrator shall initiate a risk evaluation on the *substance*.” 15 U.S.C. § 2605(b)(3)(A) (emphasis added). Similarly, the statute directs EPA to determine either that “a *chemical substance* presents” or “does not present an unreasonable risk.” *Id.* § 2605(i)(1)-(2) (emphasis added). Congress also uses the phrase “a chemical substance” or “chemical substances” in many other places in TSCA’s risk evaluation provisions. *See, e.g., id.* § 2605(b)(4)(G) (setting deadlines for completing evaluation for “a chemical substance”), (b)(2)(A), (b)(2)(B), (b)(3)(A), (c)(1).

The plain language of the risk evaluation provisions requires EPA to consider all available information about hazards, exposures, and conditions of use, without limitation. TSCA § 6(b)(4)(F)(i) expressly requires that EPA “integrate and assess available information on hazards and exposures for the conditions of use of the chemical substance.” 15 U.S.C. § 2605(b)(4)(F)(i). Thus, if there is “available information on hazards and exposures,” then EPA must integrate and assess that information as part of the risk evaluation. Similarly, TSCA § 6(b)(4)(F)(iv) requires that EPA “take into account, where relevant, the likely duration, intensity, frequency, and number of exposures under the conditions of use of the chemical substance.” *Id.* § 2605(b)(4)(F)(iv). This provision requires EPA to take into account exposures unless EPA can establish that they are irrelevant. Finally, TSCA § 6(b)(4)(F)(v) requires that EPA “describe the weight of the scientific evidence for the identified hazard and exposure.” *Id.* § 2605(b)(4)(F)(v).

All of these provisions direct EPA to consider a chemical’s hazards, exposures, and conditions of use, and none of them include any language providing EPA with any discretion to ignore any hazards, exposures, or conditions of use. While EPA previously articulated a legal theory (albeit flawed) for ignoring certain conditions of use, EPA has not pointed to any legal basis for ignoring hazards or exposures under the conditions of use being analyzed in a risk evaluation. EPA has pointed to no textual basis for such exclusions.

Moreover, when EPA promulgates risk-management regulations under TSCA § 6(a):

[EPA] shall consider and publish a statement based on reasonably available information with respect to—

- (i) the effects of the chemical substance or mixture on health and the magnitude of the exposure of human beings to the chemical substance or mixture;
- (ii) the effects of the chemical substance or mixture on the environment and the magnitude of the exposure of the environment to such substance or mixture;

15 U.S.C. § 2605(c)(2)(A). In order to accurately draft this statement, EPA will have to have considered all of the hazards posed by a chemical (i.e., its effects on human health and the environment) as well as all exposures. EPA cannot accurately describe “the magnitude of the exposure of human beings to the chemical substance,” if EPA has ignored numerous exposures. 15 U.S.C. § 2605(c)(2)(A)(i). Similarly, EPA cannot accurately describe “the magnitude of the exposure of the environment” for chemicals, *id.* § 2605(c)(2)(A)(ii), if EPA has ignored the vast majority of environmental exposures, as EPA proposes to do. Congress specifically intended for EPA to “satisfy these requirements on the basis of the conclusions regarding the chemical’s health and environmental effects and exposures in the risk evaluation itself.” 114 Cong. Rec. S3517 (daily ed. June 7, 2016). Thus, EPA must evaluate all hazards and exposures in its risk evaluations.

Moreover, TSCA requires that EPA evaluate a chemical’s risk “without consideration of costs or other nonrisk factors.” 15 U.S.C. § 2605(b)(4)(A). By excluding certain hazards, exposures, and conditions of use for reasons that bear no relationship to risk, EPA is considering nonrisk factors.

Textually, EPA’s approach also directly conflicts with TSCA § 26(k). 15 U.S.C. § 2625(k). TSCA § 26(k) requires EPA to “take into consideration information relating to a chemical substance or mixture, including hazard and exposure information, under the conditions of use, that is reasonably available to the Administrator.” *Id.* Congress included this provision to ensure that EPA could not ignore “reasonably available” “information relating to a chemical substance or mixture”; the purpose of this provision is to compel EPA to consider all reasonably available information. Congress also specified that EPA must consider the reasonably available “hazard and exposure information.” It would undermine this directive if EPA chooses to ignore certain hazards or exposures.

ii. TSCA’s overall structure requires EPA to consider all hazards, exposures, and conditions of use.

Moreover, EPA’s pick-and-choose approach cannot be squared with the overall structure of TSCA.

As EPA reasoned in its proposed Risk Evaluation Rule, when discussing conditions of use, that TSCA “provides no criteria for EPA to apply” for selecting hazards, exposures, and conditions of

use for analysis shows that the Agency does not have “license to choose” among those hazards, exposures, and conditions of use for analysis. 82 Fed. Reg. 7562, 7566 (Jan. 19, 2017). The precision with which Congress prescribed EPA’s implementation of section 6 supports this reading. Section 6 lays out detailed directions for EPA. See 15 U.S.C. § 2605(b)(1)(A) (mandating considerations for priority designations), (b)(4)(D) (identifying risk factors to include in a risk evaluation’s scope), (b)(4)(F)(i)-(v) (detailing requirements for conducting risk evaluations); see also *id.* § 2605(a) (specifying possible risk management measures). These provisions indicate that Congress did not mean to allow EPA to exclude hazards, exposures, or conditions of use from risk evaluation without any criteria or instruction. Cf. *NRDC, Inc. v. EPA*, 863 F.2d 1420, 1432 (9th Cir. 1988) (invalidating regulatory procedure that “is wholly silent as to what factors the agency is to consider in granting exceptions” and provides “no discernible standard [for] limit[ing] th[at] discretion”).

Indeed, when Congress intended EPA to exercise discretion under TSCA, it said so explicitly. See, e.g., 15 U.S.C. §§ 2613(f) (granting EPA “[d]iscretion” in handling claims to protect confidential information), 2608(a) (instructing EPA, if it “determines, in the Administrator’s discretion,” that an unreasonable risk may be prevented under a federal law administered by another agency, to notify the agency), 2608(b), 2605(b)(4)(E)(iv)(II). That Congress purposefully included the language of discretion “in one section of the statute but omit[ted] it in another section of the same Act” shows that Congress did not intend EPA to use discretion to pick and choose which hazards, exposures, and conditions of use to consider in prioritization and risk evaluation. *Hernandez v. Ashcroft*, 345 F.3d 824, 834 (9th Cir. 2003) (quoting *Andreiu v. Ashcroft*, 253 F.3d 477, 480 (9th Cir. 2001) (en banc)).

