Case No. 17-72260
Consolidated with Docket Nos. 17-72501, 17-72968,
17-73290, 17-73383, 17-73390

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**UNITED STATES COURT OF APPEALS**
**FOR THE NINTH CIRCUIT**

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SAFER CHEMICALS HEALTHY FAMILIES et al.,
*Petitioners*,

v.

U.S. ENVIRONMENTAL PROTECTION AGENCY et al.,
*Respondents*,

IPC INTERNATIONAL, INC. et al.,
*Respondents-Intervenors.*

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Consolidated Petitions for Review of
U.S. Environmental Protection Agency Rulemaking

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# MOTION FOR LEAVE TO FILE BRIEF OF *AMICUS CURIAE* PEOPLE FOR THE ETHICAL TREATMENT OF ANIMALS IN SUPPORT OF AFFIRMING U.S. ENVIRONMENTAL PROTECTION AGENCY'S RULEMAKING

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Treatment of Animals, Inc.

Pursuant to Federal Rule of Appellate Procedure 29(a), People for the Ethical Treatment of Animals ("PETA") respectfully requests leave to file an *amicus* brief in support of affirming the United State Environmental Protection Agency's ("EPA") rulemaking. The proposed *amicus* brief is attached here as Exhibit A.

PETA has no pecuniary interest in the outcome of this case.* However, PETA, has a strong interest in affirming EPA's authority to promulgate rules relating to chemical testing and safety, in order to meet their Congressional mandate to limit to the extent practicable chemical testing on animals, and positively affecting animal welfare in the United States.

Since its founding in 1980, PETA has worked to establish and protect the rights of all animals. With more than 6.5 million members and supporters, and guided by the principles that animals are not ours to eat, wear, experiment on, or use for

* PETA further represents that no counsel for a party authored this brief in whole or in part, and no party or counsel contributed money intended to fund the preparation or submission of this brief. No person other than PETA or counsel contributed money intended to fund the preparation and submission of this brief.

entertainment, PETA is the largest animal rights organization in the world. One of its key interests is to reduce and ultimately end the use and abuse of animals in experiments conducted in universities, contract laboratories, pharmaceutical and chemical companies, and government agencies.

PETA's work to reduce animal testing under the Toxic Substances Control Act (TSCA), 15 U.S.C. § 2601 et. seq., began with the Environmental Protection Agency's (EPA's) High Production Volume Chemical Challenge Program (Program) in 1998. Through this Program, EPA "challenged" chemical manufacturers to voluntarily provide basic human health and environmental effects information for chemicals produced or imported into the U.S. in quantities of 1 million or more pounds per year. Data Collection and Development on High Production Volume (HPV) Chemicals, 65 Fed. Reg. 81,686, 81,688 (December 26, 2000). These chemicals, among others, are subject to prioritization and risk evaluation under the amended TSCA.

Pursuant to this Program, EPA initially requested information from several different animal tests (described in

section IV of the proposed amicus brief) that would have used approximately 3.5 million animals through completion of the Program.† These tests are among those that EPA will likely require to prioritize and evaluate existing chemicals under the amended TSCA.

Recently, PETA has intensified its efforts to ensure that the amended TSCA's animal protection provisions are properly implemented. PETA asks to be heard in its effort to minimize animal suffering and aid the Court in upholding congressionally established authority. Accordingly, PETA respectfully requests leave of Court to file an *amicus* brief on these issues.

**Certification of Conference with Counsel**

This Court's rule for *amicus* participation here, at the merits stage for non-governmental entities, is that an *amicus* brief may only be filed (1) with leave or Court or (2) with certification of the consent of all parties. *See* Circuit Rules 29(a)(2).

† *See* Patricia L. Bishop et al., *Animal Use and Lessons Learned in the U.S. High Production Volume Chemicals Challenge Program*, 120 ENV. HEALTH PERSPECTIVES 12, 1631 (2012), available at https://ehp.niehs.nih.gov/1104666 (last viewed August 2, 2018).

