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Comments from Academics, Scientists and Clinicians on Approaches for Identifying Potential Candidates for Prioritization for Risk Evaluation Under Amended TSCA

Submitted online via *Regulations.gov* to docket EPA-HQ-OPPT-2017-0586

These comments are submitted on behalf of the undersigned academics, scientists, and clinicians. We declare collectively that we have no direct or indirect financial or fiduciary interest in any chemical or product that is the subject of these comments. The co-signers' institutional affiliations are included for identification purposes only and do not imply institutional endorsement or support unless indicated otherwise.

We appreciate the opportunity to provide written comments on approaches for EPA to identify candidates for prioritization pursuant to the Toxic Substances Control Act (TSCA), as amended by the Frank R. Lautenberg Chemical Safety for the 21st Century Act ("amended TSCA"). EPA held a meeting on December 11, 2017 in Washington, D.C., which several of the undersigned attended. We are following up with detailed comments and responses to information shared by EPA and other public commenters during this meeting.

We agree that a "pre-prioritization" process that generates and evaluates potential chemical candidates will help the Agency meet statutory deadlines and select chemicals suitable to feed into the prioritization pipeline as required by amended TSCA.[1] We recommend that the criteria Congress set forth in Lautenberg TSCA section 6(b) that EPA "shall" consider for prioritization should also guide the pre-prioritization process:

1. Hazard
2. Exposure potential
3. Persistence
4. Bioaccumulation
5. Potentially exposed and susceptible subpopulations
6. Storage near significant sources of drinking water
7. Conditions of use
8. Significant changes in conditions of use
9. Volume manufactured or processed
10. Significant changes in the volume manufactured or processed

These factors all reflect clear public health considerations, including vulnerable populations and metrics related to exposure potential such as production volume and proximity to drinking water sources. EPA has already developed sound approaches for identifying priority chemicals of concern (the TSCA Work Plan Methodology) and chemicals of low concern (the Safer Chemical Ingredients List) that consider many of the above factors. [2] The Agency's resources are best spent modifying these existing approaches to feed into the prioritization process according to the requirements of amended TSCA, with a larger

[1] Requirements in U.S.C. §2605(b), referred to throughout these comments as TSCA 6(b)

[2] EPA (2017) Discussion Document: Possible Approaches and Tools for Identifying Potential Candidate Chemicals for Prioritization

focus on high priority substances, as described in more detail below. We strongly recommend that in the final approach adopted by EPA, chemical hazard should be given priority over exposure considerations because chemical uses can change over time, thus altering the anticipated exposures.

EPA should not use the Functional Category approaches (Approaches 4 and 5 in the discussion document) for pre-prioritization because: (1) they rely heavily on exposure potential considerations based on current functional uses, with scant consideration of the other factors outlined above, as mandated in TSCA. Further, uses of chemicals can and do rapidly change which would render a prioritization relying solely on current uses inaccurate; (2) While it is clear how these approaches would benefit industry as EPA outlines in the discussion document, the benefits to public health, especially for the most vulnerable, are not clear; and (3) Both approaches, but the functional category approach based on chemical structure and function in particular, appear to consider factors related to the viability of alternatives to high priority chemicals, a non-risk factor which TSCA 6(b) explicitly prohibits.

Our comments address the following main points:

1. **EPA should focus its resources on evaluating high-priority, hazardous chemicals as intended by Congress.**
2. **To designate chemicals as low priority, EPA needs to have sufficient data as defined by existing guidelines.**
3. **EPA should exercise its authorities to gather data on chemicals for pre-prioritization under TSCA sections 4, 8, and 14.**
4. **The TSCA Work Plan Methodology is a sound approach for identifying high-priority chemicals. To meet the requirements of amended TSCA, the Work Plan Methodology must include additional factors identified in TSCA Section 6(b).**
5. **A subset of the Safer Chemical Ingredients List (SCIL) chemicals (low-hazard, green circle) are an appropriate starting place for identifying potential low-priority chemicals. To meet the requirements of TSCA 6(b) as a low-priority chemical, EPA would need to conduct further evaluation and consider other factors including all conditions of use and the sufficiency of the data.**
6. **The criteria in the TSCA Work Plan Methodology for persistent and/or bioaccumulative chemicals are supported by current science and should be used in the pre-prioritization and prioritization processes. Persistence in the body should be defined as a half-life of 1 day or greater.**

We are appreciative of the opportunity to provide public input. Please do not hesitate to contact us with any questions regarding these comments.