TSCA’s provisions direct EPA to prepare risk evaluations and the related findings for “chemical substances,” as a whole, not for specific or limited hazards, exposures, or conditions of use of those substances. For example, the risk management provision expressly requires EPA to address risks when the risks arise from combined sources of exposure. TSCA § 6(a) provides that: “If [EPA] determines in accordance with [the risk evaluation provision] that the manufacture, processing, distribution in commerce, use, or disposal of a chemical substance or mixture, or that any combination of such activities, presents an unreasonable risk of injury to health or the environment,” then EPA must issue a risk management rule. 15 U.S.C. § 2605(a); see also 15 U.S.C. § 2608(a) (using same language in provision governing requests to other federal agencies to address risks). Thus, if exposures resulting from “any combination” of conditions of use present an unreasonable risk, EPA must issue a risk management rule. But EPA must analyze *all* of the exposures resulting from these activities to assess whether *any combination* presents such a risk.

B. EPA’s own risk evaluation rule requires that EPA consider all relevant hazards and all exposures under the conditions of use within the risk evaluation.

EDF disagrees with EPA’s final Risk Evaluation Rule for numerous reasons, as discussed in our prior comments and in litigation challenging that rule. EDF reiterates and incorporates those points here.¹³⁷ Nonetheless, even EPA’s final Risk Evaluation Rule requires EPA to consider all relevant hazards and exposures under the conditions of use within the risk evaluation. The Rule specifically requires that: “Relevant *potential* human and environmental hazards will be evaluated.” 40 C.F.R. § 702.41(d)(3) (emphasis). Thus, EPA must consider any relevant “potential” hazards when preparing a risk evaluation. *See also* 40 C.F.R. § 702.41(d)(2) (“The hazard assessment process will identify the types of hazards to health or the environment posed by the chemical substance under the condition(s) of use within the scope of the risk evaluation.”). The Rule also requires that: “[e]xposure information related to potential human health or ecological hazards of the chemical substance will be reviewed in a manner consistent with the description of best available science and weight of scientific evidence.” 40 C.F.R. § 702.41(e)(3). When preparing the risk characterization, EPA shall “[t]ake into account, where relevant, the likely duration, intensity, frequency, and number of exposures under the condition(s) of use of the chemical substance.” 40 C.F.R. § 702.43(a)(4). Thus, EPA must consider all hazards and all exposures under the conditions of use. None of these duties are qualified or provide an authority for EPA to exclude hazards or exposures from analysis.

Other provisions of the rule confirm this reading. EPA requires manufacturer requests for risk evaluations to “include or reference *all* available information on the health and environmental hazard(s) of the chemical substance, human and environmental exposure(s), and exposed population(s), as relevant to the circumstances identified in the request.” 40 C.F.R. § 702.37(b)(4) (emphasis added). Thus, manufacturers must submit all available information on hazard and exposure under the identified conditions of use because EPA must consider all hazards and exposures when preparing risk evaluations.

In the preamble to the rule, EPA commits to considering all hazards and exposures under the conditions of use:

The Administrator will consider relevant factors including, but 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.

¹³⁷ EDF Comments on Ten Problem Formulations under the Toxic Substances Control Act, p.17 & Appendix A, <https://www.regulations.gov/document?D=EPA-HQ-OPPT-2016-0725-0061>.

82 Fed. Reg. at 33,735. EPA thus committed to considering the “effects of the chemical substance on health and human exposure to such substance under the conditions of use.” *Id.* These commitments are not qualified or accompanied by any assertion of discretion to ignore effects or exposure information under the conditions of use. EPA cannot fulfill this duty without considering all the hazards and sources of human exposure under the conditions of use.

Similarly, in the preamble, EPA states that “[u]sing reasonably available information, exposures will be estimated (usually quantitatively) for the identified conditions of use.” 82 Fed. Reg. at 33,742. EPA cannot prepare an accurate quantitative estimate for exposure if EPA has excluded exposure pathways. “For environmental evaluations specifically, EPA plans to include a discussion of the nature and magnitude of the effects, the spatial and temporal patterns of the effects, [and] implications at the species, population, and community level.” 82 Fed. Reg. at 33,743. EPA cannot accurately discuss the magnitude of the effects on the environment or the spatial and temporal patterns of those effects if EPA ignores the vast majority of the environmental exposures, as EPA proposes to do.

Moreover, in the preamble to the rule, while EPA went to great lengths to describe its alleged discretion to pick-and-choose conditions of use, EPA never stated that it had discretion to exclude hazards or exposures related to conditions of use within the risk evaluation. EPA’s failure to assert any discretion to exclude exposures and hazards reflects that EPA, in fact, lacks any such discretion. In sum, EPA’s arguments for excluding certain conditions of use cannot simply be extended mindlessly to exclude consideration of exposures and hazards. *See United States Sugar Corp. v. EPA*, 830 F.3d 579, 650 (D.C. Cir. 2016) (agency may not assume a rationale for one exemption identically applies elsewhere).

9. EPA should not refuse to further analyze exposure pathways on a cursory basis, and in any event, EPA still needs to consider those exposures when evaluating the combined exposures.

As in the problem formulation, in the draft risk evaluation, EPA illegally decides not to analyze certain exposures further—effectively excluding certain exposure pathways—based on, at best, cursory, unpersuasive, and unsupported analyses. *See, e.g.*, (pp. 14-17). With these rushes to judgment, EPA concludes no unreasonable risk from certain exposures based on little analysis. Throughout these comments, EDF discusses numerous instances of these unjustified exclusions and cursory analyses.

When EPA declines to analyze a pathway further, EPA must have developed and applied a sound, rational basis for assessing the exposure level, supported by scientific evidence. In addition, EPA cannot then effectively ignore the exposure. Rather, EPA still must consider how

the exposure may combine with other sources of exposure, so EPA must actually assess the level of exposure from the pathway individually and then consider how it combines with other sources of exposure.

10. Real-world exposures still occur through disposal pathways, and EPA’s cursory dismissal of these exposures has insufficient support.