PETA has sought, but been unable to obtain, consent of all parties to file its proposed brief.

Respectfully submitted,

Dated: August 9, 2018

*/s/ Paul Olszowka*

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## CERTIFICATE OF SERVICE

I hereby certify that on August 9, 2018, I electronically filed the foregoing **MOTION FOR LEAVE TO FILE BRIEF OF AMICUS CURIAE PEOPLE FOR THE ETHICAL TREATMENT OF ANIMALS IN SUPPORT OF AFFIRMING U.S. NVIRONMENTAL PROTECTION AGENCY'S RULEMAKING** with the Clerk of the Court for the United States Court of Appeals for the Ninth Circuit by using the appellate CM/ECF system.

I certify that all participants in the case are registered CM/ECF users and that service will be accomplished by the appellate CM/ECF system.

*/s/ Paul Olszowka*

DMS 13066521v1

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Consolidated Petitions for Review of
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# AMICUS CURIAE BRIEF OF PEOPLE FOR THE ETHICAL TREATMENT OF ANIMALS, INC.

## Supporting Affirmance of EPA Rulemaking

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## CORPORATE DISCLOSURE STATEMENT

Pursuant to Federal Rule of Appellate Procedure 29(a)(4)(a), People for the Ethical Treatment of Animals, Inc. (PETA) makes the following disclosures:

1) PETA has no parent corporations.

2) No publicly held companies hold 10% or more of PETA's stock as PETA is a non-stock corporation.

Dated: August 9, 2018

Respectfully submitted,

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## PETA'S STATEMENT OF IDENTITY, INTEREST, AND SOURCE OF AUTHORITY TO FILE

Pursuant to Federal Rule of Appellate Procedure 29(a)(4)(D), Amicus Curiae People for the Ethical Treatment of Animals, Inc. (PETA) states:

PETA is a Virginia non-stock corporation and a federally registered 501(c)(3) tax-exempt animal protection charity.

Since its founding in 1980, PETA has worked to establish and protect the rights of all animals. With more than 6.5 million members and supporters—guided by the principles that animals are not ours to eat, wear, experiment on, or use for entertainment—PETA is the largest animal rights organization in the world. One of its key interests is to reduce and ultimately end the use and abuse of animals in experiments conducted in universities, contract laboratories, pharmaceutical and chemical companies, and government agencies.

PETA's work to reduce animal testing under the Toxic Substances Control Act (TSCA), 15 U.S.C. § 2601 et. seq., began with the Environmental Protection Agency's (EPA's) High Production Volume Chemical Challenge Program (Program) in 1998. Through this

Program, EPA "challenged" chemical manufacturers to voluntarily provide basic human health and environmental effects information for chemicals produced or imported into the U.S. in quantities of 1 million or more pounds per year. Data Collection and Development on High Production Volume (HPV) Chemicals, 65 Fed. Reg. 81,686, 81,688 (December 26, 2000). These chemicals, among others, are subject to prioritization and risk evaluation under the amended TSCA.

Pursuant to this Program, EPA initially requested information from several different animal tests (described in section IV of the proposed amicus brief) that would have used approximately 3.5 million animals through completion of the Program.[1] These tests are among those that EPA will likely require to prioritize and evaluate existing chemicals under the amended TSCA.

PETA's work on this program led to the incorporation of animal protection provisions into the amended TSCA. PETA publicly commented on hundreds of animal testing proposals, reviewed compliance with EPA's guidance, and recommended case-specific

[1] *See* Patricia L. Bishop et al., *Animal Use and Lessons Learned in the U.S. High Production Volume Chemicals Challenge Program*, 120 ENV. HEALTH PERSPECTIVES 12, 1631 (2012), available at https://ehp.niehs.nih.gov/1104666 (last viewed August 2, 2018).

strategies to reduce and replace animal use. The most successful approaches are among those specified in the amended TSCA. *See* 15 U.S.C. § 2603(h)(1)(B). These include grouping structurally related chemicals and using the results of screening-level tests or available information to determine whether additional tests are needed. PETA's 2012 retrospective analysis of this Program shows that approximately 127,000 animals were ultimately subjected to testing, Bishop, 120 Env. Health Perspectives at 1631, a number far less than the 3.5 million initially anticipated, due in part to PETA's participation.

