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GLOBAL RISK & REGULATION NEWS

Regulatory Impact Report

The impact of TSCA on downstream users

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Introduction

This is the third Regulatory Impact Report to be published by Chemical Watch on the impact of a specific piece of legislation on downstream users of chemicals. It follows on from earlier reports on the impacts of REACH and the biocidal products Regulation in Europe, both of which can be downloaded free of charge from the Chemical Watch website.

The US's Toxic Substances Control Act (TSCA) had been in place since 1976 and just about the only thing that everyone could agree on was that it needed updating: the issue was how.

The chemicals industry has become truly globalised since then and many NGOs looked to EU REACH as a model that the US might follow, as the *de facto* gold standard in world chemical legislation. Industry, while acknowledging that TSCA had become seriously outdated and that being REACH-compliant can be a commercial advantage on a global scale, generally did not favour the hazard-based elements of REACH.

What finally came out of the pipeline - with remarkable speed and bipartisan support, considering how rancorous the political divide is in the US these days - was the Lautenberg Chemical Safety Act (LCSA).

This is now in the process of being implemented and is the reason for this report. The bureaucracy involved may not be as detailed or as lengthy as REACH, but it is certainly not straightforward either and the law of unintended consequences will no doubt come into play at some point.

Like REACH, but in very different ways, the LCSA has implications for downstream users (or 'processors', as it calls them) of chemicals. Some are spelled out, others are implicit.

Like REACH, it will require supply chains to communicate with each other as never before and vast amounts of information to be generated, communicated to the authorities and disseminated both to the public and within the industry.

This process is only just beginning and it will clearly create plenty of work and new responsibilities for trade associations and other collective bodies in downstream industries.

This Regulatory Impact Report aims to help companies using chemicals within the purview of the revised TSCA to understand the basics of this complex and novel regulation, as well as their roles and compliance obligations, and what to watch out for. It includes an introduction, a deep dive into the key obligations, definitions of key terms and links to key sources of additional information. We hope you find it useful.

Who is Chemical Watch?

Chemical Watch provides the global business community with the facts and perspectives it needs to achieve safer chemicals in products.

With a team of expert journalists keeping you abreast of global policy and business trends, our ultimate goal is to help you meet your responsibilities under chemicals legislation worldwide, including regimes such as REACH, GHS and TSCA. We are not tied to any trade associations, governments or campaign groups, which means we are able to offer objective news and analysis for all sectors.

Alongside our authoritative news coverage, we also support your professional development with our intensive courses, premium webinars and eLearning offering. Together they provide you and your teams with the training you need to manage the risks of chemicals in the workplace, through the supply chain, and in products.

To find out more about Chemical Watch and our coverage of regulatory developments in your sector, feel free to have a look at our sector pages, or take a free trial to get full access to all our coverage for two weeks.

Report Editor: Andrew Warmington

Contributing Editor: Frank Zaworski

Sub Editors: Martina Chamberlain, James Lumley

Publishing Manager: Henry Tipping

Production: Petya Grozeva

Managing Director: Stuart Foxon

Chemical Watch Directors and Co-Founders: Mamta Patel, Julian Rose

Chemical Watch
Editorial: +44 (0)20 3603 2110
Subscriptions: +44 (0)1743 818 292

CW Research Ltd, Talbot House, Market Street, Shrewsbury SY1 1LG

The impact of TSCA on downstream users

An overview to aid in the understanding of old and new requirements

The Frank R. Lautenberg Chemical Safety for the 21st Century Act (LCSA) amended the Toxic Substances Control Act (TSCA), which had been the primary chemicals management law in the US since it was enacted in 1976. Chemical manufacturers and downstream users had been calling for revisions to TSCA practically ever since its enactment. Revisions, many in response to industry requests, are now being implemented.

TSCA can seem like a daunting mountain of regulation to the downstream chemical user wanting to introduce a new product, substance or chemical use. Complying with the Environmental Protection Agency's (EPA) rules for chemical substances can certainly be difficult, but understanding some of the basic requirements will lead to success. This report presents an overview of some key elements of TSCA important for the downstream user, notably:

- the TSCA Chemical Substance Inventory;
- risk-based assessments;
- the pre-manufacturing notice (PMN); and
- significant new use rules (Snurs).

Entities that are downstream from chemical importers and manufacturers generally are considered, for TSCA purposes, to be processors and users of chemical substances and mixtures. They include:

- major manufacturers of industrial equipment and products (such as vehicles or aircraft); and
- entities that blend substances into formulations and manufacture finished products that are distributed for sale and use by business and consumers (for instance, computers, phones, cleaning products and detergents).

TSCA inventory

Section 8(b) of TSCA requires the EPA to compile, keep current and publish a list of each chemical substance that is manufactured or processed in the US, including imports. The TSCA Chemical Substance Inventory thus plays a central role in the regulation of most industrial chemicals in the US.

