Background Document
U.S. Environmental Protection Agency Significant New Use Rule (SNUR) and Health Canada/Environment Canada Significant New Activity (SNAc) Compliance Throughout the Supply Chain

Final

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Prepared for:
U.S. Environmental Protection Agency
Chemical Control Division
New Chemicals Program

Prepared by:
Noblis

Use and Disclosure of Data

The data in this report represent the opinions of Noblis and not the Federal Government.

Table of Contents

List of Figures

List of Acronyms

ASD EI&E	U.S. Assistant Secretary of Defense, Energy, Installations and Environment
CAS	Chemical Abstract Service
CBI	Confidential Business Information
CEPA	Canadian Environmental Protection Act
CLP	Classification, Labeling, Packing (European Union)
DEC	Department of Environmental Conservation
DoD	U.S. Department of Defense
DSL	Domestic Substances List (Canada)
ECHA	European Chemicals Agency
ESOH	Environmental, Safety, and Occupational Health
EU	European Union
FD&C Act	Federal Food, Drug, and Cosmetic Act (United States)
FMD	Full Material Disclosure
GCI	Green Chemistry Institute
GHS	Globally Harmonized System for Classification and Labelling of Chemicals
NCEL	New Chemical Exposure Limit
NGO	Non-Governmental Organization
NSF	National Science Foundation
PCO	Privy Council Office (Canada)
PMN	Premanufacture Notice
POP	Persistent Organic Pollutant
RCC	Regulatory Cooperation Council
RCRA	Resource Conservation and Recovery Act (United States)
REACH	Registration, Evaluation, Authorisation and Restriction of Chemicals (European Union)
SAICM	Strategic Approach to International Chemical Management
SDS	Safety Data Sheet
SNAc	Significant New Activity (Canada)
SNAN	Significant New Activity Notification (Canada)
SNUN	Significant New Use Notice (United States)
SNUR	Significant New Use Rule (United States)
SVHC	Substances of Very High Concern (European Union)
TSCA	Toxic Substances Control Act (United States)
UNITAR	United Nations Institute for Training and Research
U.S.	United States
USEPA	U.S. Environmental Protection Agency

1 Introduction

In February 2011, United States (U.S.) President Barack Obama and Canadian Prime Minister Stephen Harper launched the U.S.-Canada Regulatory Cooperation Council (RCC). The Leaders created the RCC to facilitate closer cooperation between the two countries to develop more effective approaches to regulation to make the U.S. and Canadian economies stronger and more competitive, while meeting the fundamental responsibilities to protect the safety and welfare of their citizens. They recognized that regulatory differences and duplicative procedures impose unnecessary requirements and costs on citizens, businesses, and economies. Within this context, the U.S. Environmental Protection Agency (USEPA), Health Canada, and Environment Canada are working together under the RCC framework to increase regulatory transparency and coordination between the two countries.

The initial RCC Joint Action Plan produced a nanotechnology work plan focused on sharing information and developing joint approaches on regulatory aspects of nanomaterials. Building on the initial Joint Action Plan and the momentum it has generated among government and stakeholders along with the lessons learned, the second Joint Forward Plan, published in August 2014, represents a pivot point for the regulatory relationship between Canada and the United States. Where appropriate, the governments will advance from the initial issue-based Joint Action Plan to new partnership arrangements and a framework of more institutionalized commitments by U.S. and Canadian regulators. The long-term goal is to have bilateral regulatory cooperation within the regular planning and operational activities of regulatory agencies.

One focus area coming out of the Joint Forward Plan is a comparison and potential alignment of elements of USEPA's Significant New Use Rule (SNUR) and Canada's Significant New Activity (SNAc) programs. Face-to-face meetings of government staff were held on September 3-5, 2014, to discuss early stakeholder engagement, followed by an October 7-8, 2014, kick-off event for RCC Regulators and Stakeholders hosted by the U.S. Office of Management and Budget (OMB) and Canada's corresponding Privy Council Office (PCO). A multi-stakeholder technical working group was formed in April 2015 to support implementation of the SNAc/SNUR RCC work plan and has met several times to further discussions on collaboration and alignment opportunities.

In early 2015, the Canadian Government funded an in-depth comparative analysis of the regulatory frameworks of SNAcs and SNURs.[1] Further details of the analysis are provided in Section 3.1.3. To foster stakeholder collaboration, USEPA, Health Canada, and Environment Canada plan to hold two roundtable meetings in September 2015: one in Washington, D.C., and one in Toronto, Canada. The roundtable discussions will convene stakeholders throughout the

[1]ToxEcology Environmental Consulting Ltd. (2015). "Comparative Analysis of the Regulatory Frameworks for Significant New Activity Provisions (SNAcs) of CEPA 1999 and Significant New Use Rules (SNURs) under TSCA."

supply chain from the United States and Canada to engage in discussions on supply chain communication and implications on compliance with SNAcs and SNURs. The U.S. roundtable will focus specifically on USEPA's SNUR program, whereas the Canadian roundtable will focus on Environment Canada / Health Canada's SNAc program. However, information from both roundtables will be used in both programs.

Participating stakeholders include:

- Chemical manufacturers (both domestic producers and importers of chemicals);
- Chemical processors, formulators, and users;
- Entities that manufacture, distribute, or sell chemical substances as part of articles (manufactured items); and
- Other interested stakeholders.

The facilitated discussions will focus on:

- Existing barriers as well as best practices for SNUR/SNAc compliance;
- How regulators and stakeholders can increase efficiencies in the way compliance promotion is conducted;
- How stakeholders and regulators can help promote and enhance the sharing of information throughout the supply chain to facilitate the tracking and compliance with SNURs/SNAcs; and
- Whether chemical tracking information is or should be integrated with green procurement and sustainable facility plans.

This report provides read-ahead information for participants of those two roundtables. The report (1) describes what is known about the chemical supply chain and the driving mechanisms for information sharing, (2) presents a path forward for the RCC, and (3) presents a set of relevant case studies (Appendix A).

2 Background

The background section discusses several topics at a high level to set the stage for the roundtables. These topics include: Current Political Engagement; Previous Relevant Work; Supply Chains – A Definition; What Constitutes "Chemical Data"?; and Confidential Business Information (CBI) – A Potential Barrier.

2.1 Current Political Engagement

In 2014, President Obama and Prime Minister Harper announced the second phase of the U.S.-Canada RCC. This two-year initiative builds on the previous work and brings together senior representatives of the Canadian and U.S. governments in order to increase regulatory cooperation

between the two countries. The planning and preparation for the upcoming roundtables is an example of the ongoing collaboration between USEPA, Environment Canada, and Health Canada. The efforts will help achieve the RCC objectives of developing common approaches for transparency and regulatory requirements for new uses of chemical substances.

2.2 Previous Relevant Work

Stakeholders from industry, academia, the U.S. and Canadian governments, and non-governmental organizations (NGOs) have been active in discussing SNUR and SNAc compliance and general disclosure of chemical and material content in products. In addition to the meetings discussed in Section 1, other meetings relevant to the 2015 roundtables included the December 6, 2013, and October 22, 2014, Sustainable Chemicals and Materials Roundtables in Washington, D.C., sponsored by the U.S. Department of Defense (DoD); the October 7, 2014, Canadian Environmental Protection Act (CEPA) Practical CEPA Compliance Strategies for Importers and their Supply Chain workshop in Toronto, ON, Canada; and a series of Canadian Industry-Government Teleconferences on SNAcs. These discussions and workshops have included compliance, strategies for increasing use of sustainable chemicals and materials, implementing systems to respond to rapidly changing regulations, and addressing information flow in supply chains. A few of the key findings[2,3,4] relevant to tracking chemicals in the supply chain from these recent roundtables include the following:

- Market forces as well as regulatory and legal drivers will force implementation of supply chain management systems that account for chemical and material content of items across all industries and sectors of the economy.
- There is a need for cross-industry, public-private collaboration to ensure that supply chain management systems are harmonized to avoid duplication of efforts and waste of resources.
- Finding efficiencies and best practices, including by partnering early with the supply chain, leads to better decisions and can save time and money.

