TSCA Work Plan Chemicals: Methods Document

Environmental Protection Agency

Office of Pollution Prevention and Toxics

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Background

In the Agency's August 2011 *Discussion Guide: Background and Discussion Questions for Identifying Priority Chemicals for Review and Assessment*, EPA described the two-step process the Agency intended to use to identify potential candidate chemicals for near-term review and assessment under the Toxic Substances Control Act (TSCA). The Agency intends to use these TSCA Work Plan Chemicals to help focus and direct the activities of the Existing Chemicals Program in the Office of Pollution Prevention and Toxics (OPPT). EPA invited public comment through an online discussion forum conducted from August 18 through September 21, 2011, as well as through a webinar and stakeholder meeting held on September 7, 2011. The meeting summaries and public comments are available for review in the docket for this activity, EPA-HQ-OPPT-2011-0516, which can be accessed online at http://www.regulations.gov.

As described in the *Discussion Guide*, EPA notes that identification of a chemical as a TSCA Work Plan Chemical does not itself constitute a finding by the Agency that the chemical presents a risk to human health or the environment. Such a determination would be the result of a risk assessment. Rather, identification of a chemical as a TSCA Work Plan Chemical indicates only that the Agency intends to consider it for further review. The Agency believes that identifying these chemicals early in the review process would afford all interested parties the opportunity to bring additional relevant information on those chemicals to the Agency's attention in order to further inform the review. In order to take risk management actions on a chemical substance under various sections of TSCA, the Agency would have to make the appropriate findings required by the specific provisions of the statute.

Identification of some chemicals as TSCA Work Plan Chemicals (Work Plan) does not mean that EPA would not consider other chemicals for risk assessment and potential risk management action under TSCA and other statutes. EPA will consider other chemicals if warranted by available information. In addition, EPA may subsequently identify other candidates for review in addition to this initial group, and may adapt the factors and data sources used in this process based on the experience acquired during this initial phase. Further, while the chemicals identified through this process as TSCA Work Plan Chemicals will likely be well-characterized for hazard and have information indicating exposure potential, some will have more limited data and EPA will continue to use its TSCA information collection, testing, and subpoena authorities, including sections 4, 8, and 11(c) of TSCA, to develop needed information on additional chemicals that currently have less robust hazard or exposure databases.

Two-Step Process

As described in the *Discussion Guide*, EPA's two-step prioritization process was intended to select an initial group of candidate chemicals for review by using a specific set of data sources to identify chemicals meeting one or more of the following factors:

- Chemicals identified as potentially of concern for children's health (e.g., chemicals with reproductive or developmental effects).
- Chemicals identified as persistent, bioaccumulative, and toxic (PBT).
- Chemicals identified as probable or known carcinogens.
- Chemicals used in children's products.

- Chemicals used in consumer products.
- Chemicals detected in biomonitoring programs.

EPA indicated the candidate chemicals from Step 1 would then be screened in Step 2 using information from additional exposure and hazard data sources to further analyze the chemicals and select specific chemicals for further assessment, including possible risk assessment and risk management action.

Based on comments received through the discussion forum, the webinar, and the stakeholder meeting, EPA made some adjustments both to the Step 1 factors and to the data sources utilized in both Step 1 and Step 2. With regard to the factors considered in Step 1, EPA added neurotoxicity to the initial Step 1 selection criteria because of comments noting the importance of neurotoxic effects to children's health. The Agency further added respiratory sensitization to the human health factors it would consider in Step 2, based on public comments suggesting this endpoint as identifying possible contributors to childhood asthma. Several commenters also encouraged EPA to use environmental toxicity as a prioritization factor to populate the Step 1 group of candidate chemicals. While environmental toxicity is not being used as a Step 1 prioritization factor on its own, EPA notes that many of the PBT chemicals are classed as toxic on the basis of environmental toxicity data. The Agency has also specifically factored environmental toxicity into the Step 2 analysis.

Following public comment, EPA also adjusted the proposed data sources identified in the *Discussion Guide*, particularly for Step 2, to encompass additional sources suggested by commenters, including the European Chemical Substance Information System (ESIS) and the Organization for Economic Cooperation (OECD) eChem Portal (which includes U.S. databases). EPA also eliminated certain data sources, including NHATS, NHEXAS, and TEAM, on the basis of their age. Given the difficulty of comprehensively identifying chemicals in consumer products, particularly because the 2006 Inventory Update Reporting (IUR) system made no distinction between commercial and consumer products, EPA narrowed the focus of the Step 1 prioritization factor to chemicals identified as being in children's products either through IUR reporting or through the process used by Washington State to generate its list of children's product chemicals. EPA notes, however, that chemicals identified through the application of the prioritization factors in Step 1 were further scrutinized in Step 2 against additional databases including the Hazardous Substance Data Bank (HSDB) and the Household Product Database, among others, to identify potential consumer uses.

Derivation of the Step 1 Potential Candidate Chemicals

To generate the Step 1 chemicals meeting the Agency's prioritization factor criteria as potential candidates for review and assessment, the following sources were used:

- ***Carcinogenicity:***
  - IRIS: 1986 Class A, B1; 1996 Known or Probable; 1999 or 2005 Carcinogenic
  - IARC Carcinogens, Group 1, 2A
  - NTP Known Carcinogens
- ***PBT:***
  - TRI PBT Rule
  - Great Lakes Binational PBT
  - Canadian P, B, and T (all three criteria met)
  - LRTAP POPS

    - Stockholm POPs
  - ***Children's Health:***
    - IRIS: Repro/Dev (RfD or RfC for repro or dev)
    - NTP CERHR: Infants Any Effect or Pregnant Women Any Effect
    - Cal Prop 65 Reproductive
  - ***Neurotoxicity:*** IRIS
  - ***Children's Product Use:***
    - Reported in products intended for use by children in 2006 IUR
    - Washington State Children's List
  - ***Biomonitoring*** (both human and environmental indicative of potential human exposure):
    - NHANES
    - Drinking Water Contaminants
    - Fish Tissue Studies

These sources produced a combined total of 1,235 chemicals, each of which matched at least one criterion. The resulting chemicals were then screened both for quality control to eliminate duplicate listings (an artifact of differences in the way the various data sources defined and reported chemicals), and to exclude chemicals that would not be appropriate for designation as candidates for near-term review and action under TSCA, either because they did not meet the intent of the prioritization criteria, they were not subject to action under TSCA, or they were already the subject of TSCA action.