Recently, PETA has intensified its efforts to ensure that the amended TSCA's animal protection provisions are properly implemented. For example, using information available in EPA's ChemView database, PETA found that in 2017, EPA's animal testing requirements for new chemicals increased roughly tenfold over pre-implementation levels. PETA is currently working with EPA to return animal testing requirements to pre-implementation levels or lower, as well as to ensure that EPA requests information from acceptable testing methods that do not require the use of animals and that EPA explains

the basis of any decision to use vertebrate animals in testing, as required under the amended TSCA.

This brief has been filed in conjunction with a motion pursuant to Federal Rule of Appellate Procedure 29(a).

## AUTHORSHIP AND FUNDING OF THE BRIEF

Pursuant to Federal Rule of Appellate Procedure 29(a)(4)(E),

(i) No counsel for the parties authored this amicus curiae brief in whole or in part;

(ii) No parties or counsel for the parties contributed money intended to fund the preparation or submission of this brief; and

(iii) No person other than the amicus curiae, their members, or their counsel, contributed money intended to fund the preparation or submission of this brief.

Respectfully submitted,

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## SUMMARY OF THE ARGUMENT

The Lautenberg Chemical Safety for the 21st Century Act, Pub. L. No. 114-182, 130 Stat. 448 (2016), which amended the Toxic Substances Control Act (TSCA), 15 U.S.C. § 2601 et. seq., directs EPA to "reduce and replace, to the extent practicable, scientifically justified, and consistent with the policies of this title, the use of vertebrate animals in the testing of chemical substances or mixtures under this title." 15 U.S.C. § 2603(h)(1).

If, as Petitioners assert, EPA must consider all of a chemical's conditions of use, EPA will increase its requirements for animal testing. This is because EPA will be forced to consider a greater number of potential, including *de minimis*, exposures, at least some of which it will address through animal testing.

EPA's Prioritization and Risk Evaluation Rules assert appropriate and necessary discretion in chemical risk evaluations, while affording adequate opportunity for public review and comment on the conditions of use that EPA expects to consider for any given chemical.

## ARGUMENT

### I. Congress has directed EPA to reduce and replace the use of vertebrate animals in the testing of chemical substances.

TSCA, 15 U.S.C. § 2603(h)(1) directs EPA to "reduce and replace, to the extent practicable, scientifically justified, and consistent with the policies of this title, the use of vertebrate animals in the testing of chemical substances…." TSCA's amendment reflects the longstanding commitments of Congress and federal regulatory agencies to reduce animal testing.

The ICCVAM (Interagency Coordinating Committee on the Validation of Alternative Methods) Authorization Act of 2000, 42 U.S.C. § 285l-2, et seq., was intended to promote "the regulatory acceptance of ... valid toxicological tests that protect human and animal health and the environment while reducing, refining, or replacing animal tests...."[2]

[2] *See* 42 U.S.C. § 285l-4(b) ("Each Federal Agency carrying out a program [that requires or recommends acute or chronic toxicological testing] shall promote and encourage the development and use of alternatives to animal test methods (including batteries of tests and test screens) where appropriate, for the purpose of complying with Federal statutes, regulations, guidelines, or recommendations (in each instance, and for each chemical class) if such test methods are found to be effective for generating data, in an amount and of a scientific value that is at least equivalent to the data generated from existing tests, for