Sincerely,

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DETAILED COMMENTS

1. EPA should focus its resources on evaluating high-priority, hazardous chemicals as intended by Congress.

EPA's Guiding Principle 5 states that the Agency should strive to identify more than the statutory-mandated minimum of 20 low priority chemicals.[3] This principle is not consistent with Congress' intentions for TSCA and we strongly disagree with this direction.

The Findings and Policy of TSCA remained unchanged by the Lautenberg amendments as to the purpose and focus of the Act. Specifically:

> *"The Congress finds that…among the many chemical substances and mixtures which are constantly being developed and produced, there are some whose manufacture, processing, distribution in commerce, use, or disposal may present an unreasonable risk of injury to health or the environment…*
>
> *It is the policy of the United States that…adequate authority should exist to regulate chemical substances and mixtures which present an unreasonable risk of injury to health or the environment, and to take action with respect to chemical substances and mixtures which are imminent hazards…"*[4]

Nowhere in the Findings, Policy or Intent is there mention of chemicals that are not likely to present risks. This indicates Congress' clear direction to EPA to concentrate on chemicals that may present unreasonable risks. Further, the mission of the EPA Office of Chemical Safety and Pollution Prevention (OCSPP) is: "Using sound science as a compass, OCSPP's mission is to protect you, your family, and the environment from potential risks from pesticides and toxic chemicals."[5] EPA should meet its statutory mandates under TSCA on low priority chemicals, but otherwise the public expects and the law demands that EPA focus its resources on protecting public health from dangerous chemicals--those that may present unreasonable risks.

EPA should start with identifying more high priority chemicals. Evaluating the currently existing 8,700 high production volume chemicals would take over 200 years if the Agency completed 40 evaluations at a time. With tens of thousands of chemicals in commerce in the U.S. that lack adequate safety information, EPA must plan for prioritization and assessment of a significant number of substances which may pose a hazard to the general or vulnerable populations. EPA should work with its future budget requests and fees program to ensure adequate resources for its programs.

We strongly recommend that EPA should remove Guiding Principle 5 or reword as follows:

> 5. EPA should strive to identify more than the statutory-mandated minimum of 20 high-priority chemicals to improve public health. EPA should compel the development of necessary data and provide as much information as possible to the public. EPA should implement TSCA such that

[3] EPA (2017) Discussion Document: Possible Approaches and Tools for Identifying Potential Candidate Chemicals for Prioritization. Pg. 11

[4] U.S.C. §2601(a)-(b)

[5] https://www.epa.gov/aboutepa/about-office-chemical-safety-and-pollution-prevention-ocspp. Accessed Jan 15, 2018.

the default or likely outcome is health protection for the public.

2. To designate chemicals as low priority, EPA needs to have sufficient data as defined by existing guidelines.

Under TSCA section 6(b), substances must be designated high priority if the Administrator concludes, without consideration of non-risk factors, that they "may present an unreasonable risk to health or the environment because of potential hazard and a potential route of exposure under the conditions of use." Low priority listing is appropriate for substances for which the Administrator concludes there is "sufficient information" to establish that they do "not meet the standard . . . for designating a chemical substance [as] high-priority." In other words, to designate substances as low priority, the Agency must find that they do not present unreasonable risks to health or the environment, and it must do so based on "sufficient information."

The concept of "sufficient information" generally covers both the types of data needed and the quality of each piece of data. EPA should clearly define what constitutes "sufficient information" for evaluation to make a low priority designation. This definition should include a list of traits deemed important to assess, such physical characteristics, health outcomes, effects on potentially exposed or susceptible subpopulations, etc. and a discussion of how these traits will be evaluated to determine whether "sufficient information" is available.

Some health hazard datasets EPA has utilized which could inform the Agency's definition include:

- The Screening Information Data Set from the Organization for Economic Cooperation and Development (OECD SIDS), utilized in EPA's High Production Volume (HPV) Chemical Challenge Program[6]
- The dataset from studies that determine hazard to humans required by EPA's Office of Pesticide Programs for pesticide registration[7]
- The health hazard dataset needed for EPA's Design for the Environment (DfE) program to conduct an alternatives assessment[8]

For example, the DfE criteria require evaluation of acute mammalian toxicity, carcinogenicity, mutagenicity/ genotoxicity, reproductive and developmental toxicity (including developmental neurotoxicity), neurotoxicity, repeated dose toxicity, respiratory and skin sensitization, eye and skin irritation/ corrosivity, and endocrine activity. General and specific requirements for the hazard evaluation include:

- Use of existing data should follow the EPA HPV Challenge Program and OECD HPV Programme data adequacy guidelines.
- The degradation or metabolism of a chemical into a by-product which itself is hazardous, slow to degrade, or bioaccumulative will be considered in the hazard assessment, where relevant supporting information (such as ADME data) are available. The purpose of considering

[6] Guth JH, Denison RA, Sass J. Background Paper for Reform No. 5 of the Louisville Charter for Safer Chemicals. The Louisville Charter for Safer Chemicals. 2005. Report No.: 5.