2.3 Supply Chains – A Definition

Supply chains are complex systems that involve "the material and informational interchanges in the logistical process stretching from acquisition of raw materials to delivery of finished products

[2] The Horinko Group. 2013. An Information Exchange: Moving From High Risk to Low Risk Chemicals. Sustainable Chemicals & Materials Roundtable.
[3] The Horinko Group. 2014. Sleuthing the Supply Chain: Capturing Chemical & Material Content. Sustainable Chemicals & Materials Roundtable.
[4] The Industry Coordinating Group for CEPA. 2014. Practical CEPA Compliance Strategies for Importers & Their Supply Chain. CEPA Update Conference.

to the end user."[5] Supply chains consist of interactions between different players, each with their own sphere of interest, which does not always encourage movement of information. However, there is increasing demand (and in some cases, a regulatory requirement) for chemical content information for products and materials purchased, beyond what is available in Safety Data Sheets (SDSs).

There are several entities, including consumers, proactive companies, trade associations, NGOs, and government agencies, demanding that suppliers disclose the chemical and material content of products. The drivers for disclosing and tracking chemical ingredient information in formulations and articles (manufactured items) throughout the supply chain include:

- Compliance with environmental, safety, and health laws and regulations;
- Increasing supply chain efficiencies (e.g., strategic or critical material recovery)
- Customers' heightened interest in increasing sustainability and minimizing health and environmental risks; and
- Better understanding of risks to worker health during operation and maintenance activities.

These driving mechanisms for full disclosure are discussed further in Section 3.

The process of obtaining information on a formulation or an article's chemical or material constituents can be complex. Understanding the complete chemical makeup of a formulation or an article requires the transparent sharing of material content information throughout all stages of the supply chain and across the lifecycle of the formulation/product. Figure 1 illustrates an example supply chain for a product from raw material acquisition to retail distribution.

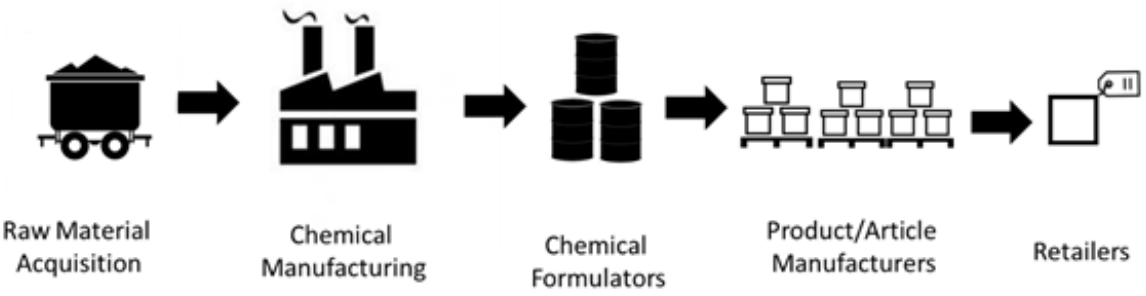


Figure 1. Simplified Supply Chain Example

Chemical manufacturers are supplied with raw materials, from which base chemicals are produced. These base chemicals can include solvents, chelating agents, alkalinity boosters, and

[5] Vitasek K. 2013. Glossary of Terms. Council of Supply Chain Management Professionals. Retrieved from https://cscmp.org/research/glossary-terms, accessed 30 June 2015.

polymers. Base chemicals are then supplied to formulators that make "ingredient packages" (e.g., fragrances, surfactants, adhesives). The formulator sells the ingredient packages to product/article manufacturers whose products are sold to retailers or directly to consumers.[6] In addition to the example shown in Figure 1, some formulators also sell their products directly to consumers.

Information flow in supply chains tends to flow downstream with the downstream entities identifying specific needs (e.g., toxicity data) and developing systems to help their suppliers provide this information. These systems include written guidance detailing chemical information needed, questionnaires addressing chemical ingredients and concentrations, and web portals for data entry.[7] Gathering information from formulators or suppliers who are several tiers removed is often a challenge and, conversely, smaller manufacturers may not have access to knowledge about environmental, health, or safety data for downstream products and applications. The number of entities involved in formulating or manufacturing a product increases the challenges to chemical content information sharing. A simple example, such as the production of synthetic shoe soles, may involve few supply chain actors. However, the sale of a T-shirt by a multinational fashion retailer can involve thousands of upstream entities (e.g., cotton production, textile production, dyeing, finishing, apparel manufacturers).[8] The completeness and certainty of understanding the chemical and material content in products decreases with each subsequent tier in the supply chain.

Over the last several years, retail companies at the end of the supply chain with a large market share have been demanding that suppliers disclose the chemicals in their products. These demands can have a major impact on brands. For instance, when a large retailer like Walmart requests chemical ingredient disclosure, suppliers are likely to comply since much of their sales are to the largest retailers. Clorox Co., for example, sells 26% of its products to Walmart stores and its affiliates.[9,10]

2.4 What Constitutes "Chemical Data"?

There are many different definitions for what constitutes chemical data. The Toxic Substances Control Act (TSCA) defines a chemical substance as an "organic or inorganic substance of a

[6] Green Chemistry & Commerce Council. 2011. Meeting Customers' Needs for Chemical Data: A guidance document for suppliers. Lowell Center for Sustainable Production.
[7] *Ibid*.
[8] Kogg B, Thidell Å. 2010. Chemicals in Products: An overview of systems for providing information regarding chemicals in products and of stakeholders' needs for such information. Lund: United Nations Environment Program DTIE/Chemicals Branch.
[9] *Ibid.*
[10] Rossi M. 2014. The Business Case for Knowing Chemicals in Products and Supply Chains, and references cited herein.

particular molecular identity, including any combination of these substances occurring in whole or in part as a result of a chemical reaction or occurring in nature, and any element or uncombined radical."[11] The TSCA New Chemicals program requires anyone who plans to manufacture (including import) a new chemical substance for a commercial purpose to provide USEPA a Premanufacture Notice (PMN) at least 90 days prior to initiating activity. Certain substances are excluded from this notification requirement under the following exemption categories: statutory excluded substances, research and development exemption, test marketing exemption, low-volume exemption, polymer exemption, and low release and exposure exemption. Additionally, chemical substances in articles[12], while not statutorily excluded, are regulatory exempted from the PMN requirements.

The types of chemical data required in the PMN include:[13]

- Chemical Identity Information. Data required depends in part on the type of substance but can include:
  - Chemical Abstract Services (CAS) chemical nomenclature
  - Molecular formula and structural diagram (complete as possible)
  - Immediate precursor substances (chemical name and CAS registry number)
  - Monomer or other reactants (and CAS registry number[s])
  - Nature of the reaction or process
  - Percent of reactant, typical and maximum weight percent composition
  - Impurities
  - Trade identification
  - Generic chemical name and synonyms
  - Byproducts
- Production, Import, and Use Information
  - Production volume
  - Use information
  - Hazard information (to include SDS)
- Human Exposure and Environmental Release
  - Operation description
  - Occupational exposure

[11] Environmental Protection Agency. 2014. Toxic Substances Control Act Basic Substances Inventory: Basic Information. Retrieved from http://www.epa.gov/oppt/newchems/pubs/pmnviewonly.pdf, accessed 30 June 2015.

[12] An article is defined as a manufactured item which: (1) is formed to a specific shape or design during manufacture; (2) has an end use function(s) dependent in whole or in part upon its shape or design during end use; and (3) either has no change of chemical composition during its end-use or only those changes in composition which have no commercial purpose separate from the article of which it is a part and that may occur as described in 40 CFR §710.4(d)(5) and 40 CFR §720.30(h)(5). From 40 CFR §720.3.

[13] USEPA. 2003. Instruction Manual for Reporting Under The TSCA §5 New Chemicals Program. Retrieved from http://www.epa.gov/oppt/newchems/pubs/tscaman2.pdf, accessed 30 June 2015.

    - Environmental release and disposal
- Pollution Prevention and Recycling Information (optional)
- Test Data (if in possession or control of the submitter)
    - Physical and chemical properties and environmental fate data
    - Health effects data
    - Environmental effects data

The *Canadian Environmental Protection Act, 1999* (CEPA 1999) data requirements for manufacturing or importing chemicals not on the Domestic Substances List depend on substance type and production volumes but at a minimum must include the following: [14]

- Chemical Identity Information:
    - CAS registry or International Union of Pure and Applied Chemistry (IUPAC) chemical name
    - Trade names and synonyms
    - CAS registry number
    - Identification information (molecular formula, structural formula, molecular weight, degree purity, known impurities)
    - Additives
    - Safety Data Sheets
- Exposure Information
    - Quantity manufactured/imported
    - Anticipated uses
    - Anticipated concentration in products
    - Environmental releases
    - Components of the environment into which it will be released
    - Destruction/disposal methods
    - Anticipated public exposure
- Test data in the possession of the manufacturer/importer relevant (or to which they ought to have access to identifying hazards) to the environment and human health and the degree of environmental and public exposure.