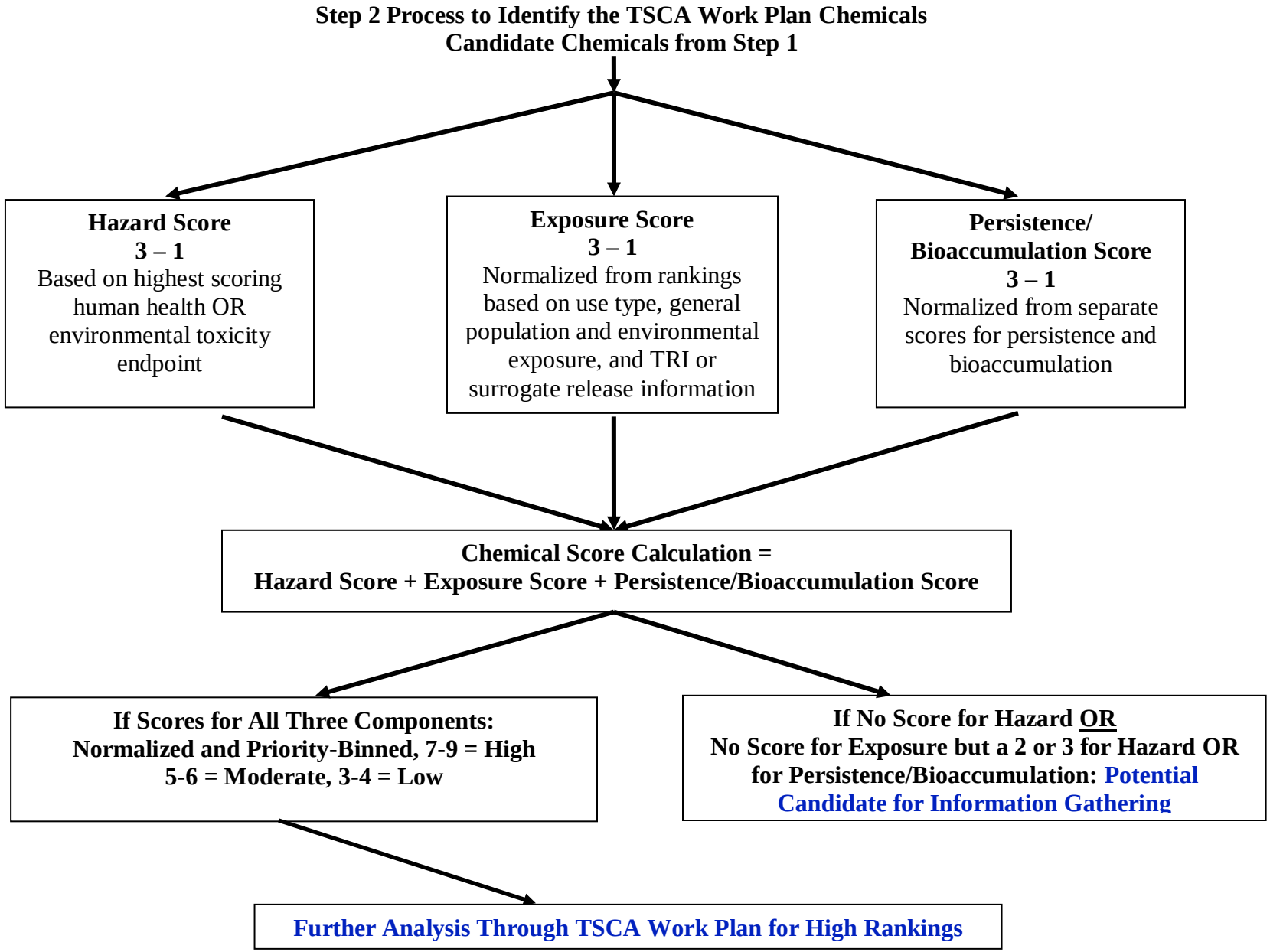
Chemicals were excluded from identification as potential candidates for any of the following reasons:

- **Pesticides:** Pesticides are excluded from regulation under TSCA because they are regulated under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA).
- **Drugs, hormones, and pharmacological chemicals:** Drugs are excluded from regulation under TSCA because they are regulated under the Federal Food, Drug, and Cosmetic Act (FFDCA). Hormones and pharmacological chemicals can be found in the environment when they are excreted or disposed of, but may not be amenable to management under TSCA.
- **Certain radioactive materials:** Radioactive chemicals are generally excluded from regulation under TSCA as source materials, special nuclear materials, or byproduct materials as defined in the Atomic Energy Act and subsequent regulations.
- **Complex process streams, byproducts not commercially produced:** Chemicals that are the reaction products of vague constituents, byproducts of complex streams, or complex mixtures are generally not readily definable in terms of their chemical identity and may vary considerably in both their composition and hazard from batch to batch, making them difficult to score consistently in this type of screening exercise. They were accordingly excluded.
- **Polymers:** Polymers typically have physical and chemical characteristics (high molecular weight, low absorbance, and low reactivity) that do not generally present significant health hazards. Some polymers that meet certain established criteria (49 FR 46066, November 21, 1984) have been specifically exempted from TSCA review under the new chemicals program because they "do not present an unreasonable risk of injury to human health or the environment." Polymers were therefore excluded from the Work Plan.
- **Gases, common naturally occurring chemicals, combustion products:** Chemicals that exist in gaseous form at normal temperatures, predominantly occur naturally in the

environment, or are produced predominantly by combustion are generally not amenable to control or management under TSCA.

- **Common oils or fats, simple plant extracts:** Chemicals in these categories are generally not anticipated to be sufficiently toxic to give rise to concerns that would make them priorities.
- **Explosive, pyrophoric, or extremely reactive or corrosive chemicals:** Chemicals that explode, burn on contact with air or water, react quickly with other chemicals, or are extremely corrosive are unlikely to present opportunities for human or environmental exposures because their high physical hazard properties make them subject to stringent handling requirements intended to guard against accidental exposures or releases.
- **Metals principally identified as toxic to the environment:** Many metals – copper, for example – are generally toxic to the environment, but do not present health issues to humans under typical conditions of use. Those metals and related compounds were excluded from the Work Plan, while metals with specific human health concerns were retained.
- **Chemicals already the subject of Action Plans or significant regulation under TSCA:** Polychlorinated biphenyls (PCBs) were excluded from the Work Plan because they are already comprehensively regulated under TSCA, which bans their manufacture, processing, use and distribution in commerce. Chemicals covered by Action Plans or other currently ongoing regulatory activities under TSCA were also excluded because they had been recently reviewed and are already being addressed.

After these chemicals were excluded and the remaining metals and their related compounds were grouped together rather than being identified separately, 345 chemicals remained as potential candidates and entered into Step 2, which is described in the next section of this paper.