[7] https://www.epa.gov/pesticide-registration/data-requirements-pesticide-registration. Accessed Jan 15, 2018.

[8] EPA (2011) Design for the Environment Alternatives Assessment Criteria for Hazard Evaluation. Available: https://www.epa.gov/sites/production/files/2014-01/documents/aa_criteria_v2.pdf

degradation products and metabolites is to gain a better understanding of the overall hazard potential of a chemical.

- Evaluation of chemicals under these criteria will be based on the best available data. In general, DfE will use data in the following order of preference: 1) measured data on the chemical being evaluated, 2) measured data from a suitable analog, and 3) estimated data from appropriate models.
- In the absence of measured data on the chemical being evaluated, measured data from a suitable analog and/or estimated data from computer models will be used. In the event that there are no suitable analogs, that suitable analogs lack measured data, and the substance, or its analog cannot be modeled, the hazard endpoint cannot be evaluated and will be designated "no data."

EPA should also develop "completeness metrics" that track how many of the desired traits could be assessed based on the available data and provide a public summary characterizing the "completeness of the database" for each chemical. EPA has adopted similar approaches in the past, for instance using published criteria from the HPV, Chemical Assessment and Management Program (ChAMP) and EPA's Risk Assessment Guidance to evaluate the data adequacy in its brominated phthalates Data Needs Assessment.[9] This information should be made publicly available along with the ultimate priority determination for each chemical.

In situations where data are lacking, EPA should proactively outline existing data gaps and explicitly state where data are most needed to facilitate the external development and design of studies that will generate these data in a timely manner. Furthermore, as described in more detail in point 3 below, EPA should also utilize their authority to issue test orders to generate the data needed for pre-prioritization.

We also recommend that EPA clearly define the data needed to make a determination that a chemical does not pose particular hazards—i.e., is not a carcinogen, is not a developmental or reproductive toxicant, etc. EPA's definition should be informed by, and consistent with, established approaches of other agencies such as the National Toxicology Program (NTP),[10] the International Agency for Research on Cancer (IARC),[11] and EPA's own guidelines including the Cancer Guidelines.[12] These guidelines clearly define what constitutes the determination of no hazard, such as the requirement for multiple concurring lines of evidence from different species in experimental and/or observational scientific studies. For example, NTP explicitly states the data requirements for making a finding of no evidence of developmental toxicity: "Negative results, in which the study animals do not exhibit evidence of developmental toxicity, do not necessarily imply that a test article is not a developmental toxicant, but only that the test article is not a developmental toxicant under the specific conditions of the study…no evidence of developmental toxicity is demonstrated by data from a study with appropriate experimental

[9] U.S. Environmental Protection Agency. 2015. TSCA Work Plan Chemical Problem Formulation and Data Needs Assessment: Brominated Phthalates Cluster Flame Retardants. Pg. 7. Available from: https://www.epa.gov/sites/production/files/2015-09/documents/brominated_phthalates_cluster_data_needs_assessment.pdf

[10] National Toxicology Program, Office of Health Assessment and Translation. 2015. Handbook for Conducting a Literature-Based Health Assessment Using OHAT Approach for Systematic Review and Evidence Integration. Available from: https://ntp.niehs.nih.gov/ntp/ohat/pubs/handbookjan2015_508.pdf

[11] IARC (International Agency for Research on Cancer). 2006. IARC Monographs on the Evaluation of Carcinogenic Risks to Humans: Preamble. Available: http://monographs.iarc.fr/ENG/Preamble/index.php

[12] U.S. Environmental Protection Agency, 2005. Guidelines for Carcinogen Risk Assessment. Available from: https://www.epa.gov/sites/production/files/2013-09/documents/cancer_guidelines_final_3-25-05.pdf

design and conduct that are interpreted as showing no biologically relevant effects on developmental parameters that are related to the test article."[13]

Establishing a clearly defined approach ensures clarity and consistency regarding the level of evidence required for making the determination of no hazard. In keeping with current scientific principles, EPA should use existing authoritative guidance documents in the development of its definition to determine the quality, level, and source of "sufficient information" to make sound and transparent determinations regarding risk. EPA should establish its definitions in a manner consistent with public health protection.