*See* Pub. L. No. 106-545, 114 Stat. 2721. In 2004, EPA asked the National Research Council, which provides objective policy advice to the federal government, to develop a long-range vision and strategy for chemical toxicity testing. *See* Daniel Krewski, et al., *Toxicity Testing in the 21st Century: A Vision and a Strategy*, 13 J. TOXICOL. ENVIRON. HEALTH B CRIT. REV. 51 (2010). The National Research Council's 2007 report, "Toxicity Testing in the 21st Century: A Vision and a Strategy," addressed many of the limitations of animal testing, including its heavy use of animals, high cost, slow pace, and relevance to humans. *Id.* at 57. In its place, the report envisioned a new toxicity-testing system that evaluates biologically significant perturbations in key toxicity pathways by using new methods in computational biology and a comprehensive array of *in vitro* tests based on human biology. *Id.* at 59-60.

The decade since the publication of the National Research Council's report has seen continued advances in technologies that can be used to understand human biology and disease at the molecular level. "[G]overnment collaborations have been formed, large-scale U.S. and international programs have been initiated, and data are being

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hazard identification, dose-response assessment, or risk assessment purposes.").

generated from government, industry, and academic laboratories…" National Academies of Sciences, Engineering, and Medicine, USING 21ST CENTURY SCIENCE TO IMPROVE RISK-RELATED EVALUATION 1 (2017). The National Academies Press (2017). These developments continue to reduce or replace the use of animal testing while providing information of equivalent or better scientific quality and relevance to support regulatory decisions, and indicate the continued evolution of animal test reduction, consistent with the mandate of the amended TSCA.

## II. Without discretion to exclude conditions of use, EPA would require a greater number of animal tests.

Petitioners incorrectly argue that, in evaluating risk, EPA must consider all of a chemical's "conditions of use" defined as "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." Brief for Petitioners at 25-31, No. 17-72260 (2018) (*quoting* 15 U.S.C. § 2602(4)). Petitioners contend that EPA will overlook important contributors to a chemical's overall risk if it excludes *any* known or reasonably foreseen circumstances from its consideration. *Id.* at 3.

Petitioners cite several examples from EPA's scoping documents for the first ten risk evaluations to be conducted under the amended TSCA. *Id.* at 36-37. However, even if EPA has excluded certain contributors to overall risk in some of these examples, it does not follow that *all* of a chemical's conditions of use are important contributors to overall risk.

If, as Petitioners insist, EPA must consider all of a chemical's conditions of use, it would necessarily consider a greater number of circumstances than EPA would if it excluded some of these use. This would likely lead EPA to identify a correspondingly greater number of concerns over a chemical's potential for risk, at least some of which it might address by requiring animal tests to evaluate hazard.

In its Risk Evaluation Rule, EPA acknowledges that its determination of a chemical's conditions of use is largely factual; however, it observes that this "determination will inevitably involve the exercise of some discretion." Procedures for Chemical Risk Evaluation Under the Amended Toxic Substances Control Act, ("Risk Evaluation Procedures"), 82 Fed. Reg. 33,726, 33,729 (July 10, 2017). Therefore, EPA states that it will identify the conditions of use for each chemical on a case-by-case basis. *Id.* at 33,728.

EPA describes certain circumstances that it may elect not to consider because they present at most "*de minimis*" exposures to a chemical, exposures so small they do not contribute significantly to a chemical's overall risk. *See, e.g.*, *Indus. Union Dep't, AFL-CIO v. API*, 448 U.S. 607, 663-4 (1980) (Burger, C.J. concurring) (not addressing TSCA specifically but noting "[i]nherent in this statutory scheme is authority to refrain from regulation of insignificant or de minimis risks. When the administrative record reveals only scant or minimal risk of material health impairment, responsible administration calls for avoidance of extravagant, comprehensive regulation.") Those circumstances "include use[]… in a closed system that effectively precludes exposure, or use as [a chemical] intermediate," intentional misuse, uses that have been adequately assessed by other regulatory agencies, and activities that do not reflect ongoing or prospective manufacturing, processing, distribution and associated disposal. *See* Risk Evaluation Procedures, 82 Fed. Reg. at 33,729-730.