Step 2 Process to Identify the TSCA Work Plan Chemicals
Candidate Chemicals from Step 1
Hazard Score
3 – 1
Based on highest scoring human health OR environmental toxicity endpoint
Exposure Score
3 – 1
Normalized from rankings based on use type, general population and environmental exposure, and TRI or surrogate release information
Persistence/ Bioaccumulation Score
3 – 1
Normalized from separate scores for persistence and bioaccumulation
Chemical Score Calculation =
Hazard Score + Exposure Score + Persistence/Bioaccumulation Score
If Scores for All Three Components:
Normalized and Priority-Binned, 7-9 = High
5-6 = Moderate, 3-4 = Low
If No Score for Hazard OR
No Score for Exposure but a 2 or 3 for Hazard OR
for Persistence/Bioaccumulation: Potential Candidate for Information Gathering
Further Analysis Through TSCA Work Plan for High Rankings

Explanation of Step 2 Process

The chemicals identified as potential candidates for review and assessment under TSCA based on the Step 1 prioritization factors were screened in Step 2. Chemicals were evaluated and received a score through the application of a numerical algorithm. This score was based on three characteristics: hazard, exposure, and potential for persistence and/or bioaccumulation. Using this system, chemicals were sorted into one of four bins. Chemicals able to be scored on all three characteristics were scored as High, Moderate, or Low based on their available information. Chemicals with High or Moderate hazard or persistence/bioaccumulation scores that could not be scored for exposure because of an absence of data, together with chemicals that could not be scored for hazard, were identified separately as potential candidates for information gathering.

This chemical candidate screening process is an interim evaluation only. It does not constitute a final Agency determination as to risk or as to whether sufficient data are available to characterize risk from specific chemicals on the TSCA Work Plan. Inclusion of a chemical on the Work Plan does not constitute any finding of risk under TSCA. This screening process is intended only to support initial decisions to determine the relative priority for further assessments and to identify potential data needs for individual chemicals or chemical groups.

Hazard Score:

The Hazard Score encompasses both human health and environmental toxicity concerns. The specific hazard classification criteria are based on the *Alternatives Assessment Criteria for Hazard Evaluation* developed by EPA's Design for the Environment Program (DfE). The DfE criteria for classifying the toxicity of specific chemicals were developed from authoritative sources including the United Nation's Globally Harmonized System (GHS) for Chemical Classification and Labeling and other EPA programs. The data determining the score for each chemical were obtained through the data sources identified in Appendix A. The hazard data reviews on each chemical were not exhaustive and do not rise to the level of assessments. Chemicals were scored on the basis of readily available data, and no judgment was made concerning gaps in or completeness of the available data set for a given chemical.

The Hazard Score was determined based on 3 hazard levels, and each hazard level had a corresponding hazard rank (High-3, Moderate-2, and Low-1). The concentration ranges or characteristics that correspond with each hazard level are listed in Table 1 below.

Candidate chemicals from Step 1 received a hazard rank score for each of the toxicity endpoints that were applicable based on the data readily available for each chemical. The highest hazard rank score a chemical received for *any* single human health or environmental toxicity endpoint became its Hazard Score. If the review on a chemical produced a High hazard score for any endpoint other than acute mammalian toxicity or acute or chronic aquatic toxicity, data on other endpoints were not sought because they would not impact the existing High score.

Table 1. Criteria for Determining Hazard Score

		High	Moderate	Low	Hazard Score
Ranking		**3**	**2**	**1**	
Chemical X					
	Acute Mammalian Toxicity Oral LD50 (mg/kg) Dermal LD50 (mg/kg) Inhalation LC50 (gas/vapor) (mg/L) Inhalation LC50 (mist/dust) (mg/L/day)	 ≤ 50 - 300 ≤ 200 - 1000 ≤ 2 - 10 ≤ 0.5 – 1.0	 >300 - 2000 >1000 - 2000 >10 - 20 >1.0 - 5	 >2000 >2000 >20 >5	**(Highest score from any toxicity category)**
	Carcinogenicity	GHS 1A, 1B, GHS2	Limited animal	Negative or SAR	
	Mutagenicity/Genotoxicity	GHS 1A, 1B, GHS 2	Positive *in vivo* or *in vitro*	Negative	
	Reproductive Toxicity Oral (mg/kg/day) Dermal (mg/kg/day) Inhalation (gas/vapor) (mg/L/day) Inhalation (mist/dust) (mg/L/day)	 <50 <100 <1 <0.1	 50-250 100-500 1-2.5 0.1-0.5	 >250 >500 >2.5 >0.5	
	Developmental Toxicity Oral (mg/kg/day) Dermal (mg/kg/day) Inhalation (gas/vapor) (mg/L/day) Inhalation (mist/dust) (mg/L/day)	 <50 <100 <1.0 <0.1	 50 – 250 100 – 500 1.0 – 2.5 0.1 – 0.5	 >250 >500 >2.5 >0.5	
	Neurotoxicity *Oral (mg/kg-bw/day)* 90-day (13 weeks) 40-50 days 28-days (4 weeks) *Dermal (mg/kg-bw/day)* 90-day (13 weeks) 40-50 days 28-days (4 weeks)	 < 10 < 20 < 30 < 20 < 40 < 60	 10 – 100 20 – 200 30 – 300 20 – 200 40 – 400 60 – 600	 > 100 > 200 > 300 > 200 > 400 > 600	

		High	Moderate	Low	Hazard Score
Ranking		**3**	**2**	**1**	
	Chronic Toxicity *Oral (mg/kg-bw/day)* 90- day (13 weeks) 40-50 days 28-days (4 weeks) *Dermal (mg/kg-bw/day)* 90- day (13 weeks) 40-50 days 28-days (4 weeks)	 < 10 < 20 < 30 < 20 < 40 < 60	 10 – 100 20 – 200 30 – 300 20 – 200 40 – 400 60 – 600	 > 100 > 200 > 300 > 200 > 400 > 600	
	Respiratory Sensitization	GHS 1A and 1B Occurrence of respiratory sensitization; Evidence supporting potential for respiratory sensitization		No evidence to support potential for respiratory sensitization	
	Acute Aquatic Toxicity (LC50 or EC50) (mg/L)	< 1.0 – 10	> 10 - 100	> 100	
	Chronic Aquatic Toxicity (NOEC or LOEC) (mg/L)	< 0.1 – 1	> 1 - 10	> 10	
					Hazard Score

Because the highest score from any individual endpoint was taken as the total Hazard Score, a chemical was ranked as either 3 (High), 2 (Moderate), or 1 (Low) for hazard.

For the toxicity endpoints Acute Mammalian Toxicity, Reproductive Toxicity, Developmental Toxicity, Neurotoxicity, and Chronic Toxicity a range of values for each Hazard Level was assigned. These values appear in the DfE *Alternatives Assessment Criteria*. In some cases DfE has 5 distinct hazard levels. For this analysis, the "Very High" and "High" levels from DfE were grouped together to represent High on this scale and DfE's "Low" and "Very Low" levels were combined to form the criteria for a Low rank.