Respondents of a recent survey of information needs for chemicals in products expressed the desire for "the names and locations of all actors involved in the supply chain, as this would

[14] New Substances Notification Regulations (Chemicals and Polymers). (2005). Retrieved from http://laws-lois.justice.gc.ca/eng/regulations/SOR-2005-247/index.html, accessed 30 June 2015.

enable them to find relevant actors in the chain if more information regarding a product or a specific component of the product is needed."[15]

With all the different definitions of chemical data, there have been recent initiatives to standardize the definition of what constitutes chemical data. The Globally Harmonized System for Classification and Labelling of Chemicals (GHS) standardizes format and guidance for providing information on both substances alone and in mixtures. More information on standardization efforts can be found in Section 4.1.

2.5 Confidential Business Information (CBI) – A Potential Barrier

Confidential business information (CBI) may include trade secrets, financial information, and (in regards to chemicals) ingredients, and toxicity information. Companies often declare that chemical data are CBI because divulging this information could be harmful to their business as competitors could reverse-engineer their products. USEPA reported that 95% of information it receives on new chemicals contains assertions of confidentiality.[16] Despite this claim, there are numerous cases where supply chain visibility has increased while protecting CBI and addressing anti-competitive issues.

Seagate Technology PLC requests full material disclosure from its suppliers. Full material disclosure for Seagate means chemical ingredient disclosure by CAS registry number. Seagate strives for 100% disclosure, but to allow for CBI claims it accepts 5% miscellaneous proprietary data at the homogenous material level. Seagate also has a list of chemicals of high concern and suppliers cannot claim CBI for those chemicals, meaning all chemicals of high concern identified by Seagate must be reported.[17]

3 Driving Mechanisms for Information Sharing

Currently, there are many data gaps for chemicals in commerce today. Increasingly, supply chains are being pressured to address data gaps for chemical information in products. That pressure is being driven by a number of mechanisms that are worth examining. The following are a selection of driving mechanisms for transparency, disclosure, and the sharing of material content information throughout the supply chain.

[15] Kogg, B., Å.Thidell. (2010). "Chemicals in Products: An overview of systems for providing information regarding chemicals in products and of stakeholders' needs for such information." Lund: United Nations Environment Program DTIE/Chemicals Branch.
[16] U.S. Government Accountability Office. (2013). Toxic Substances: EPA Has Increased Efforts to Assess and Control Chemicals but Could Strengthen Its Approach.
[17] Rossi M. 2014. The Business Case for Knowing Chemicals in Products and Supply Chains, and references cited herein.

3.1 Legal Drivers

3.1.1 United States – Significant New Use Rule (SNUR)[18]

TSCA provides USEPA the authority to collect data on chemicals in order to evaluate potential human and environmental health risks that may occur as a result of the manufacturing (including importing), processing, exporting, and use of a chemical. This authority regulates the introduction of new chemicals, while grandfathering in existing chemicals (those in existence at the time TSCA was passed in 1976), although review and regulation of existing chemicals occurs as well.

One outcome of USEPA's review of a PMN for a new chemical substance is the issuance of a Consent Order under TSCA section 5(e) based upon the determination that the production of the chemical substance may pose unreasonable risk ("risk-based" order) or significant/substantial exposure ("exposure-based" order). Some or all of the following requirements are typically included in a TSCA section 5(e) Consent Order: testing for toxicity or environmental fate once a certain production volume or time period is reached; use of worker personal protective equipment; New Chemical Exposure Limits (NCELs) for worker protection; hazard communication language; distribution and use restrictions; restrictions on releases to water, air, and land; and recordkeeping.

USEPA also has the authority to promulgate SNURs for new and existing chemicals. SNUR examples follow:

New Chemicals:

- **TSCA Section 5(e) SNURs:** When a PMN substance is the subject of a section 5(e) Consent Order, the associated TSCA SNUR designates as a "significant new use" the absence of the protective measures required in the underlying consent order. The SNURs issued in conjunction with a section 5(e) Consent Order are based on and consistent with the provisions in the underlying consent orders. Consequently, these SNURs work to level the regulatory playing field by requiring future potential manufacturers (including importers) and processors of a substance to comply with the conditions to which the original PMN submitter (i.e., consent-order signer) is held. The SNUR contains the same limitations (e.g., use restrictions, production volume limits, personal protective equipment, new chemical exposure limits, water release restrictions, etc.) as the TSCA section 5(e) Consent Order.
- **SNURs Not Associated with TSCA Section 5(e) Consent Orders**: USEPA also promulgates SNURs for new chemical substances when, although the Agency did not find that the use scenario in the PMN triggered the determinations set forth under TSCA section 5(e), the Agency determines that certain changes from the scenario described in the PMN could result in the potential for increased or different types of exposure. Further testing is only recommended and is not required.

[18] For further information – http://www.epa.gov/oppt/newchems/pubs/cnosnurs.htm, accessed 30 June 2015.

Existing Chemicals:

- **When specific use(s) of a chemical are no longer ongoing, existing chemical SNURs** require notification (i.e. SNUN) before resumption of any of those specific use(s).
- **When no use of a chemical is ongoing, existing SNURs** require notification (i.e., SNUN) upon future reintroduction of a chemical into commerce for any future use.

After USEPA proposes a SNUR, companies must submit a Significant New Use Notice (SNUN) if they intend to manufacture, process, or distribute the SNURed substance. After review of the notification and its accompanying information and test data, USEPA may then take action to control the activities proposed in the SNUN, or allow the proposed activities.

A recent Government Accountability Office report noted that USEPA quadrupled its issuances of SNURs, primarily new chemical SNURS, between 2009 and 2012, accounting for about 25% of all 2,180 chemicals subject to SNURs issued by USEPA since 1976.[19,20] However, this statistic is misleading, because during that time the Agency was addressing a backlog of SNURs on previous years' PMNs. The number of SNUR decisions for a given year remained steady.

3.1.2 Canada – Significant New Activity (SNAc) [21]

CEPA 1999 established the authority for Health Canada and Environment Canada to ensure that prior to their manufacture or import to Canada, activities involving new chemicals are assessed to determine their potential risk to human and environmental health. Environment Canada and Health Canada are responsible for evaluating substances that are listed on the Domestic Substances List (DSL) as well as those that are new to Canada. Significant New Activity (SNAc) provisions may be applied after a substance has been assessed and there is a suspicion that a significant new activity may pose a risk to human health and/or the environment. After a SNAc provision is applied, manufacture, import, or use of the substance for the new activity is prohibited until a Significant New Activity Notification (SNAN) is submitted and assessed by the government under a prescribed timeline. The SNAc provisions can be applied to new and existing substances, irrespective of commercial status.

[19] ToxEcology Environmental Consulting Ltd. (2015). "Comparative Analysis of the Regulatory Frameworks for Significant New Activity Provisions (SNAcs) of CEPA 1999 and Significant New Use Rules (SNURs) under TSCA."
[20] U.S. Government Accountability Office. (2013). Toxic Substances: EPA Has Increased Efforts to Assess and Control Chemicals but Could Strengthen Its Approach.
[21] For further information – https://www.ec.gc.ca/subsnouvelles-newsubs/default.asp?lang=En&n=AB189605-1, accessed 30 June 2015.

3.1.3 Regulatory Requirements for Notification of Downstream Users

TSCA and CEPA 1999 differ in regulatory authority, including regulatory requirements for notification of downstream users. Requirements for both countries differ with respect to new and existing chemicals. Downstream notification requirement examples follow: [22]

Under TSCA, manufacturers and processors are subject to information sharing requirements along the supply chain for new and existing substances. It is the obligation of the manufacturer or processor who intends to distribute a chemical substance into commerce to notify the recipient of the SNUR status of that substance. Additionally, the distributor (manufacturer or processer) must submit a SNUN if they are aware that the customer (recipient) will engage in a new use and not submit a SNUN themselves (Section 721.5).