EPA correctly argues that, without such discretion, "the concept of 'conditions of use' would likely result in no meaningful limitation on [its] risk evaluations," which would present "unmanageable challenges."

Risk Evaluation Procedures, 82 Fed. Reg. at 33,729. One such challenge would be to reduce and replace the use of vertebrate animals, as required by TSCA. *See* 15 U.S.C. § 2603(h)(1). With no limitation on EPA's risk evaluations, there will be no limitation on its animal testing requirements to address hazards associated with even *de minimis* exposures. To the extent consideration of these circumstances is inconsistent with TSCA's policies, in particular, the identification of chemical substances that present an unreasonable risk of injury to health or the environment, it conflicts with EPA's obligation to reduce and replace the use of vertebrate animals.[3]

In sum, EPA needs discretion to focus on those conditions of use that raise the greatest potential for risk. Excluding from its consideration circumstances that present at most *de minimis* exposures reflects EPA's appropriate use of discretion.

[3] PETA fully supports EPA's discretion to exclude conditions of use from its consideration in risk evaluations and finds that public comment provides adequate opportunity for petitioners and other stakeholders to discuss the importance of specific exclusions. *See* Text, *infra* pp. 22-24.

## III. EPA's review of new chemicals has increased animal testing and illustrates why EPA needs discretion to exclude conditions of use that involve de minimis exposures.

If EPA must consider all conditions of use, testing on animals will increase, as illustrated by EPA's review of new chemicals under the amended TSCA. While EPA has not yet completed risk evaluations for any existing chemicals under the amended TSCA, it has so far reviewed 1,487 new chemicals to determine whether they present unreasonable risks to human health or the environment.[4] In many cases, EPA required or requested that the pre-manufacture notice (PMN) submitter conduct toxicity tests in animals. *See* Joseph Manuppello & Kristin Sullivan, Comment letter and spreadsheet on TSCA Alternative Testing Methods Strategy, EPA-HQ-OPPT-2017-0559-0587 (April 23, 2018) (hereafter "Comment Letter"). In 2017, the first year of implementing the amended TSCA, EPA required or requested 331 animal tests for new chemicals. These tests would use approximately 76,523 fish, guinea

[4] EPA, Statistics for the New Chemicals Review Program under TSCA, Reviewing New Chemicals under the Toxic Substances Control Act (TSCA) (June 29, 2018), available at https://www.epa.gov/reviewing-new-chemicals-under-toxic-substances-control-act-tsca/statistics-new-chemicals-review (last viewed Aug. 6, 2018).

pigs, mice, rabbits, and rats. *See* Manuppello, Comment letter.[5] In 2016 and 2015, prior to implementing the amended TSCA, EPA required or requested only 42 and 27 animal tests for new chemicals, respectively. *See id*.

In their comments on a December 2016 public meeting on reviewing new chemicals, PMN submitters and their representatives disputed certain conditions of use that EPA considered in its reviews. *See* American Chemistry Council, Comment letter on New Chemicals Review Program under the Amended Toxic Substances Control Act; Notice of Public Meeting and Opportunities for Public Comment, EPA-HQ-OPPT-2016-0658-0041 (Jan. 17, 2017). For example, the American Chemistry Council described the experience of a submitter in which EPA requested a 90-Day inhalation test for the PMN substance, citing concerns over lung effects. However, the submitter asserted that the

[5] These numbers have increased slightly since this comment was produced, presently 335 animal tests for new chemicals were requested, using approximately 77,051 fish, guinea pigs, mice, rabbits and rats. These amended numbers account for several additional tests that the Environmental Defense Fund identified after this comment was posted on the docket. Jennifer McPartland, Comment letter, EPA-HQ-OPPT-2017-0559-0832 available at https://www.regulations.gov/document?D=EPA-HQ-OPPT-2017-0559-0832 (last viewed Aug. 7, 2018).

material would never be respirable.[6] Such conditions of use, had they been considered for existing chemicals under the Risk Evaluation Rule, might reasonably be excluded as producing at most *de minimis* exposures.