The hazard levels for Carcinogenicity were based on whether a chemical is a known, presumed, or suspected carcinogen (High); limited evidence of carcinogenicity (Moderate); or non-carcinogenetic (Low). Note that the High score for carcinogenicity in Step 2 is broader than the criteria used in the Step 1 for carcinogenicity. The Step 1 factor specified that a chemical be classified as a known or probable carcinogen, equivalent to the GHS 1A or 1B classification, in order to be included in the screening program expressly on the basis of carcinogenicity. For the purpose of further evaluating the Agency's potential concern for chemical hazard in Step 2 of this screening process, however, EPA included presumed, suspected, or likely human carcinogenicity classifications – the equivalent of GHS 2 – as also meriting a High hazard score.

The hazard levels for Mutagenicity/Genotoxicity were based on evidence that heritable mutations are known to or may occur in human germ cells, or mutagenicity demonstrated *in vivo* and *in vitro* (High); evidence of mutagenicity supported by *in vivo* or *in vitro* somatic cells of humans and animals (Moderate); or no evidence of chromosomal aberrations and gene mutations in reported studies (Low).

Respiratory Sensitization was based on GHS classifications of respiratory sensitizers. Hazard levels were based on whether there is occurrence of respiratory sensitization in humans or supporting evidence based on other tests, including the presence of structural alerts (High); or no evidence to support the potential for respiratory sensitization (Low). This endpoint was added to the prioritization template proposed in the August 2011 *Discussion Guide* following stakeholder comment that respiratory sensitization is particularly of interest to children's health issues based on the increasing trends of childhood asthma and other illnesses.

Environmental toxicity information was limited primarily to aquatic toxicity studies. If information about environmental toxicity was available, it was analyzed in conjunction with human toxicity information.

Chemicals that were scored as High for hazard only on the basis of acute mammalian toxicity were further considered on the basis of their classification for other human health endpoints. Where data on other health endpoints were available, the overall hazard score for the chemical was adjusted accordingly to reflect the highest remaining health endpoint. This was done because chemicals with high acute mammalian toxicity are generally already regulated on the basis of that toxicity and are subject to handling and use controls intended to protect workers and others potentially coming into contact with the chemical from harmful acute exposures. Scoring those chemicals on the basis of their other toxic effects was intended to acknowledge that protection against effects from acute exposures would not necessarily protect against effects from other exposures. If acute mammalian toxicity was the only available data endpoint for a chemical, the acute score remained as the overall hazard score for the chemical.

Chemicals that scored as High for hazard only on the basis of acute or chronic aquatic toxicity but that did not present human health concerns were grouped separately as being of potential concern for the environment.

If no hazard data were available on a chemical to provide a hazard score, the chemical was placed in a parallel prioritization category. These chemicals were classified as "Potential Candidates for Information Gathering. (See page 16.)" Creating a separate category ensured that chemicals with unknown toxicity would not be removed from further investigation because there was a lack of data.

Exposure Score:

The Exposure Score was based on a combination of chemical use, general population and environmental exposure, and release information. The Use Type score included consideration of consumer product applications as well as industrial and commercial uses that could result in widespread exposures. The General Population and Environmental Exposure score encompassed measured data on the presence of a chemical in biota and environmental media. The Release score was based on EPA's Toxics Release Inventory (TRI) data for chemicals subject to TRI reporting. For

non-TRI chemicals, the Release score was calculated using a method involving Inventory Update Reporting data (IUR, now called Chemical Data Reporting, or CDR), including production volume, number of sites, and type of use. Data used in the other two components of exposure scoring were obtained through the sources identified in Appendix B. The detailed description of how information from those sources was used to generate an exposure score appears in Appendix C.

Table 2. Exposure Score

			Score
I. Use Type			
Ranking	Criteria		**Use Score**
3	Consumer product widely used, high likelihood of exposure		
2	Consumer product narrow use, lower likelihood of exposure		
1	Commercial use, indicating some likelihood of exposure		
0	No reported commercial use, indicating little to no likelihood of general exposure from use		
II. General Population and Environmental Exposure			
Ranking	Criteria		**+ General Population & Environmental Exposure**
3	Present in biota (human, fish, animal or plant biomonitoring), OR measured in drinking water, indoor air, house dust		
2	Not in biota, but reported present in 2 or more environmental media		
1	Reported present in 1 environmental medium		
III. Release Score: Use III. A or III. B, As Appropriate			
III. A.	**Release Score for TRI Chemicals***		**+ TRI Release Score**
Ranking	Criteria		
3	> 100,000 lbs/year		
2	5,000 – 100,000 lbs/year		
1	< 5,000 lbs/year		
OR			**OR**
III. B.	**Release Score for Non-TRI Chemicals**		**+ Non-TRI Release Score**

The III.B. Release Score for Non-TRI Chemicals was generated by normalizing the sum of the subset rankings for Production Volume, Number of Sites, Industrial Processing and Use, and Commercial/Consumer Use differentiating between uses with high, moderate, and low potential for widespread releases, as shown below and described in detail in Appendix C:				
	Subset 1: IUR Production Volume		**PV**	
	Ranking	Criteria		
	3	≥ 1,000,000 lbs/year		
	2	≥ 500,000 – 999,999 lbs/year		
	1	< 500,000 lbs/year		
	Subset 2: IUR Number of Manufacturing, Processing, and Use Sites		**+ Site #**	
	Ranking	Criteria		
	3	≥ 1, 000		
	2	100 – 999		
	1	< 100		
	Subset 3: IUR Industrial Processing and Use (IPU)		**+ Use1**	
	Ranking	Criteria		
	3	High potential for release		
	2	Moderate potential for release		
	1	Low potential for release		
	Subset 4: IUR Commercial Use (C)		+Use2	
	Ranking	Criteria		
	3	High potential for release		
	2	Moderate potential for releases		
	1	Low potential for release		
	Subtotal Surrogate Score		=	
Total				**Exposure Score****

* TRI data included in the exposure calculation were limited to water, air, and non-contained land releases.
** Total Exposure Score is the sum of the individual scores for I, II, and III.A or III.B.

The criteria for exposure potential in the Use Types category were based on a chemical's presence and characteristics of use in consumer, commercial, or industrial products as indicated in the data sources in Appendix B. Chemicals in consumer products judged widely used with a high potential for exposure received the highest rank. Chemicals that are present in consumer products but are more narrowly used and have lower likelihood of exposure were ranked as moderate. Chemicals that are not high or moderate but have commercial uses reported in IUR were ranked as low, acknowledging that such uses may present some potential for exposures not only to workers but also to the general population and the environment. Chemicals with no commercial use reported in IUR

received a rank of zero. Further information on this approach and examples of ranking by use type are provided in Appendix C.