Furthermore, a SNUR may require various record-keeping requirements, including records documenting the names and addresses (including shipment destination address, if different) of all persons outside the site of manufacture, importation, or processing to whom the manufacturer, importer, or processor directly sells or transfers the substance, the date of each sale or transfer, and the quantity of the substance sold or transferred on such date (Section 721.125).

Under CEPA 1999, in circumstances where a SNAc Notice is issued for a new substance (i.e., not on the DSL), it is the responsibility of every person who transfers the physical possession or control of the substance to notify all persons to whom the possession or control is transferred of the obligation to comply with the SNAc Notice and of the obligation to notify any new activity and all other information as described in the SNAc Notice. This obligation is not limited to the transport of the substance into commerce and extends to all circumstances under which this transfer of possession/control would occur. It is the responsibility of the users of the substance to be aware of and comply with the SNAc Notice and to submit a SNAN to the Minister prior to the commencement of a significant new activity associated with the substance.

The information-sharing requirement does not apply to substances subject to SNAcs that are on the DSL (i.e., existing substances). In contrast, USEPA SNURs require information-sharing down the supply chain for SNUR requirements regardless of whether they are new or existing substances.

Comparison of Article/Item Exemption Provisions

While there is no statutory exemption for importers or processors of a chemical substance in an article, TSCA regulations governing the promulgation of a SNUR include an exemption for persons importing or processing the chemical substance as part of an article.[23] However, USEPA has shifted its approach to articles and has specified in several SNURs that the general exemption is inapplicable. In response to comments that USEPA lacked the authority to regulate articles under a SNUR, the Agency claimed it was not "regulating articles, per se, but the chemical substances that are a part of the article, authority clearly granted to it by the statute."[24] In response to comments that the SNUR did not consider the costs associated with screening

[22] ToxEcology Environmental Consulting Ltd. (2015). "Comparative Analysis of the Regulatory Frameworks for Significant New Activity Provisions (SNAcs) of CEPA 1999 and Significant New Use Rules (SNURs) under TSCA."
[23] 40 C.F.R. 721.45(f).
[24] USEPA. Final Rule: Benzidine-Based Chemical Substances; Di-n-pentyl Phthalate (DnPP); and Alkanes, C12-13, Chloro; Significant New Use Rule. Federal Register, Vol. 79, No. 248. December 29, 2014.

articles to determine whether the SNURs would apply, the Agency pointed to the increasing number of industry-wide processes and resources already in place to screen for chemical substances in articles. To the extent that potential exposure to a chemical as part of an article contributes to USEPA's determination pursuant to the factors in section 5(a)(2) of TSCA that the new use is significant (i.e., the Agency has reason to anticipate that use as part of an article would raise important questions, related to potential exposure, that USEPA should have an opportunity to review before such use could resume or occur), it is appropriate to make the exemption inapplicable.

Examples of SNURs in which the general article exemption was deemed inapplicable include mercury, erionite, perfluoroalkyl sulfonates and long-chain perfluoroalkyl carboxylate chemical substances (final)[25] and toluene diisocyanates and related chemicals (proposed)[26].

In contrast, SNAc provisions do not require the notification of any substances contained in manufactured items.

3.1.4 European Union (EU) – Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH)

The EU Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) regulation "aims to improve the protection of human health and the environment from the risks that can be posed by chemicals, while enhancing the competitiveness of the EU chemical industry."[27] Additionally, REACH established the European Chemicals Agency (ECHA). ECHA ensures the consistent implementation of regulations across the EU and the countries in the European Economic Area – Iceland, Lichtenstein and Norway. ECHA works with the European Commission and the EU Member States to identify "substances of very high concern" for human health and the environment and to decide which substances require regulatory risk management at EU level. The ultimate goal is to replace them with safer alternatives. The EU intends REACH to promote alternative test methods, enhance competitiveness and innovation, and encourage the free circulation of substances on the internal market.[28] REACH affects manufacturers, importers, and downstream users by making the industry responsible for assessing the potential risks posed by chemicals and providing information to their respective users. The ECHA expects 30,000 existing chemicals to be registered by 2018.[29] REACH covers all substances on their own or in

[25] USEPA. Final Rule: Perfluoroalkyl Sulfonates and Long-Chain Perfluoroalkyl Carboxylate Chemical Substances; Final Significant New Use Rule. Federal Register, Vol. 78, No. 204. October 22, 2013.
[26] USEPA. Proposed Rule: Toluene Diisocyanates (TDI) and Related Compounds; Significant New Use Rule. Federal Register, Vol. 80, No. 10. January 15, 2015.
[27] European Chemicals Agency (2007). Registration, Evaluation, Authorisation and Restriction of Chemicals. Retrieved from http://echa.europa.eu/regulations/reach/legislation, accessed 30 June 2015.
[28] Noblis, Inc. (2013). Management of Materials and Chemicals in the Supply Chain: List of organizations and tools for supply chain transparency, data gathering, and communication.
[29] European Chemicals Agency. Why are chemicals important? Retrieved from http://echa.europa.eu/en/chemicals-in-our-life/why-are-chemicals-important, accessed 30 June 2015.

mixtures (with exceptions), which includes manufacture, importation, or placement on the market. Classification criteria and labeling rules are integrated with the United Nations' GHS with community legislation.

REACH requires notification to ECHA of substances included in the Candidate List that are contained in articles. The information required includes information on a substance and its uses in articles. Notification of a substance in articles is required by an article producer or importer when the substance is present in articles produced and/or imported at a concentration of above 0.1% (w/w), and the total amount of the substance present in all articles produced and/or imported, which contain more than 0.1% (w/w) of the substance, exceeds 1 tonne per year for the producer/importer.

In addition of notification requirements to ECHA, suppliers of articles containing a substance included in the Candidate List in a concentration above 0.1% (w/w) have to provide relevant safety information about this substance available to them to the recipients of these articles. At a minimum, the name of the substance in question has to be communicated to the recipient (industrial or professional users and distributors). Additionally, information available to the article supplier necessary to ensure safe use of an article must also be provided to consumers upon request. Consumers have to be provided with this information within 45 days of their request, free of charge.[30]

The requirements for the compilation of the safety data sheets are specified in Annex II of REACH. A supplier needs to provide a safety data sheet in the following cases:

- Substances and mixtures classified as hazardous according to EU's Classification, Labeling, Packaging (CLP) regulation,
- A substance that is persistent, bioaccumulative and toxic (PBT) or very persistent and very bioaccumulative (vPvB), as defined in REACH (Annex XIII), or
- A substance is included in the candidate list of substances of very high concern.[31]

Under certain conditions, described in Article 31(3), some mixtures, which do not meet the criteria for classification as dangerous or hazardous, also require a safety data sheet.[32]

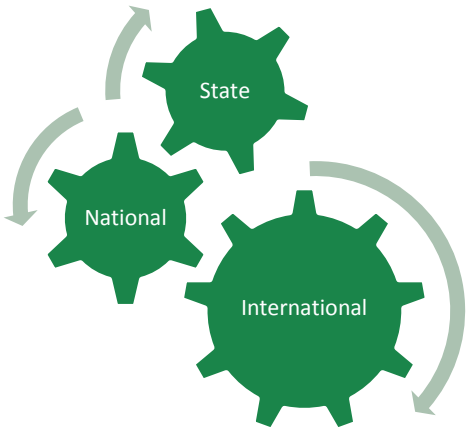
[30] European Chemicals Agency. (2011). Guidance in a Nutshell. Requirements for Substances in Articles. http://echa.europa.eu

[31] European Chemicals Agency. (2015) Safety Data Sheets. Updated 2015. http://echa.europa.eu/web/guest/regulations/reach/safety-data-sheets. Accessed July 22, 2015.

[32] European Chemicals Agency. (2011). Guidance in a Nutshell. Requirements for Substances in Articles. http://echa.europa.eu

3.1.5 Other Legal Drivers

Regulation of chemicals in products does not occur exclusively on the national level. State, national, and international communities can each impose their own rules and frameworks, independent of one another. In the United States, state actions often precede national legislation and national legislation can either drive or follow an international framework.