"New Approach Methods" (NAM) data alone should not be used to designate a chemical as low-priority as this is not consistent with the statute's requirement for "sufficient information." A recent National Academies of Sciences (NAS) report describes how data generated by NAMs (such as high-throughput screening methods) are not different than any other type of *in vitro* or cell-based assay data that would be considered in reviewing evidence on a chemical.[14] These kinds of assays provide mechanistic data, and the NAS report explicitly considered how mechanistic data could be utilized in evidence integration. The committee came to two conclusions. First, a pre-defined protocol for evaluating relevance and study quality must be developed for the mechanistic data evidence stream, as is done for other evidence streams such as epidemiological or toxicology data. This must include the pre-defined determinations of what types of evidence will be included/excluded, how the risk of bias and quality of studies will be evaluated, and how the mechanistic evidence will be integrated with other evidence streams. These protocols should be made publicly available for stakeholder review prior to the initiation of the assessment. As an example, in the NAS' case study on phthalates, the committee was not able to integrate results from high-throughput assays because the cell lines used were of unknown relevance to the *in vivo* mechanism of phthalate toxicity.[15]

Second, the foundation of a hazard classification is the animal and human data, with the mechanistic data playing a supporting role. If mechanistic data is relevant, it can be used to upgrade a hazard classification, or increase the confidence of a finding made based on evaluation of animal and human data. A hazard classification is never made based on high-throughput or other kinds of NAM data alone.[16,17] EPA should continue to follow this established scientific practice.

3. EPA should exercise its authorities to gather data on chemicals for pre-prioritization under TSCA sections 4, 8, and 14. [18]

As required by law, EPA can only designate a chemical as low priority if there is sufficient evidence to conclude that the chemical does not pose an unreasonable risk to health or environment, including to

[13] NTP (2009) Explanation of Levels of Evidence for Developmental Toxicity. Available: https://ntp.niehs.nih.gov/ntp/test_info/ntp_devtox20090507.pdf

[14] The National Academies of Sciences. Application of Systematic Review Methods in an Overall Strategy for Evaluating Low-Dose Toxicity from Endocrine Active Chemicals. Washington, D.C.: National Academies Press; 2017.

[15] The National Academies of Sciences. Application of Systematic Review Methods in an Overall Strategy for Evaluating Low-Dose Toxicity from Endocrine Active Chemicals. Washington, D.C.: National Academies Press; 2017. Pg. 78

[16] Id. Pp. 10; 158-9

[17] NTP (2015) Handbook for Conducting a Literature-Based Health Assessment Using OHAT Approach for Systematic Review and Evidence Integration

[18] U.S.C. §2603, §2607 and §2613, referred to in these comments as TSCA 4, 8 and 14.

highly exposed, susceptible, or vulnerable populations. EPA requests for additional data on chemicals will be key to achieving sufficient evidence.

The Policy statement for TSCA was unchanged by the Lautenberg amendments and is particularly clear that adequate data is needed for chemicals, and that manufacturers and processers are responsible for generating this information:

> *It is the policy of the United States that…adequate information should be developed with respect to the effect of chemical substances and mixtures on health and the environment and that the development of such information should be the responsibility of those who manufacture and those who process such chemical substances and mixtures…*[19]

As described above, EPA should generate completeness metrics on the database for each chemical, describe the key areas where data is lacking, and issue orders pursuant to TSCA Section 4 and/ or Section 8 to obtain these data. Section 4 test orders should outline the most relevant test models, exposure pathways, health outcomes, and target populations (including any vulnerable or sensitive populations) anticipated to support the generation of high-quality and relevant evidence to support timely decision-making.

The responses and data received from EPA requests should be publicly available. TSCA section 14 clearly states that health and safety studies are not considered confidential business information (CBI) and thus are not protected from disclosure. As described above, EPA should also provide a public summary characterizing the data and its completeness for each chemical.

4. The TSCA Work Plan Methodology is a sound approach for identifying high-priority chemicals. To meet the requirements of amended TSCA, the Work Plan Methodology must include additional factors identified in TSCA Section 6(b).