The data supporting ranking in the General Population and Environmental Exposure category came from the databases and peer-reviewed studies included in the list presented in Appendix B. The highest rank was based on presence in biota, because chemicals measured in humans, fish, animals, or plants demonstrate clear evidence of exposure; and on measured presence in indoor air, house dust, or drinking water, because presence in those specific media provides a strong indication of exposure potential. Presence in two or more environmental media indicates a reasonable potential for environmental exposure, which was the criteria for a moderate exposure ranking. Measured presence in one environmental medium provides some indication of potential environmental exposure, and was given a low ranking.

The Release Score was determined in one of two ways. If the chemical was reported under TRI, the TRI data were used to infer potential for environmental and general population exposure. The breakdowns for the high, moderate and low ranks were based on a distribution of pounds released for the chemicals reported by industry in the database.

If no TRI data existed, a release score was calculated on the basis of IUR data using production volume, number of sites, and use codes classified according to how likely the uses were to result in releases. The description of how these non-TRI release scores were derived, along with examples of how IUR use codes were associated by EPA with high, moderate, or low potentials for release, appears in Appendix C. While a chemical's production volume, use type, and number of manufacturing, processing, and industrial use sites do not provide exposure data, they can be used as an indicator of potential releases and resulting potential exposures.

All Exposure category scores were added up and then normalized on an overall High-Moderate-Low scale. To prevent the prioritization process from being biased unduly either toward or against data-rich chemicals, the normalization process differed depending on how many of the three categories – Use Type, General Population & Environmental Exposure, and Releases – had sufficient data to provide a score for the category.

For chemicals with scores in all three categories, "9" was the highest possible score, and the normalization scoring structure was:

Total Exposure Score from Table 2	Overall Rank	Normalized Overall Exposure Score
8 - 9	High	3
5 - 7	Moderate	2
2 - 4	Low	1

For chemicals with scores in only two of the three categories, "6" was the highest possible score, and the normalization scoring structure was:

Total Exposure Score from Table 2	Overall Rank	Normalized Overall Exposure Score
5 - 6	High	3
3 - 4	Moderate	2
1-2	Low	1

In the absence of exposure data on chemicals sufficient to populate at least two of the exposure categories in Table 2 and produce a meaningful score, such chemicals receiving moderate or high hazard scores, or that also could not be scored for hazard because of an absence of hazard data, were placed in a parallel prioritization category. These chemicals were classified as "Potential Candidates for Information Gathering. (See page 16.)" EPA created this separate category to ensure that chemicals with unknown toxicity or with known potential human health or environmental toxicity implications would not be removed from further investigation simply because there was a lack of exposure information, an issue stakeholders identified during the webinar and discussion forum as being of concern.

Potential for Persistence/Bioaccumulation:

Chemicals received a separate score to rank their potential for persistence and/or bioaccumulation. Persistent and bioaccumulative chemicals present special issues because organisms can remain exposed to them for a very long time and organisms higher up the food chain may be exposed to larger quantities of the chemicals through their food supply. EPA considers it particularly important that these chemicals not be removed from consideration for further investigation simply because they may lack either hazard or exposure information, or both.

Persistence scoring consisted of the evaluation of the potential half-life in air, water, soil, and sediment while considering the expected partitioning characteristics of the chemicals and all potential removal pathways based on standard physical-chemical properties and environmental fate parameters. Data sources listed in Appendix B were searched to locate studies on biotic and abiotic transformation (e.g., biodegradation, hydrolysis, photolysis) in order to estimate half-lives for the chemicals in the environment.

Bioaccumulation scoring consisted of evaluation of bioaccumulation/bioconcentration (measured or estimated BAF/BCF) data. When BAF data were not available, bioconcentration data (measured or estimated) were used to evaluate the potential for a chemical to bioaccumulate in organisms in the environment.

In the absence of test data establishing the chemical's measured persistence or bioaccumulation potential, EPA used EPI Suite™ version 4.10 to derive a ranking for the chemical. Specifically, BIOWIN, HYDROWIN, AOPWIN, BCF/BAF and Level III fugacity models were used to assess biodegradation, hydrolysis, atmospheric oxidation, bioaccumulation/bioconcentration and environmental partitioning.

Table 5. Persistence/Bioaccumulation Potential

			Overall Persistence/ Bioaccumulation Score
I. Persistence			
Ranking	Criteria		Persistence
3	Half-life > 6 months		
2	Half-life ≥ 2 months		
1	Half-life < 2 months		
II. Bioaccumulative Potential			
Ranking	Criteria		+ Bioaccumulation
3	BCF or BAF > 5000		
2	BCF or BAF ≥ 1000		
1	< 1000		
Total			**Persistence/ Bioaccumulation Score**

These criteria for judging persistence and bioaccumulation are the ones used in EPA's New Chemicals program. The separate scores for persistence and bioaccumulation were added together to produce a total score, which was normalized as follows:

Persistence/Bioaccumulation Score	Ranking	Normalized P/B Score
5 - 6	High	3
3 - 4	Moderate	2
2	Low	1

Categorizing Candidates for Inclusion as TSCA Work Plan Chemicals

After the candidate chemicals in Step 1 received normalized scores for Hazard, Exposure, and Persistence/Bioaccumulation, those scores were totaled to roughly group the chemicals receiving scores in all three categories into High, Moderate, and Low groupings as follows:

Normalized Total Score	Ranking
7 - 9	High
4 - 6	Moderate
1 - 3	Low

Appendix D identifies the 83 candidate chemicals from Step 1 that received scores on all three ranking factors and ranked High on the basis of their total score, including human health hazard concerns, and provides a brief summary of the information that produced that ranking. This table also includes chemicals that may not have presented human health concerns, but met all the criteria for identification as persistent, bioaccumulative, and environmentally toxic chemicals. These are the

TSCA Work Plan Chemicals, from which the Agency intends to select chemicals for near-term review and assessment.

EPA notes that some chemicals identified as High through this scoring system may not necessarily be practical candidates for assessment under TSCA when other information is factored into the process. For example, the particular risks presented by certain chemicals may already be addressed by significant regulation under other statutes. One such example is quartz, which presents a hazard only in the context of silicosis from the inhalation of very fine crystalline dust particles, which could generally occur only during such occupational activities as sandblasting or stone cutting; these potential exposures are specifically controlled under regulations issued by the Occupational Safety and Health Administration (OSHA).

Potential Candidates for Information Gathering

Chemicals that could not be scored for hazard, or that were scored as moderate or high for either hazard or for persistence/bioaccumulation but could not be scored for exposure, have been grouped separately. These chemicals may be potential candidates for information-gathering activities focused on producing sufficient information to determine where they would rank in the prioritization process. EPA may consider a variety of such information-gathering activities, including both voluntary data submission and regulations issued under Sections 4 and 8 of TSCA.