Most often, state efforts aim to address what are seen as gaps in U.S. Federal legislation, such as regulation of chemicals that were grandfathered under TSCA. For instance, since 2003, twelve states and the District of Columbia have passed regulations on the use of the flame retardants penta- and octa-bromodiphenyl ether (pentaBDE and octaBDE) in consumer products. Of these, eight states and the District of Columbia also regulate deca-bromodiphenyl ether (decaBDE).[33] Many of these state actions occurred prior to the release of USEPA's Polybrominated Diphenyl Ethers (PBDEs) Action Plan in 2009 and subsequent federal regulatory actions (e.g., negotiated voluntary manufacturing/importation phase outs, SNURs).[34,35,36]

Another concrete example of a state effort is California's Proposition 65. Under Proposition 65 (also known as the Safe Drinking Water and Toxic Enforcement Act of 1986), the State of California is required to publish and update a list of chemicals that are known to cause birth defects or other reproductive harm. Proposition 65 requires businesses to notify Californians regarding significant amounts of these chemicals in the products they purchase, in their homes or workplaces, or that are released into the environment. There are four ways a chemical may be added to the list; one of the ways is for the chemical to be identified as causing cancer, birth defects, or other reproductive harm by authoritative institutions such as USEPA. As of June

[33] National Conference of State Legislatures. State Regulation of Flame Retardants in Consumer Products. Updated February 2015. http://www.ncsl.org/research/environment-and-natural-resources/flame-retardants-in-consumer-products.aspx. Accessed July 5, 2015.
[34] EPA. (2009). Polybrominated Diphenyl Ethers (PBDEs) Action Plan. Retrieved from http://www.epa.gov/oppt/existingchemicals/pubs/actionplans/pbdes_ap_2009_1230_final.pdf, accessed 30 June 2015.
[35] EPA. (2009). "DecaBDE Phase-Out Initiative." Retrieved from http://www.epa.gov/opptintr/existingchemicals/pubs/actionplans/deccadbe.html, accessed 30 June 2015.
[36] Cordner, A., & Brown, P. (2015). A multisector alliance approach to environmental social movements: flame retardants and chemical reform in the United States. *Environmental Sociology*, *1*(1), 69-79.

2015, there were 595 chemicals on the Proposition 65 list. Businesses are required to provide a "clear and reasonable warning" on the product containing a listed chemical.[37]

In Canada, there are numerous federal regulatory and non-regulatory drivers, which may require information on chemicals throughout the supply chain in order to ensure compliance. One example of a federal regulation is the Prohibition of Certain Toxic Substances Regulations, which prohibit the manufacture, import, use, sale and offer for sale of a number of substances, with some exemptions. The most recent amendments to these regulations propose to include HBCD, PFOA, Long Chain PFCAs, PBDEs, and PFOS.

3.2 Consumer Markets and Advocacy

In recent years, market forces, such as customer demand, media attention, and NGO advocacy, are driving companies to obtain more information about the chemicals in their products and encourage visibility within their supply chains. This demand has led to higher scrutiny of chemical and material content of products. This new level of attention has direct consequences to business reputation, profitability, and the supply chain being disrupted. For example, after lead was discovered in children's toys, toymakers were confronted with a product recall along with adverse impacts to their brands. Mattel, Inc. and several other brands agreed to meet new Federal standards prior to the date they went into effect, pledged not to sell any toys known to contain lead, and paid $550,000 for lead testing and improved consumer notification.[38,39]

Consumer advocacy groups have contributed to heightened interest in product content and have increased legal pressure for information transparency for chemical content of products. Earthjustice, along with several other environmental advocacy groups, sued several chemical formulators under New York state law to disclose chemical content along with health and environmental effects associated with both commercial and household cleaning chemicals.[40] Although the suit was thrown out, the New York Department of Environmental Conservation decided to begin enforcement of the law.

In response to consumer pressures, customer-facing businesses are leading the way in sustainability, disclosure, and transparency. Achieving chemical data and information

[37] Office of Environmental Health Hazard Assessment. Proposition 65. Retrieved from http://www.oehha.ca.gov/prop65/background/p65plain.html, accessed 30 June 2015.
[38] McFadden, R. D. (2011). The business case for transitioning to safer chemicals. NEW SOLUTIONS: A Journal of Environmental and Occupational Health Policy, 21(3), 403-416.
[39](2008). "Toy Makers Settle Lead-Contaminated Toy Lawsuit," Insurance Journal, Retrieved from http://www.insurancejournal.com/news/west/2008/12/05/96065.htm, accessed 30 June 2015.
[40] Earthjustice. Manufacturers Flout Law, Refuse to Disclose Toxics in Household Cleaners. Retrieved from http://earthjustice.org/news/press/2009/manufacturers-flout-law-refuse-to-disclose-toxics-in-household-cleaners, accessed 30 June 2015.

transparency is just one aspect of what many organizations are doing under the umbrella of sustainability. A vice president of the Retail Industry Leaders Association recently stated that "sustainability is seen as offering a competitive advantage."[41] Additionally, a 2012 survey by the Economist Intelligence Unit[42] reported that 61% of respondents indicated "supply chain collaboration and transparency will make a significant or very significant contribution to their profits."[43] These market forces have pressured for the substitution of safer, more sustainable chemicals and materials in commerce.

4 SNUR/SNAc Compliance Activities

A number of best practices were identified for the collection, dissemination, and access to chemical and material content information in supply chains. These activities also facilitate and support compliance with SNURs and SNAcs. The scope of compliance mechanisms uncovered within each of the activities varied by industry and application. However, overlapping influences were found in four key areas: standardization, supplier data requirements, environmental management systems, and green procurement and sustainable facilities initiatives.

4.1 Standardization

In response to the wide variation of chemical data being collected, there have been recent initiatives for standardization. The GHS standardizes format and guidance for providing information on both substances in mixtures and alone. To the extent that individual jurisdictions wish to adopt classification and labeling requirements for chemicals, they can rely upon the GHS in developing these requirements. Technical assistance for the development of such requirements is available through the United Nations Institute for Training and Research (UNITAR) and other institutions.[44]

The National Science Foundation (NSF) National Center for Sustainability Standards (NCSS) and the American Chemical Society (ACS) Green Chemistry Institute (GCI) jointly developed the NSF/GCI/ANSI 355: Greener Chemicals and Processes Information,[45] which provides a means to report chemical data over its entire lifecycle. By providing this reporting mechanism,

[41] Rizzuto, P. (2014). "Manufacturers, Retailers Seek Convergence on Data Sharing across Supply Chains." Bloomberg BNA. Retrieved from http://www.nsf.org/media/enews/documents/boomberg_bna_special_report_chemicals.pdf, accessed 30 June 2015.
[42] A division of The Economist Group providing forecasting and advisory services through research and analysis.
[43] "KPMG Global Manufacturing Outlook 2012: Fostering growth through innovation." Economist Intelligence Unit. May 2012.
[44] Becker, M., J. Hutchins, R. Massey, & J. Tickner. (2008). "Toxic Substances in Articles: The Need for Information." Nordic Council of Ministers.
[45] http://www.nsf.org/services/by-industry/sustainability-environment/green-chemistry/nsf-gci-ansi-355/, accessed 30 June 2015.

scenarios under which a supplier does not have the knowledge or ability to produce chemical data for downstream requirements can be avoided.

4.2 Supplier Data Requirements

Supplier requirements for specific data elements may be imposed at multiple phases of the lifecycle including the manufacture, delivery, use, and disposal of items. An organization may use their significant purchasing leverage as a means to overcome supplier hesitation to providing the data. Requiring a supplier to increase their reporting of chemical data can help standardize the mechanism to transfer content information as well as determine necessary data elements.