EPA appears to rely upon regulation under other statutory authorities as a basis for preparing a remarkably cursory analysis of exposures from all disposal-related pathways and associated activities (e.g., collection, processing, storage and transport) associated with PV29. In particular, EPA points to the disposal of PV29 in landfills that are regulated under the Resource Conservation and Recovery Act (RCRA) as subtitle-D lined landfills, and EPA appears to view these regulations as *per se* adequate to justify ignoring exposures through this exposure pathway. (p. 21). As EDF has previously explained, EPA cannot ignore ongoing, real-world exposures that occur even if they fall under the jurisdiction of other EPA-administered statutes.¹³⁸ EDF incorporates those comments by reference here.

As particularly relevant to PV29, EPA has never established or shown that the disposal regulations under RCRA “eliminate[s]” the unreasonable risk or “reduce[s] [the risk] to a sufficient extent.” 15 U.S.C. § 2608(b)(1). Subtitle D municipal solid waste (MSW) landfills and industrial-non-hazardous and construction/demolition waste landfills are primarily regulated under state regulatory programs. Subtitle D is intended “to assist in developing and encouraging methods for the disposal of solid waste which are environmentally sound and which maximize the utilization of valuable resources including energy and materials *** and to encourage resource conservation.” 42 U.S.C. § 6941. EPA presents no analysis or data demonstrating how effective Subtitle-D landfills are likely to be at reducing exposure to PV29.

EPA’s analysis of biosolids is particularly lacking. EPA repeatedly invokes PV29’s low water solubility to justify parts of its analysis, but as a result “sorption to *** biosolids for [PV29] are expected to be strong.” (p. 21). Thus, a thorough analysis of biosolids would be appropriate, particularly given that PV29 is poorly biodegradable. (p. 39). Instead, EPA largely dismisses the risks presented by exposure through biosolids on the basis that leaching is expected to be negligible. *Id.* But EPA ignores the exposures from PV29 present in the biosolids themselves, aside from leaching. In the draft Problem Formulation, EPA stated that “land application of biosolids is not expected to be a release pathway for the manufacturer, so this pathway is

¹³⁸ EDF Comments on Ten Problem Formulations under the Toxic Substances Control Act, pp.23-27, 38-39, 44-47, 50, 51-56, <https://www.regulations.gov/document?D=EPA-HQ-OPPT-2016-0725-0061>.

outside of scope of this assessment.”¹³⁹ EPA’s explanation in this cursory analysis is difficult to follow: EPA notes that the manufacturer of PV29 sends its sludge to a RCRA Subtitle D landfill,¹⁴⁰ but it is not clear why that would mean EPA can therefore disregard exposures from biosolids. As just one example, workers handling these materials at the landfill might well be directly exposed to them. EPA’s analysis of occupational exposure does not address or account for exposures from biosolids as potentially affecting exposure rates.¹⁴¹

Moreover, downstream processors and users could engage in land application of biosolids containing PV29, a scenario that EPA simply ignores because of assumed lower per-site volumes handled by downstream entities. (p. 21). Given PV29’s expected presence in biosolids, EPA should analyze this pathway unless EPA has empirical evidence showing that it will not lead to exposures.

11. EPA needs to analyze potential exposures from distribution, as well as from known and reasonably foreseeable accidental exposures.

The draft risk evaluation states that distribution “will be considered throughout the [PV29] life cycle, rather than using a single distribution scenario.” (p. 12). But then EPA never appears to analyze distribution within the draft risk evaluation. EPA’s analysis of occupational exposure does not address or account for distribution as potentially affecting exposure rates. *See* (pp. 22-23).

The draft risk evaluation also gives no attention to potential releases and exposures resulting from accidental releases. EDF does not suggest that EPA needs to consider every possible scenario, but the risk of accidental releases and exposures is very real and certainly “reasonably foreseen” in many respects, and EPA has authority to mandate steps to reduce those risks. For example, as and after Hurricane Harvey passed through Houston, over 40 sites released toxic chemicals into the environment.¹⁴² Given accidental releases are known to occur, such events are clearly reasonably foreseen and hence EPA needs to give more consideration to the potential for accidental releases.

¹³⁹ PV29 Problem Formulation, p. 33.

¹⁴⁰ *Id.*

¹⁴¹ *Id.* at 22-23.

¹⁴² *See, e.g., More Than 40 Sites Released Hazardous Pollutants Because of Hurricane Harvey*, N.Y. TIMES (Sept. 8, 2017), <https://www.nytimes.com/interactive/2017/09/08/us/houston-hurricane-harvey-hazardous-chemicals.html? r=0>.

12. EPA must consider “reasonably available” information, and thus EPA must use its authorities under TSCA §§ 4 and 8 to obtain additional information.

TSCA orders EPA to consider “available” and “reasonably available” information in crafting a risk evaluation, 15 U.S.C. §§ 2605(b)(4)(F)(i), 2625(k), and under the new risk evaluation rule, EPA defined “[r]easonably available information” to mean “information that EPA possesses or can reasonably generate, obtain, and synthesize for use in risk evaluations, considering the deadlines specified in TSCA section 6(b)(4)(G) for completing such evaluation.” 40 C.F.R. § 702.33, promulgated at 82 Fed. Reg. 33,748 (July 20, 2017). Thus, under its own rule, EPA has to consider information that it “can reasonably generate, obtain, and synthesize.” In addition, EPA must consider all information within EPA’s possession, even if has not been public disclosed, as EDF has explained in prior comments incorporated by reference here. EDF Comments on Ten Scopes under the Toxic Substances Control Act, pp.15-16, <https://www.regulations.gov/document?D=EPA-HQ-OPPT-2016-0725-0041>;

In our prior comments on the scope documents, EDF expanded on EPA’s duties to use its authorities under TSCA §§ 4 and 8 to obtain additional information about PV29, and EDF incorporates those arguments here.¹⁴³ In response to EDF’s comments, EPA acknowledged its duty to consider “reasonably available information” and EPA described its efforts to gather information up to this point.¹⁴⁴ While EPA detailed its “data gathering activities,” EPA has not established that these activities will result in EPA obtaining all the reasonably available information that EPA could “generate, obtain, and synthesize” if EPA also used its authorities under TSCA §§ 4 and 8 to obtain additional information. Thus, EPA has not established that it will obtain all reasonably available information. Notably, while EPA has changed its language to reflect its statutory obligations, EPA has not actually changed its conduct. In the scopes, EPA stated that it would use “readily available data and information from public sources,” and EPA has not taken any additional steps to actually expand its search to reach “reasonably available information.” Thus, as a practical matter, EPA is still relying solely on “readily” available information, not all reasonably available information.