EPA's review of new chemicals also demonstrates that TSCA's requirement that EPA consider using test methods and strategies that reduce or replace the use of vertebrate animals is unlikely to protect animals sufficiently. *See* 15 U.S.C. § 2603(h)(1)(B)(i). As one example, in 2017, EPA required or requested 32 skin sensitization tests, even though in its own publication, EPA states that key events in the skin sensitization toxicity pathway have allowed the integration of *in vitro*, *in chemico*, and *in silico* alternatives into approaches which EPA accepts to replace these tests. *See* Strategic Plan to Promote the Development and Implementation of Alternative Test Methods Within the TSCA Program, EPA-740-RI-8004, at 18 (June 22, 2018).

EPA also requested an acute eye irritation "Draize" test in which irritating or corrosive substances would be applied directly to a rabbit's

[6] American Chemistry Council, Comment letter on New Chemicals Review Program under the Amended Toxic Substances Control Act; Notice of Public Meeting and Opportunities for Public Comment, EPA-HQ-OPPT-2016-0658-0029 at 5 (Jan. 18, 2017).

eyes (potentially causing redness, swelling, discharge, ulceration, hemorrhaging, cloudiness, or blindness before the rabbit is killed).[7] EPA has imposed this requirement, even though it lists eye and skin irritation as having existing alternative test guidelines which meet its needs.[8]

Both EPA's review of new chemicals under the amended TSCA and its previous Program illustrate the types of animal tests that might be required for existing chemicals.

For new chemicals, in 2017, EPA required 23 and requested 25 different types of animal tests.[9] The animal test that EPA required most frequently was the combined repeated dose toxicity with reproduction/ development toxicity screening test. Patricia L. Bishop, Joseph R. Manuppello, Catherine E. Willett, & Jessica T. Sandler,

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[7]OCED Guideline for the Testing of Chemicals: Acute Eye Irritation/ Corrosion (Oct. 2, 2012) avail. at https://ntp.niehs.nih.gov/iccvam/suppdocs/feddocs/oecd/oecd-tg405-2012-508.pdf (last viewed Aug. 6, 2018).

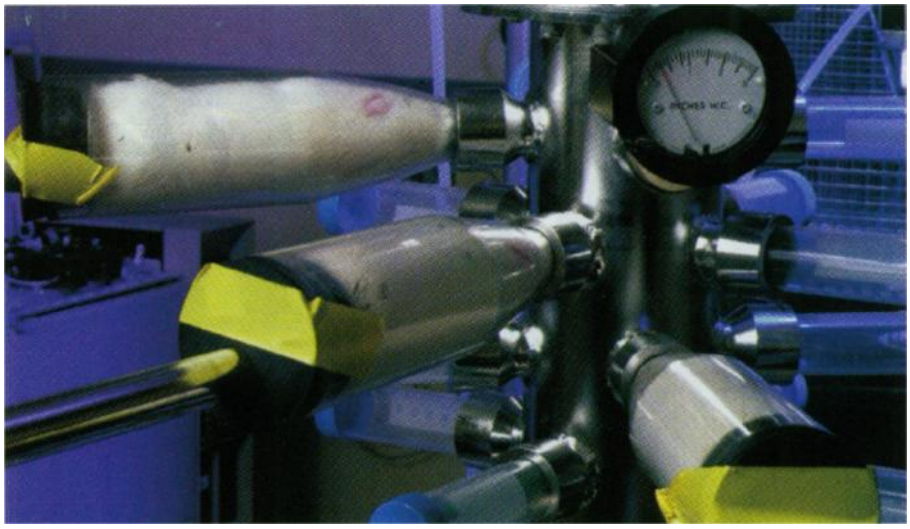
[8] EPA, Consent Order, Matter P-16-0595, avail. at https://chemview.epa.gov/chemview/proxy?filename=sanitized_consent_order_p_16_0595.pdf (last viewed Aug. 6, 2018).