A recent incident involving the DoD's tracking of strategic and critical materials demonstrates the need for more robust information on chemical and material content. High-valued and potentially hazardous copper-beryllium alloys were being combined with other scrap metals, listed as either brass or copper, and subsequently sold to metal recyclers without acknowledging their beryllium content and associated health risks to personnel.[46]

One of the most frequently used methods for transparency is requiring a list of declarable substances. Based on their own risk management plans, some organizations may require more identification of information than others. Any company, industry, government, or end-user may impose unique lists of declarable substances, hazard characterization disclosure requirements, chemicals or materials of concern for avoidance, controlled substances, outright banned chemicals, or a list of approved alternatives to meet individual requirements. Suppliers are often required to declare and provide data for substances that are on a list. As an example, Canon's suppliers must report comprehensive information on substances, including REACH's Substances of Very High Concern (SVHCs). Canon also uses the criteria from ECHA's Candidate List for their suppliers. "Of the chemical substances handled during manufacturing at Canon, approximately 3,000 are controlled substances that require regulation due to such issues as toxicity, effect on the environment and combustibility. Canon separates these substances into three categories: A) Prohibited substances, B) Emission-reduction substances, and C) Regulated substances. Effective measures are in place for each category. Furthermore, we have reinforced our management practices by linking our purchasing system with our chemical management system in order to reduce environmental accidents and pollution risks associated with the use of chemical substances."[47]

[46] ODUSD(I&E). (2011). Closing the Loop: An Assessment of the Life Cycle of Beryllium-Containing Materials in the Department of Defense. (Contract Number: N00178-05-D-04255/FC01/TI8005).
[47] Canon Inc. Management of Hazardous Substances and Legal Compliance: Reducing Emissions of Controlled Chemical Substances. Retrieved from http://www.canon.com/environment/produce/substances.html, accessed 30 June 2015.

Manufacturers may request information on the identity of all known chemical ingredients in an item or formulation or all the known information above a certain threshold. Johnson & Johnson requests chemical identity information for all chemicals present in a supplied material at concentrations of 1 part per million (ppm) or higher. For its TerraCheck products, True Textiles requests chemical ingredient information for all intentionally added ingredients and specific impurities.[48]

4.3 Environmental Management Systems

Environmental Management Systems and chemical data registries are a common system or feature across programs. Open communication of these types of system and registry is shown to add value to supply chain partnerships and increases awareness of the need for chemical data.

Additionally, these systems and registries play a key role in the handling of CBI, and are either set up directly by the customer or by a third party. Use of third parties can provide greater assurance of protection of CBI and help streamline costs.

BOMcheck, a collaboration among manufacturers, is a web-based portal and database in which suppliers can submit information in standardized regulatory compliance declarations. In order to improve efficiency, stakeholders are pushing for Full Material Disclosure (FMD) amongst suppliers in order to streamline response to upcoming regulations across the globe. FMDs are confidential, and BOMcheck continuously updates regulatory status, notifying suppliers of changes that may affect their compliance.

SC Johnson receives chemical data directly from formulators for its Greenlist™ process. In order to assure suppliers of confidentiality, SC Johnson provides three levels of confidentiality. Under the first level, the data are made freely available to SC Johnson. The second level of confidentiality consists of signing a Non-Disclosure Agreement, which stipulates only SC Johnson toxicologists are allowed to review the data. For highly proprietary products, the suppliers complete their own assessments and SC Johnson audits the assessment.[49]

4.4 Green Procurement

Green procurement (e.g., sustainable procurement) activities are changing chemical and material requirements, and chemical content plays an important role in the process. In some cases, disclosure and sustainability language is incorporated into the procurement process and in other cases the customer even changes the supplier to ensure the product meets internal requirements.

[48] Green Chemistry & Commerce Council. (2011). "Meeting Customers' Needs for Chemical Data: A guidance document for suppliers." Lowell Center for Sustainable Production.
[49] Green Chemistry & Commerce Council. (2011). "Meeting Customers' Needs for Chemical Data: A guidance document for suppliers." Lowell Center for Sustainable Production.

In addition to the Product Material Content system that tracks substances in products, Raytheon's Design for Sustainability initiative includes the source selection process. Raytheon requests and considers information on suppliers' sustainability efforts when conducting many of their supplier sourcing activities. Sustainability language is incorporated into enterprise agreements and Raytheon plans to continue to incorporate sustainability metrics and reporting in key supplier business reviews.

In an effort to improve sustainable sourcing, Seventh Generation is moving to purchase ingredients directly from formulators and not from distributors. This allows Seventh Generation to better ensure sustainability metrics are being implemented, improve relationships with suppliers, lower risk, all while lowering costs.[50]

Additionally, information transparency is increasingly a part of customer-facing business models. Seventh Generation includes a full description of ingredients on product labels including descriptions of each ingredient following a Federal format for cosmetics as guidance.

Walmart's transparency initiative involving formulated products includes full disclosure of all product ingredients to a third party, The Wercs®. Walmart plans to display product ingredients online, and also display all priority chemicals on packaging beginning in January 2018.

4.5 The Path Forward

This background report provides a foundation for discussions at the upcoming September 2015 roundtables. The roundtable discussions will focus on:

- Existing barriers to compliance and best practices for SNUR/SNAc compliance,
- How regulators and stakeholders can increase efficiencies in the way compliance promotion is conducted,
- How stakeholders and regulators can help promote and enhance the sharing of information down the supply chain to facilitate the tracking and compliance with SNURs/SNAcs, and
- Whether chemical tracking information is or should be integrated with green procurement and sustainable facility plans.

Following the roundtables, a final report detailing best practices and providing recommendations for more consistent and effective approaches to SNUR/SNAc compliance promotion activities will be produced. The report will cover whether compliance challenges are common to both the United States and Canada, what systems can be put in place to improve tracking of

[50] Rapaport, D. Safer Chemicals Policy Reform—Bringing Transparency to Chemicals Management. Seventh Generation.

SNURs/SNAcs, and what mechanisms could be used to help improve stakeholder understanding and compliance with SNURs/SNAcs.

Appendix A Case Studies

Case Study 1: CEPA 1999 Compliance – Concerns, Challenges, and Applicable Solutions[51]

At the most recent CEPA 1999 update conference, Catharine Urquhart, Regulatory Affairs Manager for 3M Canada, discussed CEPA 1999 compliance in the manufacturing sector. In particular, she discussed concerns and challenges for compliance and addressed solutions through a series of case studies.

3M is a multinational manufacturing company with manufacturing operations in Canada, and has over 50,000 products globally, including industrial and household chemicals. Concerns related to CEPA 1999 compliance include incomplete information on materials imported, information gathering, foreign suppliers not understanding Canadian requirements, and changing supply chain systems.

There following case study dealt with something that was not on the DSL - there was no SNAc involved – but is used to highlight how the Foreign Supplier submission can help when you are having difficulties obtaining information and highlight that you need to be careful regarding confidentiality in these cases.

3M's compliance program includes Raw Material Information Forms that are used globally, which streamlines the process for obtaining chemical data. Although 3M requests data included on the form, not all suppliers are willing to disclose this information.

3M Canada introduced a new product that involved a foreign (U.S.) supplier. After review of the product composition, 3M's internal regulatory affairs group informed the Canadian business manager that there would be a maximum amount of goods that could be imported into Canada due to the "new" substance regulation. There was a belief that demand for the product was strong and that the threshold would be reached within a year. 3M Canada contacted 3M United States, who had developed the product, to get information on the product and determine if it would be acceptable to work with the supplier of the raw material that was contributing to the new substance. The raw material supplier did not want to share information with 3M Canada directly, but agreed to a foreign supplier submission. 3M Canada initiated the New Substance Notification and then provided the New Substance Notification number to the foreign supplier so that they could provide the information directly to Environment Canada.

The challenge lies in the need to ensure that the supplier understands what information is required and that they are the technical contact for that information. If there is insufficient understanding, the form can be filled out incorrectly and confidentiality of the information can be compromised.

[51] Urquhart, C. (2014). Managing CEPA Compliance. CEPA Update Conference.

Case Study 2: Walmart

At the most recent Sustainable Chemicals and Materials Roundtable, Richard Leahy, Vice President of Environmental Health and Safety (EH&S) Compliance at Walmart, discussed Walmart's efforts to gather information on the chemical and material content of formulated consumer products from its supply chain.

Walmart is the world's largest retailer, operating 11,000 retail units in 27 countries with 2.2 million associates and 150,000 different products available to customers. The global supply chain that Walmart deals with is enormous and involves tens of thousands of suppliers. The lack of visibility of product ingredient information needed for compliance and sustainability programs presents a great challenge at this scale. Information is needed to comply with various regulatory requirements (e.g., Resource Conservation and Recovery Act [RCRA]; Federal Insecticide, Fungicide, and Rodenticide Act [FIFRA]; U.S. Department of Transportation hazmat shipping; etc.) and meet sustainability program goals and metrics (e.g., chemical ingredients for green chemistry initiatives).