In particular, EDF’s prior comments established that relying solely on voluntary requests for information, may result in limited, biased, inaccurate, or incomplete information on the

¹⁴³ EDF Comments on Ten Scopes under the Toxic Substances Control Act, pp.11-16, <https://www.regulations.gov/document?D=EPA-HQ-OPPT-2016-0725-0041>.

¹⁴⁴ EPA’s Responses to Public Comments Received on the Scope Documents for the First Ten Chemicals for Risk Evaluation under TSCA at pp.10-14, <https://www.regulations.gov/document?D=EPA-HQ-OPPT-2016-0725-0051>.

chemicals. EDF incorporates those arguments here and repeats them in Part C.¹⁴⁵ EPA's response to this comment was that "EPA has not indicated it would rely solely on voluntary requests for information."¹⁴⁶ Thus, EPA appears to recognize that voluntary requests standing alone are insufficient. Despite that acknowledgement, EPA appears to have relied heavily on voluntary requests in preparing the draft risk evaluation, and EPA still has not relied on its available authorities to obtain additional information. EDF urges EPA to do so.

EPA's primary response to EDF's request that EPA consider all reasonably available information appears to be that the information EPA currently has is "adequate."¹⁴⁷ But, as a general matter, EPA has to consider all reasonably available information; TSCA does not authorize EPA to stop its analysis on the basis that EPA believes its current information is adequate. And as explained more below, it is clear that the information is not yet adequate to meet EPA's obligations under TSCA.

A. Any information that EPA can obtain under the exercise of its authorities under §§ 8(d), 8(a), and 8(c) is "reasonably available information," so EPA must exercise those authorities.

EPA must promulgate reasonable regulations under § 8(d) and 8(a) to obtain information about hazards, exposures, and conditions of use for PV29; EPA should also exercise its authority under § 8(c) to obtain additional information. Consistent with TSCA § 8(a)(5), EPA can take steps to reduce unnecessary and duplicative reporting. Because TSCA requires EPA to produce robust risk evaluations that reflect "reasonably available" information, and information available under these authorities is "reasonably available" on its face, EPA must use these authorities to fulfill its duty. Moreover, this risk evaluation is crucial to establishing the credibility of the TSCA program under the Lautenberg Act, and EPA can only establish that credibility by using its full authority to obtain "reasonably available information" on the chemical, as required by the law. Collecting this information is also necessary to fulfill EPA's duty to use the best available science under TSCA § 26.

TSCA § 8(d) allows EPA to "require any person who manufactures, processes, or distributes in commerce *** any chemical substance or mixture *** to submit to the Administrator—lists of health and safety studies: (A) conducted or initiated by or for such person with respect to such

¹⁴⁵ EDF Comments on Ten Scopes under the Toxic Substances Control Act, pp.16-20, <https://www.regulations.gov/document?D=EPA-HQ-OPPT-2016-0725-0041>.

¹⁴⁶ EPA's Responses to Public Comments Received on the Scope Documents for the First Ten Chemicals for Risk Evaluation under TSCA at p.13, <https://www.regulations.gov/document?D=EPA-HQ-OPPT-2016-0725-0051>.

¹⁴⁷ See *id.* at pp. 13, 10-14.

substance or mixture at any time, (B) known to such person; or (C) reasonably ascertainable by such person.” 15 U.S.C. § 2607(d). EPA should issue § 8(d) rules for PV29. To obtain a complete picture, EPA should expressly require both manufacturers and processors to report on these chemicals under the § 8(d) rules. *See* 40 C.F.R. § 716.5(c). EPA has never issued such a rule for PV29. *See* 40 C.F.R. § 716.120. Thus, issuing a § 8(d) rule for this chemical is particularly important.

Notably, EPA’s regulations correctly interpret “health and safety study” broadly to incorporate “[a]ny data that bear on the effects of a chemical substance on health or the environment.” 40 C.F.R. § 716.3. These include numerous tests for health and environmental effects. *See id.* They also include monitoring data and other assessments of human and environmental exposures. *See id.* EPA should also review these studies upon receipt and request underlying data under 40 C.F.R. §§ 716.10(a)(4), 716.40(a). EPA should also separately request reporting on PV29 when it is manufactured, processed, or distributed as an impurity, 40 C.F.R. § 716.20(a)(9), because impurities may be an important source of exposure and thus risk.

Under TSCA § 8(a), EPA may require manufacturers and processors to provide extensive information. *See* 15 U.S.C. § 2607(a)(2). EPA “shall, to the extent feasible” “not require reporting which is unnecessary or duplicative” and also “apply any reporting obligations to those persons likely to have information relevant to the effective implementation of this title.” *Id.* § 2607(a)(5). To avoid duplication, EPA need not request reporting on information EPA has already obtained through other recent submissions such as through the Chemical Data Reporting (CDR) process. *See* 40 C.F.R. Part 711. But the CDR process does not require manufacturers and processors to provide all information that EPA can reasonably obtain under TSCA § 8(a) which is relevant to the risk evaluations. For example, EPA should require reporting of: “[a]ll existing information concerning the environmental and health effects of” PV29; “the byproducts resulting from the manufacture, processing, use, or disposal of” PV29; more detailed information about exposures to PV29, including the duration, frequency, and timing of exposures; and additional information about disposal. *See* 15 U.S.C. § 2607(a)(2). In particular, EPA can require submission of any data available on releases or exposures in the workplace and environment, and those data would be crucially important to an accurate risk evaluation. To decrease the burden on industry, EPA should pursue both rulemakings simultaneously, and EPA can provide that when information is submitted under one rule, the same information need not be submitted under the other. But EPA should use both authorities to ensure that it does not miss any information that may fall within one authority but not the other.

In addition, EPA should rely on its request authority under TSCA § 8(c). Under TSCA § 8(c), “[a]ny person who manufactures, processes, or distributes in commerce any chemical

substance or mixture shall maintain records of significant adverse reactions to health or the environment, as determined by the Administrator by rule, alleged to have been caused by the substance or mixture.” 15 U.S.C. § 2607(c). EPA promulgated rules governing this recordkeeping requirement at 40 C.F.R. Part 717. The rules apply to most manufacturers and many processors. 40 C.F.R. § 717.5. Manufacturers and processors must maintain records of many types of allegations, as detailed in 40 C.F.R. §§ 717.5 and 717.10. The regulation defines “significant adverse reactions” to include, but not be limited to, many specific types of harm that are highly relevant to the ultimate question presented in a risk evaluation: “whether a chemical substance presents an unreasonable risk of injury to health or the environment.” 15 U.S.C. § 2605(b)(4)(A). Firms must maintain these records for 30 or 5 years, depending on the circumstances. 40 C.F.R. § 717.15(d).