The TSCA Work Plan Methodology was developed and refined through a transparent process with multiple opportunities for stakeholder participation.[20] It is informed by current scientific principles, reliable data sources and priority public health considerations; accordingly, we support its continued use in the pre-prioritization and prioritization processes, with the modifications recommended below.

Of the 10 factors listed in TSCA Sec 6(b), the Work Plan Methodology already considers 7 of them to some extent, as shown in the table below.

Factor in TSCA 6(b)	TSCA Work Plan Methodology Consideration
1. Hazard	Reproductive, developmental, neurotoxicity, carcinogenicity
2. Exposure potential	Consumer product uses; biomonitoring detection; Chemical Data Reporting (CDR) uses and Toxics Release Inventory (TRI) releases
3. Persistence	Chemicals scored on persistence according to current scientific criteria

[19] U.S.C. §2601(b)

[20] Meeting summaries and public comments available in docket: https://www.regulations.gov/docket?D=EPA-HQ-OPPT-2011-0516

4. Bioaccumulation	Chemicals scored on bioaccumulation according to current scientific criteria
5. Potentially exposed and susceptible subpopulations	Considered hazards (reproductive/ developmental toxicity) and exposures (e.g., children's product uses) relevant to children and pregnant women; considered hazard (cancer) seen at elevated rates in workers like firefighters
6. Storage near significant sources of drinking water	
7. Conditions of use	Considered consumer product and children's product uses
8. Significant changes in conditions of use	
9. Volume manufactured or processed	Considered production volume for chemicals not on Toxics Release Inventory
10. Significant changes in the volume manufactured or processed	

We recommend that EPA augment the Work Plan Methodology to improve upon the existing factors and expand to include the factors not addressed but required by TSCA. EPA could generate a list of chemicals with storage near significant sources of drinking water (including groundwater) and then screen it using the existing Work Plan Methodology. Alternatively, EPA could screen the current Work Plan list for chemicals stored near significant sources of drinking water, or use some combination of these approaches.

We also recommend that the revised methodology should consider:

- All conditions of use, including reasonably foreseen uses.
- Chemicals with exposure disparities for susceptible populations including children, pregnant women, workers, and communities of color or low socio-economic status;
- Chemicals with conditions of use (manufacturing, processing, use, recycling, disposal) in proximity to communities of color or low socio-economic status;
- Classes or clusters of chemicals, using the chemical categories from the New Chemicals Program as a foundation,[21] or potentially considering functional use approaches.

EPA should add additional relevant sources, such as the California Environmental Contaminant and Biomonitoring Program[22] or other state programs, to the list of data sources on pg. 12-13 of the Discussion Document.

The take-home pathway is an important consideration for prioritization of children's exposures. Workers track home occupational chemicals, as demonstrated with asbestos, lead and pesticides. Families of workers historically have been exposed to dangerous workplace chemicals because of contaminated clothing, equipment and belongings that come home from work with them. EPA should consider such "take-home" exposures as it makes determinations about prioritizing chemicals.

[21] EPA (2010) TSCA New Chemicals Program (NCP) Chemical Categories. Available: https://www.epa.gov/sites/production/files/2014-10/documents/ncp_chemical_categories_august_2010_version_0.pdf

[22] https://biomonitoring.ca.gov/

Finally, EPA should evaluate in its pre-prioritization process chemicals of the highest priority to workers, tribes, environmental justice and fence-line communities (those located in proximity to the conditions of use of a chemical). EPA should engage in dialogues with these groups to determine their highest priority chemicals.

5. A subset of the Safer Chemical Ingredients List (SCIL) chemicals (low-hazard, green circle) are an appropriate starting place for identifying potential low-priority chemicals. To meet the requirements of TSCA 6(b) as a low-priority chemical, EPA would need to conduct further evaluation and consider other factors including all conditions of use and the sufficiency of the data.

EPA's Safer Choice program, which developed and maintains the SCIL list, enjoys widespread support from businesses and NGOs.[23] The Safer Choice Master Criteria for Safer Ingredients are science-based and use authoritative, established criteria including those from the United Nation's Globally Harmonized System (GHS) for the Classification and Labeling of Hazard Substances.[24] We support the use of the SCIL as a starting place for pre-prioritization and prioritization, with the recommendations below.