Being such a large retailer in an aggressive regulatory environment, Walmart undergoes 22,000 compliance inspections, 1,800 environmental inspections, and 25,000 facility audits per year. Until the last ten years, USEPA's RCRA program had not focused much attention on retailers and large hazardous waste enforcement fines caught many retailers by surprise. In California, for instance, Walmart was fined $27.6 million in 2010 for improper disposal of consumer products. Because of product disposal—mostly related to nicotine, which is listed as an acutely toxic substance—many Walmart stores and other retailers are considered large-quantity generators under RCRA. The application of RCRA hazardous waste regulations to consumer product retailers in recent years has doubled the number of large quantity generators on the RCRA registry in the last year.

Mr. Leahy outlined a number of challenges to complying with RCRA for consumer products: (1) the product makeup is normally a trade secret, (2) the SDS is not designed to indicate RCRA status if the product is disposed, (3) the products are regulated under other regimes as safe for consumer use, and (4) the retailer must train associates to manage products they use in their homes as hazardous wastes.

To address these challenges, Walmart partnered with The Wercs® (Worldwide Environmental Regulatory Compliance Solutions),[52] a third party that collects and analyzes information submitted by Walmart's suppliers. To have a product sold at Walmart, suppliers are required to submit product composition information to The Wercs®. If the product is a pesticide, aerosol, or chemical, The Wercs® conducts an assessment to determine its regulatory status. This information is then used to populate the item file in Walmart's database and is transferred via

[52] Retrieved from http://www.thewercs.com, accessed 30 June 2015.

barcode scanning so that the item may be properly managed in the stores. Using scanners, store associates are asked questions and given disposal instructions based on the product's information and characteristics.

Walmart also focuses a great deal of attention on sustainability initiatives that go beyond compliance including a Sustainable Chemistry in Consumables Policy.[53] Under this policy, Walmart considers chemicals on regulatory lists, such as REACH, USEPA lists, state lists, etc., to be priority chemicals. The policy aims to reduce the aggregate amount of priority chemicals used in consumer products and provide the safest product without raising the cost. There are three pillars to this effort. The first, transparency, is focused on beginning ingredient disclosure online in 2015, and listing priority chemicals on the consumer package beginning in 2018. Safer formulation, the second pillar, aims to reduce, restrict, and eliminate use of priority chemicals using informed substitutions. Walmart has identified ten high-priority chemicals based on ubiquity, exposure issues, volumes in supply chain, potential for regulation, and feasibility of an informed substitution. Using The Wercs®, Walmart is able to identify which products have chemicals of high priority and share this information with suppliers to alert them and encourage them to work on safer substitutions. Finally, the third pillar focuses on Walmart's private brand, encouraging all the private brand suppliers to obtain USEPA Design for the Environment certification.

Case Study 3: Consumer Advocacy Push for Transparency

Women's Voices for the Earth, Inc. v. Procter & Gamble Company

In February 2009, Earthjustice teamed with Women's Voices for the Earth (WVE), American Lung Association in New York, Riverkeeper Inc., Environmental Advocates of New York, New York Public Interest Research Group, and Sierra Club, and filed suit in New York state court against the Procter and Gamble Company, Church and Dwight Inc., Reckitt Benckiser, and Colgate-Palmolive, Inc., demanding compliance with chemical disclosure laws. These consumer advocacy groups argued that chemical disclosure could protect consumers and decided to bring the fight to court for information on transparency regarding chemicals contained in household and commercial cleaning products.

Earthjustice sued under a "long-forgotten New York state law which requires household and commercial cleaner companies selling their products in New York to file semi-annual reports with the state listing the chemicals contained in their products and describing any company research on these chemicals' health and environmental effects. But in the three decades since the

[53]Retrieved from http://www.walmartsustainabilityhub.com/app/answers/detail/a_id/310, accessed 30 June 2015.

1976 law was passed, companies failed to file a single report."[54] The lawsuit targeted companies that ignored or refused Earthjustice's request to comply with the law.

"In August 2010, New York Supreme Court Justice Richard F. Braun dismissed *Women's Voices for the Earth, Inc v. Procter & Gamble Company* for lack of standing without ruling on its merits. As the WVE team readied to appeal the court decision, the New York Department of Environmental Conservation (DEC) Commissioner, Pete Grannis, announced that the agency would implement the law and begin requiring companies to reveal the ingredients in their products *and* any health risks they pose."[55] The move to begin enforcement by the New York DEC could have national implications as retailers would have to push their supply chain to implement systems capable of disclosing chemical data including content, and health and environmental effects of cleaning products.

Case Study 4: International Material Data System (IMDS) and Global Automotive Declarable Substance List (GADSL)

At the most recent Sustainable Chemicals and Materials Roundtable, Brenda Baney, Product Stewardship Manager of Delphi Automotive; and, Amy Lilly, Senior Environmental Regulatory Engineer of Hyundai-Kia gave an overview of the automotive industry's mature policies, procedures, and its tool to track its supply chain contents. The process, known as the International Material Data System (IMDS)[56], was developed in response to automotive industry-specific chemical regulations in Europe, called the End of Life Vehicles (ELV) Directive for automobiles[57]. The directive includes specifications for heavy metals and improving recycling percentages, causing auto manufacturers to realize they needed to gather information from their supply chains. Numerous other regulatory activities around the world addressing chemicals also have an impact on the automotive industry, including RoHS and REACH (Europe), California Green Chemistry and TSCA (U.S.), CEPA (Canada), and the global Stockholm Convention.

When the ELV Directive was initiated, original equipment manufacturers (OEMs) were using paper surveys to collect information from about 3,000+ vehicle components through 17+ tiers of the supply chain. This approach was burdensome for both the OEMs and the suppliers. In 1999, a group of seven OEMs developed a standardized, web-based data collection tool in collaboration with EDS (now Hewlett Packard). This effort, funded by the OEMs, would eventually become the IMDS and include over 45 OEMs.

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[54] Earthjustice. Manufacturers Flout Law, Refuse to Disclose Toxics in Household Cleaners. Retrieved from http://earthjustice.org/news/press/2009/manufacturers-flout-law-refuse-to-disclose-toxics-in-household-cleaners, accessed 30 June 2015.

[55] Women's Voices for the Earth. New York Disclosure Law. Retrieved from http://www.womensvoices.org/issues/tell-congress-to-protect-us/new-york-disclosure-law/, accessed 30 June 2015.

[56] www.mdsystem.com

[57] http://ec.europa.eu/environment/waste/elv_index.htm

As part of the IMDS, the Global Automotive Declarable Substance List (GADSL) was developed. It is not risk-based and instead simply includes substances expected in an automobile part that are regulated or are pending regulation. Suppliers are required to report on all substances included in GADSL present at the specific threshold level, which is 0.1% as a default or is based on the lowest level required by regulation or scientific evaluation. They are able to report some as pseudo substances (e.g. polymers, ceramics) and can put up to 10% (by weight total) of the non-GADSL material content in "jokers" or "wildcards" to protect proprietary information. There are mechanisms at the within the supply chain to flag if a substance reported in wildcard form gets added to GADSL, and messages are sent to consumers down the supply chain if this is the case.

The IMDS standardizes how this information is communicated through the seven or so tiers of the automotive supply chain. Each supplier enters the substance information for their component into IMDS, where it then goes into the secure databases of all of their customers. The information passes in that manner from the raw material supplier, through the various tiers of the supply chain, to the OEM. As information is passed down, suppliers who want the data in a usable format, pay to get it out of the IMDS, but at each tier, suppliers have the ability to see and verify most of that information all the way up the supply chain. Chemicals used in production that are not in the final product do not need to be reported under the IMDS requirements.

In recent years, updates have focused on a modern look and feel of the platform as well as more advanced functionality for data quality, data ownership, and faster updates from material manufacturers through the supply chain to downstream end customers. The next round of updates will focus on unified requirements from OEM's and supply chain tiers, supply chain confidentiality, published data accuracy and accountability, as well as building in flexibility for new environmental regulations (e.g., biocides). A committee of OEMs and suppliers is working to look at upcoming regulations and revise the GADSL list once a year. Each time the GADSL list evolves, suppliers may have to re-report some of the data on materials. This is a time intensive process, starting from the raw material suppliers and rolling down the supply chain, but ultimately the system is effective.