EPA should use its authority to request these records on alleged significant adverse reactions caused by PV29 and add them to the administrative record. EPA can request records from manufacturers and processors that reported PV29 in response to any § 8(a) and 8(d) rules or in response to CDR reporting. *Id.* § 717.17. EPA can request those records by letter. *Id.* § 717.17(b). Finally, EPA can also notify all people holding such records to provide them by a notice in the Federal Register. *Id.* These records may provide valuable information on hazards, exposures, and conditions of use, since the records may reveal not only significant adverse reactions but also information about the specific exposure and use that may have caused the reaction.

B. EPA must identify any information gaps and use its authority under TSCA § 4 to the fullest extent possible to fill those gaps.

EPA should make robust use of its § 4 authority to fill the gaps in information for PV29. EDF recognizes that some time constraints apply to PV29 and thus some types of testing may not be possible, but EPA had three years to develop a risk evaluation for PV29, so any testing that could have been completed in that three year timeframe meets EPA’s regulatory standard for “reasonably available information” because it is information that EPA could “reasonably generate *** for use in [the] risk evaluation[], considering the deadlines specified in TSCA section 6(b)(4)(G) for completing such evaluation.” 40 C.F.R. § 702.33.

In developing this draft risk evaluation, EPA should have begun by clearly identifying *all* significant information gaps on hazards or exposures. Based on its own regulation, EPA should then have used its authority under TSCA § 4(a)(2) to require the development of new information to fill those gaps wherever possible. Information that EPA can generate under TSCA § 4(a)(2) is reasonably available under EPA’s own regulation as “information that EPA *** can reasonably generate [and] obtain *** for use in risk evaluations.” 40 C.F.R. § 702.33. Thus,

EPA should have identified such information gaps and then promptly required the conduct of all testing that could be done and still meet the statutory deadlines for the risk evaluations.

TSCA § 4(a)(2) provides that EPA “may, by rule, order, or consent agreement require the development of new information relating to a chemical substance *** if the Administrator determines that the information is necessary *** to perform a risk evaluation under section 6(b).” 15 U.S.C. § 2603(a)(2)(A)(i). Congress provided this additional testing authority allowing EPA to require testing or other data development efforts solely upon a determination “that the information is necessary *** to perform a risk evaluation under section 6(b).” *Id.* In light of deadlines, EPA can and should use its order authority and does not need to make the additional findings required for a rule under TSCA § 4(a)(1).

Below, EDF identifies precise information gaps that EPA needs to fill to prepare an adequate risk evaluation for PV29. Most or all of the tests *could* have been prepared if EPA had used its authorities at the outset, as EDF urged in its original comments. EPA cannot evade its duty to collect reasonably available information on the basis that it has failed to comply with that duty up to this point. EPA must order that testing now.

In particular, EPA must order the development and submission of the following information:

Use data

- Range of concentrations in industrial, commercial, and consumer products
- Measured levels of residual PV29 left in products made using PV29 as an intermediate, where PV29 is a reactant or where PV29 is added to adjust the color of other pigments
- Empirical data on frequency of product use for industrial, commercial, and consumer products
- Empirical data on duration of product use for industrial, commercial, and consumer products

Fate data

- Measured data on absorption by inhalation, dermal, and oral routes, for PV29:
 - as produced in solid (powder) form
 - as produced in solution form
 - in each type of formulation in which it is present
- Measured water solubility in a reliable study that accurately accounts for pH
- Measured bioconcentration factor (BCF) and bioaccumulation factor (BAF)
- Appropriate values to assess bioconcentration/bioaccumulation directly from air

Environmental release and exposure data

- Measured data for air, water, and waste releases from sites of manufacture, processing, and industrial or commercial use; wastewater treatment (both effluent and sludges/biosolids); landfill leachate and effluent and sludges/biosolids from leachate treatment
- Measured data for presence/concentration in environmental media and organisms (air, water, sediment; aquatic, sediment-dwelling, and terrestrial organisms) near manufacturing, downstream processing and use, and disposal and land (biosolids) application sites

Occupational exposure data (for all manufacturing and downstream processing and use sites)

- Monitoring of air concentrations, for dust, mists, aerosols, vapors
- Monitoring of dust on surfaces and concentrations in solutions in all settings where skin contact with the surfaces or solutions could potentially occur
- Numbers of workers potentially exposed in each activity/setting, at each site
- Specific engineering controls, PPE and workplace practices in place at each site/setting, and data on their extent of use and efficacy
- Safety Data Sheets (SDSs): If EPA plans to rely on SDSs, then EPA needs empirical data on:
 - extent of their availability and comprehension to all potentially exposed workers
 - their completeness, accuracy and currency
 - extent of compliance with protective measures they specify

Hazard data

- Acute toxicity to sediment-dwelling organisms
- Chronic toxicity including to aquatic organisms including:
 - aquatic plants
 - fish
 - aquatic invertebrates
- Chronic toxicity to terrestrial organisms (including sediment-dwelling organisms)
- Repeated dose toxicity
 - sufficient to account for exposures via dermal, inhalation, and oral routes
- Chronic mammalian toxicity to reproduction and development and carcinogenicity
 - sufficient to account for exposures via dermal, inhalation, and oral routes

EPA also must develop this information to fulfill its obligations under TSCA § 26(h) to use “the best available science.” 15 U.S.C. § 2625(h). EPA currently relies on numerous modeled or estimated values that have significant uncertainty when EPA could easily issue orders to obtain actual measured values for these parameters. For example, EPA repeatedly assumes that absorption by all routes of exposure is expected to be poor, *see, e.g.*, (p. 21), but EPA could easily obtain actual evidence on absorption. Actual measured values are as a rule more reliable and accurate than EPA’s weak assumptions. EPA has certainly not established that its reliance

on weak assumptions and values modeled on limited data comply with TSCA § 26(h) and constitute the “best available science” compared to the tests and information EPA easily could have obtained through its authorities under TSCA § 4 as well as § 8.

C. Relying on voluntary requests for information will result in limited, biased, inaccurate, or incomplete information on the chemicals.