The SCIL list categorizes chemicals according to three different codes: (1) full green circles are considered low hazard; (2) half-green circle are expected to be low hazard but some data are lacking and (3) yellow triangles have some hazard profile issues. Of these three, only the full green circle chemicals (605 total) are appropriate to consider as potential low priority chemicals. The half green circle chemicals should be targeted for data generation as described in point 3 above because they currently have data gaps. Finally, the yellow triangle chemicals with known hazards clearly do not meet the statutory criteria for low priority chemicals.

For the full green circle SCIL list chemicals, EPA would need to evaluate all conditions of use, including reasonably foreseen uses, as only a limited subset of uses related to particular products were evaluated for the SCIL listing. EPA would also need to evaluate additional hazard endpoints, as the Safer Choice Master Criteria include only 8 health and 2 ecological hazard endpoints for all chemicals. Notably missing is endocrine activity, which should be evaluated using a comprehensive protocol such as the Tiered Protocol for Endocrine Disruption (TiPED)[25] or equivalent. High-throughput assays for estrogen receptor (ER) or androgen receptor (AR) bioactivity are inadequate because they have not been sufficiently validated and demonstrated effectiveness in identifying chemicals of concern. The mathematical models used to evaluate data on ER and AR bioactivity discounted potential low-dose effects or non-monotonic dose response (NMDR), contrary to recent reports from the National Academies which specified opportunities to improve data on the evaluation of chemicals for low-dose effects and NMDR.[26,27] These reports highlight ways that EPA could incorporate more modern science

[23] See, for example, the agenda for the 2016 Safer Choice Partner and Stakeholder Summit, available: https://www.epa.gov/sites/production/files/2016-10/documents/summit-agenda-2016-oct28.pdf

[24] EPA (2012) EPA's Safer Choice Program Master Criteria for Safer Ingredients. Available: https://www.epa.gov/sites/production/files/2013-12/documents/dfe_master_criteria_safer_ingredients_v2_1.pdf

[25] Schug TT, Abagyan R, Blumberg B, Collins TJ, Crews D, DeFur PL, et al. Designing endocrine disruption out of the next generation of chemicals. Green Chem. 2013;15(1):181.

[26] Application of Systematic Review Methods in an Overall Strategy for Evaluating Low-Dose Toxicity from Endocrine Active Chemicals (2017)

[27] Review of the Environmental Protection Agency's State-of-the-Science Evaluation of Nonmonotonic Dose-Response Relationships as they Apply to Endocrine Disruptors (2014)

and mechanisms for doing so, particularly for chemicals and classes of chemicals that have the potential to interact with hormonal pathways. Finally, an exclusive focus on the ER and AR pathways will result in a lack of coverage for other endocrine pathways that could be disrupted by chemicals.

To designate a SCIL chemical as low priority, EPA would need to have sufficient data as described in point 3 above.

6. The criteria in the TSCA Work Plan Methodology for persistent and/or bioaccumulative chemicals are supported by current science and should be used in the pre-prioritization and prioritization processes. Persistence in the body should be defined as a half-life of 1 day or greater.

The criteria used in the TSCA Work Plan Chemicals Methods Document[28] to categorize persistence and bioaccumulative potential are supported by current science and are consistent with well-established criteria used in regulatory science and regulation, including EPA's New Chemicals Program and the Stockholm Convention on Persistent Organic Pollutants.[29,30] EPA should continue to apply these criteria in its pre-prioritization and prioritization processes, as these existing criteria are robust and sufficient to define persistence and bioaccumulation.

However, if measured and modeled data for environmental media are not available, it is also appropriate to define a chemical with a half-life greater than or equal to one day in the body (animal or human) as the highest ranking of persistence. Half-life variability due to well-known factors such as age, body fat, smoking and/ or breastfeeding would need to be accounted for.[31]

[28] US EPA (Feb 2012) TSCA Work Plan Chemicals: Methods Document, pg. 15

[29] Federal Register, Vol 64, No 213. Nov 4, 1999. EPA: Category for Persistent, Bioaccumulative, and Toxic New Chemical Substances.

[30] Stockholm Convention on Persistent Organic Pollutants, Annex D. Information Requirements and Screening Criteria. Available: http://chm.pops.int/Portals/0/download.aspx?d=UNEP-POPS-COP-CONVTEXT-D.En.pdf

[31] Milbrath MO, Wenger Y, Chang C-W, Emond C, Garabrant D, Gillespie BW, et al. Apparent half-lives of dioxins, furans, and polychlorinated biphenyls as a function of age, body fat, smoking status, and breast-feeding. Environ Health Perspect. 2009 Mar;117(3):417–25.