[9] See *ChemView Database*, United States Environmental Protection Agency (Feb. 15, 2018), available at https://chemview.epa.gov/chemview; Comment Letter, EPA-HQ-OPPT-2017-0559-0587 (last viewed Apr. 23, 2018).

*Animal Use and Lessons Learned in the U.S. High Production Volume Chemicals Challenge Program*, 120 ENVIRON. HEALTH PERSPECTIVES 1631 (2012). EPA required 30 of these tests, each of which uses approximately 580 animals. *Id.*

Another test that EPA frequently requested was the 90-Day inhalation toxicity test. *Id.* EPA requested 56 of these tests, each of which uses approximately 80 animals. *Id.* This test is frequently conducted by nose-only exposure. For six hours each day, the animals are constrained in plastic tubes only slightly larger than their bodies in order to prevent them from turning to avoid the test substance being administered through the nose end of the tubes. OECD Guidelines for the Testing of Chemicals, Section 4: Test No. 413: Subchronic Inhalation Toxicity: 90-Day Study, (2018). This test is depicted below. [10]

[10] Rats subjected to inhalation toxicity test. May, M. "Breathtaking Research." 108 ENVIRONMENTAL HEALTH PERSPECTIVES 4, 169 (2000).



Animal tests that EPA requested for existing chemicals in the Program are also likely to be required to prioritize and evaluate the risk of existing chemicals under the amended TSCA include the following:

- Acute toxicity studies on mammals measure a chemical's capacity to cause harm or death within two weeks of a single, brief exposure. Chemicals are administered to animals (usually rodents), in extremely high doses, typically by a force-feeding tube or syringe. Acute toxicity studies inflict extreme suffering on animals, who may endure severe abdominal pain, diarrhea, bleeding from the nose, mouth, and genitals, convulsions, seizures, and paralysis before they ultimately die. *See* Organization for Economic Co-operation and Development (OECD) Guidelines for

the Testing of Chemicals, Section 4: Test No. 425: Acute Oral Toxicity: Up-and-Down-Procedure (2008).

- Acute toxicity studies in fish (a type of "ecotoxicity" test) measure a chemical's effects on the environment and wildlife. Chemicals are administered into the water of tanks holding the fish, who are exposed to the test chemical for several days. The number of fish who die each day is recorded, and the chemical concentration that kills one-half of the fish is calculated. Each test requires 60 fish. *See* OECD Guidelines for the Testing of Chemicals, Section 2: Test No. 203: Fish, Acute Toxicity Test (1992).

- Repeated dose toxicity studies measure the effects of multiple chemical exposures on animals' livers, kidneys, lungs, hearts, and nervous systems. Animals (usually rodents) are exposed to repeated, lower doses of chemicals for one to three months. Repeated dose studies are highly stressful, as animals are subjected to frequent handling, and restraint, in addition to suffering the toxic effects of the chemicals under investigation. *See* OECD Guidelines for the Testing of Chemicals, Section 4: Test No. 408: Repeated Dose 90-Day Oral Toxicity Study in Rodents (2018).

- Reproductive toxicity studies in mammals measure a chemical's effects on reproductive organs and fertility. They are based on repeated dose toxicity studies in rodents, and the animals are examined for changes in sexual behavior, hormonal activity, sperm and egg production, fertilization, and development in the uterus. At the conclusion of the study, the animals are killed and their reproductive organs are removed for examination. Each test requires 1,160 animals. *See* OECD Guidelines for the Testing of Chemicals, Section 4: Test No. 416: Two-Generation Reproduction Toxicity (2001).