Identifying Work Plan Chemicals for Risk Assessment in 2012 and Beyond

In identifying a smaller set of chemicals for work in any given year, EPA considers a number of factors, including:

- Whether the chemical was identified as a "High" ranking chemical.
- Whether the chemical reflects more than one of the factors identified in Step 1 (for example, chemicals that were identified as a potential concern for children's health and also were persistent, bioaccumulative, and toxic) and whether each of the factors was covered by the set of chemicals. These factors included health and environmental hazards, children's health, use in consumer products and dispersive uses, persistence and bioaccumulation, and detection in biomonitoring and environmental monitoring.
- Whether certain chemicals, or groups of chemicals, would benefit from some preliminary work to assure that risk assessments are targeted and scoped appropriately, and therefore would best be addressed in an out year.
- Whether certain chemicals, or groups of chemicals, have previously been assessed and addressed by the Agency, so that risk assessment in later years may be more appropriate than in the earlier years of the work plan.
- Agency work load considerations, including scope and timing of work needed on specific chemicals, and existing commitments for assessment.

For 2012, EPA identified an initial group of seven chemicals, which can be found on the first page of the table in Appendix D. EPA will identify a group of chemicals each year for risk assessment, completing a number of risk assessments that year and initiating new assessments from the remaining chemicals on the work plan in the coming years. This spring, the Agency plans to identify specific chemicals for which it plans to conduct risk assessment in 2013 and 2014.

APPENDIX A: Data Sources for Hazard Scoring

Data Sources for Hazard Scoring

Hazard Information (Data on all toxicological endpoints)	
Providers/ Data Source	**Description**
USEPA: IRIS	Integrated Risk Information System (IRIS): http://www.epa.gov/iris/index.html
USEPA: HPVIS	Hazard Characterizations prepared by EPA on chemicals in the High Production Volume Challenge Program (HPV): http://iaspub.epa.gov/oppthpv/hpv_hc_characterization.get_report?doctype=2 Risk-Based or Hazard-Based Prioritizations prepared by EPA under the Chemical Assessment and Management Program (ChAMP): http://iaspub.epa.gov/oppthpv/existchem_hpv_prioritizations.report
USEPA: ISIS	The Integrated Scientific Information System (ISIS) is a chemical relational database application originally developed by Molecular Design Limited (MDL) Information Systems and utilized by the EPA New Chemicals program; the EPA version of this database contains confidential information.
United Nations World Health Organization: IARC	International Agency for Research on Cancer (IARC): http://monographs.iarc.fr/ENG/Classification/index.php
National Toxicology Program	NTP Report on Carcinogens: http://ntp.niehs.nih.gov/?objectid=03C9AF75-E1BF-FF40-DBA9EC0928DF8B15 NTP/CERHR Monographs on Potential Reproductive and Developmental Effects: http://ntp.niehs.nih.gov/?objectid=974B2C24-030F-D308-60E11D088F83FADB
Organization for Economic Cooperation and Development (OECD): eChem Portal	http://www.echemportal.org/echemportal/substancesearch/page.action?pageID=0 The OECD eChemPortal allows simultaneous searching of reports and datasets by chemical name and number and by chemical property. Direct links to collections of chemical hazard and risk information prepared for government chemical review programs at national, regional and international levels are obtained. Classification results according to national/regional hazard classification schemes or to the Globally Harmonized System of Classification and Labelling of Chemicals (GHS) are provided when available. The list of participating databases can be accessed here: http://www.echemportal.org/echemportal/substancesearch/page.action;jsessionid=1AB4C820B2D854B7FB9381877022B9F6?pageID=2

Hazard Information (Data on all toxicological endpoints)	
Providers/ Data Source	**Description**
National Library of Medicine Databases	http://chem.sis.nlm.nih.gov/chemidplus/chemidheavy.jsp Accessed through ChemID Plus, searching on a chemical name or ID produces results that are linked to all NLM databases, including: Registry of Toxic Effects of Chemical Substances (RTECS) ATSDR Public Health Statements ATSDR Toxicological Profiles ATSDR ToxFAQS
TSCATS	The Toxic Substance Control Act Test Submission Database http://www.syrres.com/esc/tscats.htm
California Office of Environmental Health Hazard Assessment	Risk assessment documents prepared by OEHHA on certain Proposition 65 chemicals can be accessed through the links provided in the spreadsheet at: http://oehha.ca.gov/prop65/prop65_list/files/P65list110411links.xlsx
USEPA - Ambient Water Quality Criteria Documents	http://www.epa.gov/waterscience/criteria/wqcriteria.html
USEPA - Drinking Water Standards Health Effects Support Documents	http://www.epa.gov/safewater/standards.html
USEPA - ECOTOX Database	http://www.epa.gov/ecotox
IPCS Concise International Chemical Assessment Documents (CICADs)	http://www.inchem.org/pages/cicads.html

APPENDIX B: Data Sources for Exposure Scoring

Data Sources for Exposure, Uses, and Environmental Fate (P and B) Scoring

Data Type	Data Source
Uses	Inventory Update Reporting and Chemical Data Reporting (IUR/CDR) Premanufacture Notice (PMN) Database (confidential) Design for the Environment chemicals database (confidential) High Production Volume (HPV) Challenge Submissions EPA Hazard Characterizations and Risk Based Prioritizations OECD Screening Information Assessment Profiles and Reports Screening Information Data Sets (SIDS) Documents National Institutes of Health (NIH) Household Product Database NLM Hazardous Substances Data Bank NLM- Hazmap-Occupational exposure to hazardous agents Source Ranking Database Chemical assessments by other governmental organizations Open literature
Environmental releases	Toxics Release Inventory (TRI) National Emission Inventory (NEI) Database U.S. EPA NIH Hazardous Substances Data Bank
General human exposures, including indoor air contaminants	National Report on Human Exposure to Environmental Chemicals (CDC NHANES) Report to the California Legislature Indoor Air Pollution in California. http://www.arb.ca.gov/research/indoor/ab1173/rpt0705.pdf German Environmental Survey- chemicals in indoor air http://www.umweltbundesamt.de/gesundheite/survey/index.htm NLM Hazardous Substances Data Bank Open Literature
Environmental exposures	National Air Quality System (AQS) U.S. EPA National Contaminant Occurrence Database (NCOD) U.S. EPA Current National Recommended Water Quality Criteria U.S. EPA National Water-Quality Assessment Program (USGS NAWQA) EPA Fish Tissue Studies Clean Air Act Hazardous Air Pollutants (HAPs) Clean Water Act Priority Pollutants Superfund Chemical Data Matrix EPA: Targeted National Sewage Sludge Survey Report Groundwater chemicals Desk reference Chemicals in Groundwater Desk reference 2007 EPA Drinking water Chemical contaminant lists New York State Ambient Air monitoring program California Air Resources Board (ambient air) Washington State Background Soil concentration study NLM Hazardous Substances Data Bank Open literature