In the draft risk evaluation, EPA repeatedly relies upon information that was voluntarily submitted by Sun Chemical Corporation and CPMA, and EPA builds entire swathes of its analysis on these voluntary submissions. The shortfalls in these voluntary submissions highlight that EPA should instead rely on its mandatory authorities. For example, EPA builds its entire inhalation analysis on the assertion that “workplace air concentration of 0.5 mg/m³ would be expected over a 12 hour shift.” (p. 22) (citing Mott). This submission does not even clarify whether the value represents the concentration of PV29 or total dust. *Id.* At least as far as the public can discern, the submission does not appear to contain any actual study supporting the value or any detail about how the value was derived. In contrast, EPA has clear authority to require actual workplace monitoring that could have provided detailed and clear analysis of the workplace air exposure to PV29. In terms of completeness and accuracy, the voluntary submission clearly falls short of what EPA could have and should require through its mandatory authorities.

Rather than relying solely on voluntary submissions—an approach that has proven insufficient in the past and has proven insufficient here as well—EPA should use its information authorities to obtain necessary information on conditions of use, exposures, hazards, and potentially exposed or susceptible subpopulations.

There are several obvious problems and limitations with this voluntary approach which EPA has still not addressed.

First, a voluntary call is much less likely to produce all of the necessary information than rules or orders mandating that affected parties provide the requested information. If manufacturers and processors are legally required to provide the information, that legal obligation provides a strong incentive for them to develop or obtain and submit all relevant information. Absent that incentive, some companies may choose to focus time and attention on other matters.

Notably, EPA overwhelmingly relies on information voluntarily submitted by the sole reported manufacturer of PV29. EPA does not appear to have received or obtained significant information from the processors of PV29, creating a key data gap. There is no reason to assume that the manufacturer’s production of PV29 necessarily presents the most or only risky conditions of use of PV29; processors may, for example, have a higher air concentration of

PV29 even if they use a smaller volume of the chemical. Mandatory reporting can require processors to provide information about PV29 that would fill this information gap.

Second, EPA has provided no empirical evidence establishing that this voluntary approach will result in EPA obtaining all “reasonably available” information. Unless EPA has some empirical basis for stating that the voluntary approach will allow EPA to obtain all reasonably available information that it can obtain under its legal authorities, EPA must rely on its existing authorities to obtain a complete set of information.

Indeed, EPA’s prior experience with voluntary reporting provides strong evidence that a voluntary approach is unlikely to provide complete and accurate data. For example, an EPA advisory committee called for the development of nanomaterial reporting rules in 2005, but EPA instead spent several years developing and carrying out a voluntary reporting program, the Nanoscale Materials Stewardship Program (NMSP). This voluntary reporting program produced minimal information as revealed by EPA’s 2009 interim report on the NMSP.¹⁴⁸ “[I]n the report EPA estimated that companies provided information on only about 10 percent of the chemical substances manufactured at the nanoscale that may be commercially available in 2009.” 80 Fed. Reg. 18,330, 18,334 (April 6, 2015). In 2017, over a decade after the data need was identified, EPA finally finalized a § 8(a) reporting rule to acquire the data. 82 Fed. Reg. 3641 (Jan. 12, 2017). Given the past failures of voluntary approaches, EPA should not rely on them here.

Third, manufacturers and processors of PV29 have a vested interest in EPA finding that it does not present an unreasonable risk. A no-unreasonable-risk finding reduces the likelihood of government regulation, including potential restrictions, and it may reduce any stigma they may otherwise face in the marketplace. The financial costs of regulation may ultimately be very high for some specific firms and individuals, and even if not, many firms and individuals may believe that the costs of regulation will be high. These companies have a “financial interest” in the outcome of these proceedings, and they are not impartial. *See, e.g.*, 28 U.S.C. § 455(b)(4) (requiring Judges to disqualify themselves in proceedings where they have a financial interest). Because of this reality and appearance of partiality, relying solely on voluntary measures decreases the credibility of this risk evaluation.

Relying solely on voluntary presentation of information raises the concern that the companies or trade associations may present an incomplete or skewed picture. Companies and trade associations may choose to “cherry pick” information and provide only the information that paints PV29 in a favorable light. They may provide only summaries of information that reflect

¹⁴⁸ Nanoscale Materials Stewardship Program, Interim Report, OPPT (Jan. 2009), <https://www.regulations.gov/document?D=EPA-HQ-OPPT-2010-0572-0003>.

conscious and subconscious judgment calls that result in unduly favorable conclusions; and without access to the full information neither EPA nor the public can independently assess such conclusions. They may choose not to review records robustly when the review may disclose unfavorable information. They may seek to put their best foot forward and describe the ideal scenario of use and safety measures. Or, if they have unfavorable information, they may choose not to provide any information at all and simply not participate in these proceedings.

EPA cannot simply assume that members of the regulated community will voluntarily disclose unfavorable or complete information about their practices and products. See THE FEDERALIST NO. 51 (James Madison) (“If men were angels, no government would be necessary. *** [E]xperience has taught mankind the necessity of auxiliary precautions.”); *Williams v. Pennsylvania*, 136 S. Ct. 1899, 1905-06 (2016) (“Bias is easy to attribute to others and difficult to discern in oneself. *** This objective risk of bias is reflected in the due process maxim that ‘no man can be a judge in his own case and no man is permitted to try cases where he has an interest in the outcome.’”). Here, manufacturers and processors obviously have an interest in the outcome, and EPA must craft its procedures and approaches with that reality in mind. Requiring the submission of information is the safest approach to ensuring that these parties provide all relevant information, and that is in turn crucial to establishing and demonstrating the credibility of this process.

If EPA acts under TSCA §§ 8(a), (c), and (d), the regulations impose some requirements that will help ensure the accuracy and completeness of the information. First, EPA can require that certain information and underlying information be provided in full, which ensures completeness. In addition, a § 8(d) rule requires that people engage in an adequate search of records. 40 C.F.R. § 716.25. Second, submitters must file certification statements by authorized officials that certify that the submitted information has been submitted in compliance with the requirements of this process. See, e.g., 40 C.F.R. § 711.15(b)(1). Third, submitters often must retain records of required submissions for a period of five years, and the retention of records can help encourage accurate reporting since those records would be available should a submission later be investigated. See, e.g., 40 C.F.R. § 711.25. None of these features apply to the voluntary requests for information EPA has indicated it is relying on.