Some lessons learned and challenges have been identified through the IMDS and GADSL evolution. The well-established process now provides a consistent means of reporting across the industry and reduces costs by harmonizing rules for various chemical regulatory regimes. It was useful for the industry that the legislation in Europe was tied to the type-approval of a car. For instance, lead in solder has been declared exempt until newly type-approved cars starting in model year 2016. It did, however, take five years to reach a point where data quality was sufficiently reliable, and data quality and accuracy are still an issue. Data quality challenges often emerge from companies on the upper tiers who don't have the expertise in chemistry or toxicology to enter data properly. The wildcard system is important to protect CBI, but it will always be slightly problematic because protecting information results in limiting access to

information. Furthermore, the system only applies to existing regulations and is not forward-looking. Discussions on how to expand to include forecasted substances are ongoing. If a material is not regulated, or pending regulation, and thus not on the GADSL list, there is not an easy way to know if it is in the supply chain. Often, information gathering from individual suppliers is necessary. Even if the substance is reported in IMDS, an investigation via IMDS can take months.

The auto industry suppliers are very interested in having a cross-industry system, where at the bottom level the data would all look the same, so that the reporting burden would be reduced for materials suppliers at the bottom tier of the supply chain who are selling to a number of different industries. Those suppliers would benefit immensely from knowing the various lists of interest to each industry and having a streamlined process and a single format to disclose the necessary information. Such an effort would be useful for creating sustainable product development processes, improving risk management, and exporting a global culture of responsibility.

Case Study 5: DoD Acknowledged Need for Minimum Set of Data

The acquisition of systems by the DoD is described in two primary documents: DoD Directive 5000.01–The Defense Acquisition System[58] and DoD Instruction 5000.02 – Operation of the Defense Acquisition System.[59] In addition to general policy and instructions on the overall acquisition process, these two documents provide broad guidance on the evaluation of environmental, safety, and occupational health (ESOH) risks. However, these documents do not identify the specific data to be generated in order to perform the evaluation of the environmental and human health hazards or when such data should be generated during the acquisition process.

source: www.defense.gov

In 2009, the Assistant Secretary of Defense, Energy, Installations and Environment (ASD EI&E) recognized that decision makers in the acquisition process often did not have the necessary guidance or information on chemicals and materials regarding their potential impact to ESOH. As a result, the ASD EI&E funded the preparation of a document, Environmental and Human

[58] http://www.dtic.mil/whs/directives/corres/pdf/500001p.pdf, accessed 30 June 2015.
[59] http://www.acq.osd.mil/fo/docs/500002p.pdf, accessed 30 June 2015.

Health Hazard Assessment of Chemicals to Support DoD Acquisitions, that describes specific data needs for informed environmental- and human health-sensitive choices among available chemicals and materials in systems acquisition. Environmental and human health hazards can be managed, lifecycle costs can be reduced, and environmental sustainability can be enhanced by informed chemical and material choices driven by environmental and human health considerations, in concert with performance requirements, throughout the acquisition process.

The document provides a systematic process to evaluate the potential impact to human health and the environment of chemicals developed for, or incorporated into, components or systems acquired by the DoD through the acquisition process, during their entire lifecycle—from laboratory synthesis through demilitarization and disposal. The document identifies information and data needed at each stage of the chemical's lifecycle to fully evaluate its environmental fate and toxicity. Such an evaluation, when combined with performance testing, will allow DoD Program Managers to make informed decisions regarding their potential liabilities and environmental and human health risk-management requirements. The document describes a system for guiding environmental and human health hazard information collection or generation at appropriate points in the item's lifecycle and is intended to be flexible and applicable to the entire breadth of DoD acquisitions. The document is applicable to all chemicals and materials except for nanomaterials, foods, drugs, personal care products, or pesticides.

The foremost purpose of the document is to facilitate the timely identification and collection or generation of the information needed to understand the environmental and human health hazards of chemicals and materials in parallel with performance evaluation of the articles of which they are a component throughout the acquisition cycle and to ensure that the handling, use, and disposal of DoD materials throughout their lifecycles are protective of human health and the environment. The primary audiences for the document are the DoD organizations that conduct systems acquisitions involving the development or use of chemicals or materials. The information generated from this guidance will be useful for the development, production, use, and end-of-life disposal or recycling of chemicals—throughout the lifecycle of an acquired system, as well as the lifecycle of the chemical or material evaluated.

Case Study 6: U.S. Army Qualification of New Product or Technology Requires Full Disclosure

Within the DoD, full disclosure of a composition's makeup is becoming more common. As an example, the U.S. Army recently updated a widely used process and now requires vendors to provide statements of composition (full disclosure) for qualification of new product and technologies for Chemical Conversion Coatings and Pretreatments for Ferrous Surfaces (process specification TT-C-490).[60] This specification (TT-C-490) references a widely used wash primer

60 http://www.google.com/url?sa=t&rct=j&q=&esrc=s&source=web&cd=4&ved=0CDUQFjAD&url=http%3A%2F%2Fe

process for treating metals prior to painting. That referenced wash primer process uses hexavalent chromium on applications throughout DoD. A memorandum from Department of Defense acquisition chief John J. Young, Jr. (April 8, 2009)[61] mandating a reduction in the use of hexavalent chromium led to elimination of specification TT-C-490 on most new contracts.

With the ability to treat ferrous surfaces being restricted, the Army initiated an effort to modify the specification to allow the testing and qualification of new technologies and products for use on DoD weapons systems.

The qualification process (Figure 2) is conducted to ensure the effectiveness of the product or technology. It provides data for an independent evaluation required for material release so that the evaluator can address the adequacy of the material with respect to the stated requirements. The purpose of qualification is to ensure continued product performance, quality, and reliability, and provide for the completion of long or highly-complex evaluations and tests prior to, and independent of, any acquisition or contract. Qualification comprises the entire process by which a manufacturer's products or processes and materials are proven to be in conformance with the requirements set forth in the governing specification. A qualification program reduces acquisition costs by reducing or eliminating repetitive surveillance audits, first article tests, or qualification tests for each individual product procurement and contract. Qualification also reduces unit product costs and improves readiness through ensured continuous availability of products with requisite quality, reliability, performance, and safety.

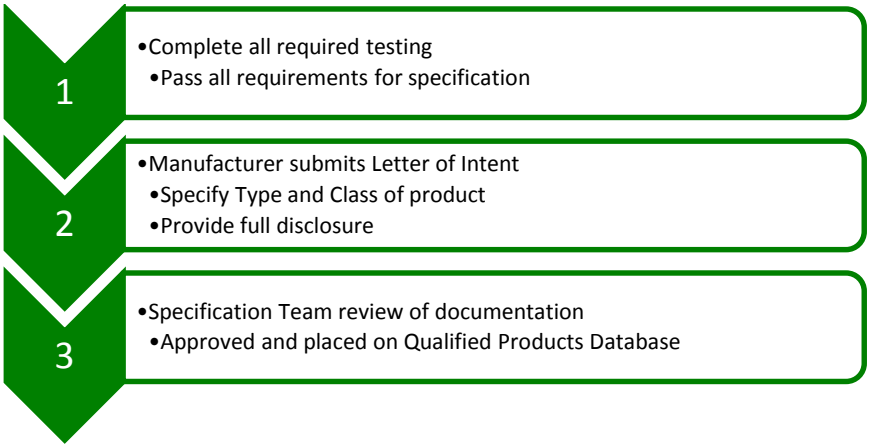

Figure 2. Process for Qualification of New Product or Technology

Process specification TT-C-490 now requires all vendors who want to qualify their technology or product to provide full disclosure of every component in the formulation.

veryspec.com%2FFED_SPECS%2FT%2Fdownload.php%3Fspec%3DTT-C-490.025036.pdf&ei=oCaUVaOOCoj5yQS074HgAg&usg=AFQjCNEMMb7sWLIBxticSt35YUsSN7KEXQ&sig2=EFgdTQ_y2hJ_nzACJztnJQ&bvm=bv.96952980,d.aWw, accessed 30 June 2015.

[61] http://corrdefense.nace.org/corrdefense_summer_2009/images/memo.pdf, accessed 30 June 2015.