- Developmental toxicity studies measure a chemical's effect on developing offspring during critical periods of growth. They are based on a repeated dose toxicity study in pregnant rodents and are sometimes carried out for extended periods to study several generations of offspring. These offspring, if they survive, may suffer gross birth defects such as developmental abnormalities or debilitating physical deformities. Each test requires 1,160 animals. *See* OECD Guidelines for the Testing of Chemicals,

Section 4: Test No. 414: Prenatal Development Toxicity Study (2018).

## IV. Notice and comment provide adequate opportunity to address concerns over excluded conditions of use.

In its Risk Evaluation Rule, EPA states that it intends to provide an opportunity for public comment on drafts of future scoping documents, while for the first ten chemicals being evaluated, EPA has published and is taking comment on Problem Formulation documents which refine the draft scoping documents. Risk Evaluation Procedures, 82 Fed. Reg. at 33,729. If Petitioners or other members of the public believe that a circumstance excluded by EPA in a particular case is an important, rather than a *de minimis*, contributor to a chemical's overall risk, public comment provides adequate opportunity to express such concerns.

The utility of this process is demonstrated by these Problem Formulation documents, which account for comments received on the draft scoping documents. For example, EPA removed seven product categories from the list of legacy uses it would exclude from its consideration of asbestos, because they "fall under broader categories

that EPA has identified as conditions of use" and "could be considered under the risk evaluation" in these categories. EPA, Office of Chemical Safety and Pollution Prevention, Problem Formulation of the Risk Evaluation for Asbestos, EPA-740-R1-7018 at 20 (2018).

## V. Conditional recommendation regarding setting *de minimis* exposure levels.

We fully support EPA's discretion to exclude conditions of use from its consideration in risk evaluations and find that public comment provides adequate opportunity for petitioners and other stakeholders to discuss the importance of specific exclusions. However, in the event that the court finds merit in the petitioners' argument, we offer a recommendation that could serve as a compromise.

The petitioners frequently describe EPA's discretion as "unfettered," while EPA asserts discretion to exclude only circumstances that produce *de minimis* exposures. Apart from the legal definition, the meaning of *de minimis* as it relates to chemical exposures is undefined. We recommend that EPA describe, in its guidance to industry, the process by which it will set *de minimis* exposure levels for the purposes of prioritization and risk evaluation

under TSCA. Further, in its scoping documents, EPA should report the levels it has determined and show that any circumstances it has chosen to exclude produce only exposures that fall below these levels. Both such general guidance and scoping documents would provide additional opportunity for comment. Such an approach offers a remedy to the petitioners' concerns that is more practical and less onerous than requiring EPA to consider all conditions of use for the chemicals it evaluates.

## CONCLUSION

For the reasons stated, Amici respectfully request that this Court affirm the rulemaking of U.S. Environmental Protection Agency.

Respectfully submitted,

*/s/Paul Olszowka*

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## RULE 32(g)(1) CERTIFICATE OF COMPLIANCE

I certify that this brief contains 3,595 words, excluding parts exempted by Federal Rule of Appellate Procedure 32(a)(7)(B), according to a count by Microsoft Word and has been prepared in 14-point Century Schoolbook, a proportionally-spaced font, and therefore complies with the limits set forth in Federal Rule of Appellate Procedure 32(a)(5), 32(a)(6), and 32(a)(7)(B)(i) as modified by Federal Rule of Appellate Procedure 29(d) for amicus parties.

*/s/Paul Olszowka*
Paul Olszowka

## CERTIFICATE OF SERVICE

I hereby certify that on August 9, 2018, I electronically filed the foregoing AMICUS CURIAE BRIEF with the Clerk of the Court for the United States Court of Appeals for the Ninth Circuit by using the appellate CM/ECF system.

I certify that all participants in this case are registered CM/ECF users and that service will be accomplished by the appellate CM/ECF system.

*/s/ Paul Olszowka*
Paul Olszowka

DMS 13013017v2