Data Type	Data Source
Environmental Fate (Persistence and Bioaccumulation)	USEPA: HPVIS Hazard Characterizations prepared by EPA on chemicals in the High Production Volume Challenge Program (HPV): http://iaspub.epa.gov/oppthpv/hpv_hc_characterization.get_report?doctype=2 Risk-Based or Hazard-Based Prioritizations prepared by EPA under the Chemical Assessment and Management Program (ChAMP): http://iaspub.epa.gov/oppthpv/existchem_hpv_prioritizations.report Organization for Economic Cooperation and Development (OECD): eChem Portal http://www.echemportal.org/echemportal/substancesearch/page.action?pageID=0 http://www.echemportal.org/echemportal/substancesearch/page.action;jsessionid=1AB4C820B2D854B7FB9381877022B9F6?pageID=2 SRC Environmental Fate Databases http://www.srcinc.com/what-we-do/efdb.aspx National Library of Medicine Hazardous Substances Databank http://toxnet.nlm.nih.gov/cgi-bin/sis/htmlgen?HSDB Japanese National Institute of Technology and Evaluation (NITE). Biodegradation and Bioconcentration of the Existing Chemical Substances under the Chemical Substances Control Law NITE http://www.safe.nite.go.jp/english/kizon/KIZON_start_hazkizon.html

APPENDIX C: Derivation of Exposure Scores for Use Types and Release Scores for TRI and Non-TRI Chemicals

Criteria I: Use Type

A variety of use information was reviewed to determine whether chemicals were used for consumer, commercial, or industrial purposes. At least two data sources were used to confirm consumer uses. For example, a reported use in EPA's IUR alone was not deemed sufficient to identify a chemical as being in a consumer product. Also note that many chemicals are present in several different product use and functional use categories. All reported uses were considered, and the use with the highest exposure potential informed the prioritization ranking. See Appendix B for additional information on data sources.

Chemicals that were given a rank of three are believed to be present in consumer products and have high potential for exposure due to widespread uses. Chemicals that received a high score have higher potential for exposure due to high likelihood of releases from the product (off-gassing) and high potential for direct contact during application or use based on close proximity. Examples of product criteria that have an increased likelihood of exposure include: products that are not fully cured (chemical reaction is occurring on-site); products that are spray-applied or brush-applied; products that are liquids, gases, or otherwise have the potential to volatilize; products that have the potential to off-gas, degrade, or otherwise emit chemicals over time; and products that have the potential to be incorrectly applied or used also received a rank of three. Some organizations may identify higher exposure potential uses as being dispersive. Examples of product use categories that have this increased likelihood of exposure include: paints and coatings; adhesives, sealants, and elastomers; building materials such as insulation; soaps and detergents; hair care products; water treatment products; floor coverings; automotive care products; and arts, crafts, and hobby materials.

Chemicals that were given a rank of two had moderate exposure. Chemicals that received a moderate score have moderate potential for exposure because they may be present within a chemically stable matrix; have lower or slower likelihood of release from the product, and have more indirect or bystander exposure. There may be increased distance and time between product sources and individual receptors. These chemicals may slowly off-gas or partition to dust over time. Examples of product use categories include: plastic and rubber products, electronics products, furniture, and foam seating and bedding products.

Chemicals were given a rank of one if at least one commercial use for that chemical was reported in IUR.

Chemicals that were not reported in IUR or were reported in IUR with industrial uses but no commercial or consumer uses were given a rank of zero for the use type criterion of exposure.

Criteria II: General & Environmental Exposure

A variety of data sources were used to compile information on chemicals present within the environment: ambient air, surface water, groundwater, drinking water, soil, indoor environments (air or dust), and chemicals present within biota (humans, fish, animals, or plants). Only a small percentage of all chemicals are actually measured for in various media for reasons such as a lack of

adequate sampling and analytical methods and insufficient resources to collect data. Many of the chemicals identified were not able to be ranked for this criterion due to lack of data.

A summary of the number of chemicals identified in different media is provided below. Note that this compilation of chemicals is an initial effort based on readily available and publicly accessible data. It is not a complete or comprehensive assessment of number of chemicals present in any given environmental or biological media. Approximately two-thirds of these chemicals are on the TSCA inventory while the other one-third is not. Refer to Appendix B for additional information on data sources for each media.

Number of Chemicals Reported in Environmental Media

Occurrence of chemicals (by media)	Number of chemicals
Surface water	401
Ground water	407
Ambient air	409
Soil	270
Indoor environments	300
Drinking water	247
Biota	360
Total	1215

Criteria III: Release Score

III. A. Release Scores for TRI Chemicals

The release score for each chemical was determined using the aggregated releases from the TRI data fields listed in the following table. The 2008 TRI database was used for the chemical ranking scheme. A ranking of 3 was assigned for a sum of releases greater than 100,000 lb/yr, a ranking of 2 for a sum of releases greater than 5,000 lb but less than or equal to 100,000 lb/year, and a ranking of 1 for a sum of releases less than 5,000 lb/yr.

2008 TRI Data Fields for Release Score

TRI Data Field	
Total Fugitive Air Emissions	Wastewater Treatment (Excluding POTWs)
Total Stack Air Emissions	Landfills/Disposal Surface Impoundments
Total Surface Water Discharge	Surface Impoundment
Total Other On-Site Land Releases (Other Landfills)	Other Landfills
Total Land Treatment	Land Treatment
Total Surface Impoundments	Other Land Disposal
Total Other Disposal	Unknown
POTWs - Total Transfers - Metals Only	RCRA Subtitle C Surface Impoundments (M66)
Transfers To POTWs (Non-Metals)	Other Surface Impoundments (M67)
Transfers To POTWs (Metals And Metal Compounds)	

III. B. Release Scores for Non-TRI Chemicals

For chemicals not reported to TRI, 2006 IUR data were used to rank chemicals for potential to be released to the environment. The release ranking was derived based on at least three of the following four factors: (1) IUR Production Volume Ranking; (2) IUR Number of Manufacturing, Processing, and Use Sites Ranking; (3) IUR Industrial and Downstream Processing and Use Ranking; and (4) IUR Commercial/Consumer Use Rankings.

Production Volume and Number of Sites Rankings

For the production volume ranking, data from the non-CBI public IUR database were used to rank chemicals using the following cut-offs: greater than or equal to 1,000,000 lb/year for a high ranking of 3; less than 1,000,000 and greater than or equal to 500,000 lb/year for a medium ranking of 2; and less than 500,000 lb/year for a low ranking of 1.