Here, Sun Chemical and CPMA chose exactly how much and what information to provide to EPA about PV29. Sun Chemical and CPMA could easily have additional information that they are withholding; EPA has taken no steps (despite clear authority) to ensure that it has obtained all reasonably available information.

D. EPA cannot rationally rely on unvetted industry submissions, and to the extent EPA relies on voluntary submissions from industry, EPA must take numerous additional steps to increase their reliability and transparency.

In the draft risk evaluation, EPA uncritically relies on industry submissions, and this reliance does not comply with TSCA § 26(h), including the duty to use the best available science. In the most extreme examples, EPA cites to pieces of correspondence where the actual text of the correspondences is not available, nor are the surrounding circumstances or any supporting evidence. *See, e.g.*, (pp. 14, 20-23). From these records, it is not possible for the public to even begin to assess the accuracy of the underlying statements or EPA's conclusions based on them.

To the extent it relies on voluntary submissions, EPA can and should take additional steps to better ensure that the voluntary information it receives is accurate and complete. EPA would need to develop a far more rigorous and structured process than it currently has. For example, EPA's submission process does not appear to require anyone to certify that the information in their comments is accurate or complete to the best of their knowledge. EPA should consider approaches for vetting statements and assertions, particularly when made by entities with a financial interest in the outcome of these risk evaluations.

EPA should also request that submitters always provide full studies, as well as underlying data whenever reasonably available or obtainable. Setting aside concerns about partiality, EPA needs the underlying data to ascertain the accuracy of the information and associated statements or conclusions, as well as to determine how much confidence or uncertainty applies to a particular submission.

In addition, EPA should seek input directly from workers for manufacturers and processors, providing them an easy method to submit information on workplace practices and conditions independently from management. EPA needs to take steps to allow workers to provide input in a manner that reduces the risks of any potential retaliation from management.

13. EPA should identify people living near disposal sites, sources of contamination, and other conditions of use as potentially exposed or susceptible subpopulations.

EPA should identify people living near disposal sites as potentially exposed or susceptible subpopulations for the reasons articulated in EDF's prior comments.¹⁴⁹ Similarly, EPA should

¹⁴⁹ EDF Comments on Ten Problem Formulations under the Toxic Substances Control Act, pp.65-67, <https://www.regulations.gov/document?D=EPA-HQ-OPPT-2016-0725-0061>; EDF Comments on Ten Scopes under the Toxic Substances Control Act, pp.8-9, <https://www.regulations.gov/document?D=EPA-HQ-OPPT-2016-0725-0041>.

identify people living in proximity to sources of contamination as potentially exposed or susceptible subpopulations.¹⁵⁰ And EPA should identify people subject to greater exposure due to their proximity to conditions of use as a potentially exposed or susceptible subpopulation; most of the other problem formulations correctly identified this subpopulation. The reasoning that supports identifying these subpopulations for the other chemicals similarly applies here, absent a compelling explanation for excluding these subpopulations. EDF incorporates its prior comments on these points here.

14. EPA needs to accurately evaluate real-world occupational and consumer exposures.¹⁵¹

A. EPA needs to explain how it will incorporate consideration of engineering controls and personal protective equipment (PPE) into its analyses.

In the draft risk evaluation, EPA discusses engineering controls and personal protective equipment when assessing occupational exposures. *See* (p. 22). But EPA has provided an inadequate explanation for how EPA considered this information or what assumptions EPA made when doing so. For example, as a practical matter, EPA appears to have assumed that every downstream processor and user of PV29 will use engineering controls and other measures sufficient to ensure that air concentration of the chemical would never exceed .5 mg/m³ over 12 hours/day. But EPA never articulates this assumption and never documents the basis for it; instead, EPA simply assumes that downstream processors and users would never have concentrations exceeding those reported by the manufacturer.

In its response to comments on its earlier Scope Documents, EPA stated that: “When appropriate, in the risk evaluation, OPPT will use exposure scenarios both with and without engineering controls and/or PPE that may be applicable to particular worker tasks on a case-by-case basis for a given chemical.”¹⁵² As a general rule, at a minimum, EPA should always evaluate each exposure scenario without the engineering controls and PPE unless EPA has solid evidence that the scenario without engineering controls and/or PPE never occurs in the real world. In addition, EPA needs to rely on its information authorities to obtain accurate empirical evidence about how widely these measures are used as well as how effective these measures

¹⁵⁰ EDF Comments on Ten Problem Formulations under the Toxic Substances Control Act, pp.67-68, <https://www.regulations.gov/document?D=EPA-HQ-OPPT-2016-0725-0061>.

¹⁵¹ EDF has discussed the limitations of EPA’s assumptions about and reliance on these measures in section 4.A.iii. and iv. of these comments. Here we set forth how they should be accounted for.

¹⁵² EPA’s Responses to Public Comments Received on the Scope Documents for the First Ten Chemicals for Risk Evaluation under TSCA p.4, <https://www.regulations.gov/document?D=EPA-HQ-OPPT-2016-0725-0051>.

are at reducing exposure. Absent such evidence, EPA cannot assume that they are widely used or effective.

B. Even where engineering controls and/or PPE are used to some extent, EPA should always evaluate exposures scenarios without engineering controls and PPE in order to assess exposures and risks to those subpopulations not subject to such controls.

Rarely if ever in the real world will an exposure scenario involve 100% use and efficiency of engineering controls and/or PPE, so EPA always will need to evaluate exposure scenarios both with and without such controls. This is because, under TSCA, EPA is required to evaluate and protect against risk to potentially exposed or susceptible subpopulations including those “who, due to *** greater exposure, may be at greater risk.” 15 U.S.C. § 2602(12).

If EPA has reliable affirmative evidence as to the extent of use and efficiency of use of engineering controls and PPE for a given scenario, it may be able to estimate overall exposures arising from the scenario. However, that does not absolve the agency of an obligation to evaluate exposures and risks for the subset of people for whom those controls are not in place or do not reach 100% efficiency.

Absent such empirical evidence, EPA should assume no use of engineering controls or PPE in evaluating exposure, or at least apply reasonable worst-case assumptions as to the extent and efficiency of their use.

EPA should additionally analyze the exposure scenario with engineering controls and/or PPE, to evaluate exposures for the subset of people for whom those controls are in place. In doing so, however, EPA should evaluate exposures resulting from varying efficiencies in exposure reduction achieved by the controls. Such analyses may also be valuable at a later risk management stage.