The number of industrial sites ranking, data on manufacturing, processing, and use sites in non-CBI public IUR database were used to rank chemicals using the following cut-offs: greater than or equal to 1,000 sites for a high ranking of 3; less than 1,000 and greater than or equal to 99 sites for a medium ranking of 2; and less than 100 sites for a low ranking of 1.

Industrial Processing and Use (IPU) Ranking

For the industrial processing and use ranking, EPA examined the following codes reported under IUR for each chemicals (see the table of sample categories, below): North American Industrial Classification System (NAICS) code, Process or Use code, and the Industrial Function Category. Each 3-code combination was assigned a ranking (high/moderate/low) based on the potential to be released during the industrial processing/use and downstream use. The Agency ranked each 3-code combination using expert judgment, generic scenarios, and past experience with new and existing chemical assessment. The 3-code combination with highest ranking was used as the score for the IPU ranking for the chemical.

The resulting industrial rankings were modified based on whether the chemical was reported as site-limited by all IUR submitters of that chemical or whether industrial uses may have been required to be reported in IUR. Site-limited chemicals were given an IPU Ranking of 1.

Under the IUR, reporters had an option to indicate if industrial processing and use (IPU) information was not applicable to their chemical; if all reporters of a chemical indicated that the industrial processing and use information was not applicable, EPA assumed there was no such use and assigned a low ranking of 1. For chemicals with an IPU ranking of 1 or 2 that had one or more IPUs reported as "NRO," the rankings were developed based solely on reported IPUs. No ranking was developed for chemicals with all IPUs reported as "NRO." EPA assigned a high ranking of 3 for chemicals with at least one reported IPU code with a high potential for widespread releases.

Sample of 2006 IUR Industrial Processing and Use Reporting Categories		
Industrial Function Categories	**Industrial Processing or Use**	**Small Sample of NAICS**
Adsorbents and absorbents	Processing as a reactant	Petrochemical manufacturing
Adhesives and binding agents	Processing – incorporation into formulation, mixture or reaction product	Synthetic dye and pigment manufacturing
Aerosol propellants	Processing – incorporation into article	Other basic inorganic chemical manufacturing
Agricultural chemicals (non-pesticide)	Processing – repackaging	Resin and synthetic rubber manufacturing
Anti-adhesive agents	Use - non-incorporative activities	Fertilizer manufacturing
Bleaching agents		Paint and coating manufacturing
Coloring agents, dyes		Printing ink manufacturing
Coloring agents, pigments		Plastics bottle manufacturing
Corrosion inhibitors and anti-scaling agents		Tire manufacturing
Fillers		Cement manufacturing
Fixing agents		Abrasive product manufacturing
Flame retardants		Ferrous metal foundries
Flotation agents		Electric power generation
Fuels		
Functional fluids		
Intermediates		
Lubricants		
Odor agents		
Oxidizing agents		
pH-regulating agents		
Photosensitive chemicals		
Plating agents and metal surface treating agents		
Processing aid, not otherwise listed		
Process regulators, used in vulcanization or polymerization processes		
Process regulators, other than polymerization or vulcanization processes		
Reducing agents		
Solvents (for cleaning or degreasing)		
Solvents (which become part of product formulation or mixture)		
Solvents (for chemical manufacture and processing and are not part of product at greater than one percent by weight)		
Stabilizers		
Surface active agents		
Viscosity adjustors		
Other		

Commercial Use (C) Release Ranking

For the commercial use ranking, EPA examined each IUR Commercial Use Code reported for the chemicals and assigned a ranking based on their potential to be released during use. For the purpose of this screening exercise, it was assumed that all the "C" use codes in the 2006 IUR included commercial uses. The Agency used past experience in new and existing chemical assessments of similar chemicals and exposure scenarios, coupled with expert judgment, to examine each use to place the chemical in a high, moderate, or low ranking. The use code with the highest ranking was used as the score for the commercial use ranking for the chemical.

The following table lists samples of rankings associated with certain uses. Commercial uses considered likely to result in air and/or water releases were assigned a high ranking score of 3. Uses with low or no potential for releases were given a low score of 1. The rest of the uses were given a score of 2.

Under the IUR, reporters had an option to indicate if commercial/consumer information was not applicable to their chemical. If all reporters of a chemical indicated that the commercial/consumer information was not applicable, EPA assumed there was no commercial use of the chemical, resulting in a low ranking (i.e., score of 1). For chemicals with a ranking of 1 or 2 that had one or more commercial/consumer uses reported as "not readily obtainable" (NRO) or "Others," rankings were developed based solely on the remaining reported uses. No ranking was developed for chemicals with all commercial/consumer uses reported as "NRO" Or "Others." EPA assigned a High ranking of 3 for chemicals with at least one reported C code with a high potential for widespread releases. If multiple uses were reported, EPA referred to the use code that resulted in the highest ranking.

2006 IUR Commercial Use Categories

2006 IUR Commercial Use
C01 Adhesives and sealants
C02 Agricultural products (non-pesticide)
C03 Artists' supplies
C04 Automotive care products
C05 Electrical and electronic products
C06 Fabrics, textiles and apparel
C07 Glass and ceramic products
C08 Lawn and garden products (non-pesticide)
C09 Leather products
C10 Lubricants, greases and fuel additives
C11 Metal products
C12 Paints and coatings
C13 Paper products
C14 Photographic supplies
C15 Polishes and sanitation goods
C16 Rubber and plastic products
C17 Soaps and detergents
C18 Transportation products
C19 Wood and wood furniture

Scoring Releases for Non-TRI Chemicals

The four ranking scores described above – Production Volume (PV), Number of Sites, Industrial Processing and Use (IPU) ranking, and Commercial Use (C) ranking – were added to develop the release score for non-TRI chemicals. When either IPU or C could not be scored, but all the other factors could be scored, the release score was derived based on the remaining three ranking scores. If neither the IPU nor the C codes could be scored, no release score was assigned to the chemical.

When all four sub-scores were available, the possible total score ranged from 4 to 12, and the non-TRI Release scores were ranked as follows:

High (3) = 9 - 12
Moderate (2) = 7 - 8
Low (1) = 4 - 6

When only three out of the four sub-scores were available (if either IPU or C could not be scored), the possible total score ranged from 3 to 9, and the non-TRI Release scores were ranked as follows:

High (3) = 7 - 9
Moderate (2) = 5 - 6
Low (1) = 3 – 4

The Non-TRI Release score for each chemical was added to the other exposure component scores to derive the Total Exposure Score, as described in the body of this paper.

APPENDIX D: The TSCA Work Plan Chemicals