C. EPA should never rely on PPE as a basis to assume low or no exposure, given the major real-world limitations of these measures.

As noted in section 4.A. above, EPA should not inaccurately assume that people always use PPE. EDF strongly urges EPA to consider real-world exposures reflecting the reality of the sometimes low-compliance with or non-existence of these measures.

Reliance on PPE has major practical limitations and, at best, exhibits mixed effectiveness in the real world. For example, OSHA concluded that respirators are the “least satisfactory approach to exposure control.” The agency provides the following explanation:

*** to be effective, respirators must be individually selected, fitted and periodically refitted, conscientiously and properly worn, regularly maintained,

and replaced as necessary. The absence of any one of these conditions can reduce or eliminate the protection the respirator provides.

Respirator effectiveness ultimately relies on the practices of individual workers who must wear them. *** Furthermore, respirators can impose substantial physiological burdens on workers, including the burden imposed by the weight of the respirator; increased breathing resistance during operation; limitations on auditory, visual, and olfactory sensations; and isolation from the workplace environment.

OSHA therefore continues to consider the use of respirators to be the least satisfactory approach to exposure control ***.¹⁵³

This reality has long been memorialized through OSHA's Industrial Hygiene Hierarchy of Controls (HOC), which prioritizes measures to eliminate or reduce the presence of a hazard in occupational settings (e.g., substitution/use of less toxic chemicals and institution of engineering controls) over measures that shift burdens onto the workers themselves, such as through reliance on PPE and warning labels.¹⁵⁴ The HOC exemplifies the best available science for creating safe, healthful workplace environments.

EPA should account for such real-world limitations of PPE in the risk evaluation by either collecting or requiring the development of empirical data, or, in their absence, using worst-case assumptions to assess the extent of exposure reduction resulting from PPE. Procurement and reliance on such data clearly constitute best available science (a requirement under TSCA § 26), and EPA has clear authority to collect or require the development of such data under § 4(b)(2)(A). And absent empirical evidence establishing the extent to which people are using these measures and doing so effectively, EPA should assume that they are or may not be. Indeed, EPA's need for accurate information about actual compliance is another reason to rely on its authorities under TSCA § 8 to mandate that manufacturers and processors provide such information.

¹⁵³ Comment by David Michaels, Assistant Secretary for OSHA, on Significant New Uses of Chemical Substances: Updates to the Hazard Communication Program and Regulatory Framework pp.1-2, <https://www.regulations.gov/document?D=EPA-HQ-OPPT-2014-0650-0041>

¹⁵⁴ HAZARD PREVENTION AND CONTROL, <https://www.osha.gov/shpguidelines/hazard-prevention.html> (last visited Jan. 14, 1029).

In comments EDF has earlier submitted, EDF previously commented on the serious limitations of PPE, as well as the importance of adherence to the hierarchy of controls to limit workplace exposures.¹⁵⁵ EDF incorporates and reiterates the points made in those comments here.

15. EPA has not complied with TSCA § 6(b)(4)(F) or its risk evaluation rule in preparing the draft risk evaluation.

EPA has not complied with TSCA § 6(b)(4)(F) or its own risk evaluation rule, 40 C.F.R. §§ 702.41 and 702.43, because the draft risk evaluation does not consider all of the factors required by these provisions.

Under TSCA § 6(b)(4)(F), EPA must “take into account, where relevant, the likely duration, intensity, frequency, and number of exposures under the conditions of use of the chemical substance.” 15 U.S.C. § 2605(b)(4)(F)(iv). EPA did not take into account the likely duration, intensity, frequency, or number of exposures for PV29 in its draft risk evaluation. (pp. 20-23, 28-30).

EPA’s risk evaluation rule requires that the “The environmental health exposure assessment will characterize and evaluate the interaction of the chemical substance with the ecological receptors identified in the final scope document published pursuant to paragraph (c)(8) of this section.” 40 C.F.R. § 702.41(e)(5)(i). The scope identified aquatic and terrestrial species as ecological receptors. In its section on environmental releases and exposures (section 3.2), EPA fails to characterize and evaluate adequately or at all the interactions between PV29 and these receptors. (pp. 20-21). Instead, EPA simply dismisses the environmental exposures as “likely to be limited.” (p.21).

EPA’s risk evaluation rule requires that the risk characterization include a discussion of: “Information about uncertainty and variability in each step of the risk evaluation *** will be integrated into an overall characterization and/or analysis of the impact of the uncertainty and variability on estimated risks.” 40 C.F.R. § 702.43(b)(1). EPA’s risk characterization never mentions variability except in invoking uncertainty factors when calculating its benchmark margin of exposure. (p.29). The risk characterization therefore fails to address variability at each step or its impact on estimated risks. (pp. 26-31).

¹⁵⁵ See, e.g., EDF Comments on TSCA Review and Scoping for First 10 Chemicals under the Lautenberg Act at 6 (Mar. 15, 2017), <https://www.regulations.gov/document?D=EPA-HQ-OPPT-2016-0736-0046>; EDF Comments on Significant New Uses of Chemical Substances; Updates to the Hazard Communication Program and Regulatory Framework; Minor Amendments to Reporting Requirements for Premanufacture Notices (Nov. 21, 2016), <https://www.regulations.gov/document?D=EPA-HQ-OPPT-2014-0650-0052>.

EPA's risk evaluation rule requires that the risk evaluation include a discussion of the extent of independent verification or peer review of the information used in the risk evaluation. See 40 C.F.R. § 702.43(b)(2). EPA failed to comply with this duty, as well as its duty under TSCA § 26(h)(5). 15 U.S.C. § 2625(h)(5). For example, EPA relies on numerous industry submissions without any independent verification and fails to address that issue in its draft risk evaluation. In addition, EPA's method of systematic review has not been independently verified or peer reviewed.

EPA's risk evaluation rule states that "If appropriate and relevant, where alternative interpretations are plausible, a discussion of alternative interpretations of the data and analyses will be included." 40 C.F.R. § 702.43(b)(3). Given the major data gaps and lack of information about PV29, there are numerous plausible alternative interpretations of the data and analyses. In particular, given the absence of information about chronic hazards, one plausible interpretation of the data and analyses is that EPA has inadequate information to reach a determination about whether PV29 presents an unreasonable risk. EPA must, at a minimum, discuss this alternative interpretation and address it in the risk evaluation.

* * * * *

EDF appreciates the opportunity to provide comments and EPA's consideration of them.