If a chemical substance is on the inventory, it is considered an 'existing' chemical substance in US commerce. Any chemical that is not on it is considered a 'new chemical substance'. The public inventory currently lists about 68,000 chemicals and the EPA says that it adds about 400 more each year. The agency has published detailed information on how to access the inventory.

There is a confidential portion of the inventory as well as the public portion. Companies who manufactured or processed a chemical substance on the confidential portion that was added to the inventory before 22 June 2016 must submit a request to the EPA if they wish to maintain an existing claim for protection against disclosure of the specific chemical identity of the substance as confidential.

Risk-based assessment

The revised TSCA requires the EPA to conduct risk-based assessments of new chemical substances. This was the situation under the old TSCA and there had been pressure to move towards more hazard-based assessment, like under REACH. Industry spent a lot of energy fighting against this.

"It is imperative that these assessments are implemented in a manner that is open and in which public participation is solicited and valued, and that decisions made by the EPA are not based strictly on potential hazards, but on reliable science

and an objective assessment of risk," says Lawrence Cullen of law firm Arnold & Porter.

"The new chemicals programme should be aware of the importance of product substitutions and how a particular new chemistry which may be innovative can have an overall positive effect on the risk equation when the entire lifecycle of the chemical - or the use for which it is intended - is considered," Mr Cullen says.

For example, he adds, blocking the entry of a new chemical into the US market can force potential customers to continue to rely on older technologies that might require the use of substances of greater toxicity or to rely on manufacturing processes that demand greater energy consumption and which can have unintended consequences on the environment.

New rules that are implemented in the amended Section 8(b) also require the EPA to designate all substances on inventory as either 'active' or 'inactive' in US commerce. The agency will then prioritise and conduct risk evaluations of the active substances under two new rules that implement the amended Section 6.

Meanwhile, in order to identify active substances, the EPA is now requiring importers and manufacturers, and allowing (but not requiring) processors to report substances added to the inventory before 21 June 2006, that they imported, manufactured or processed for any non-exempt commercial purpose during a ten-year 'lookback period' from then until 21 June 2016.

The EPA published its new active substances reporting rule in August 2017. Importers' and manufacturers' mandatory reports were due to be submitted to the EPA by 7 February 2018 and processors' voluntary reports are due to be submitted by 5 October 2018.

If a company imported or manufactured chemical substances that are listed on the inventory during the lookback period and had an appropriate system for complying with TSCA at the time, it should not encounter serious obstacles to complying with the new active substances reporting rule, according to the EPA. This is because relevant import or manufacturing records in the firm's possession or control will be substantially complete (barring accidents) and organised by substance.

First ten substances

As this report was being published, the EPA was seeking comments from stakeholders on problem formulation documents it had issued for the first ten high-priority chemical substances, on which it is conducting risk evaluations under the revised TSCA. These are:

- asbestos;
- 1-bromopropane;
- carbon tetrachloride;
- 1,4-dioxane;
- the cyclic aliphatic bromides cluster;
- methylene chloride;
- n-methylpyrrolidone;
- perchloroethylene;
- pigment violet 29; and
- trichloroethylene.

Asbestos is one of the first ten high priority chemical substances

View from the associations

According to the American Chemistry Council (ACC), the new TSCA strengthens regulation of chemicals used in countless consumer products in a way that supports safety, economic growth and innovation. TSCA mandates that safety reviews are risk-based so they consider potential harm, uses and exposures, and their conclusions reflect real-world consequences.

"The changes to TSCA have placed an increased importance on ensuring that EPA has the most complete understanding as possible of the use and exposure of chemicals and potentially impacted product categories," says Dr Steve Bennett, senior vice-president of scientific affairs at the Household and Commercial Products Association (HCPA), who also serves on the TSCA Science Advisory Committee on Chemicals (SACC).

Trade associations like the HCPA can assist with this, he adds, via consortia designed to collect detailed exposure information, while protecting CBI and facilitating direct conversations between companies and the agency. "Reporting under the TSCA active/inactive rule has been a significant endeavour, either because of the review of manufacturer reporting to ensure chemicals of interest remain active or the ongoing processor reporting if they did not," he adds.

However, Dr Bennett continues, the effects to date of the revised TSCA on downstream chemicals users have been difficult to quantify. "Certainly, there have been modifications to the new chemicals programme that have reverberated throughout the supply chain," he says. "Undoubtedly, internal systems have been modified to gather and track additional ingredient information, and companies have made business decisions on products containing the first ten chemicals."

Dr Bennett adds that it is important for businesses to know their products. "The intentional ingredients are easy, but what about unintentional ingredients, or proprietary supplier ingredients? It is critical that there should be increased communication up and down the supply chain to ensure that manufacturers understand how their chemicals are used and that downstream companies have a complete picture of the ingredients present in their formulations."

He further suggests that downstream users read the problem formulations for the first ten chemicals under review at EPA, even if they do not think they are impacted. "You will have insights about EPA's approach and will minimise the likelihood of surprises," he said.

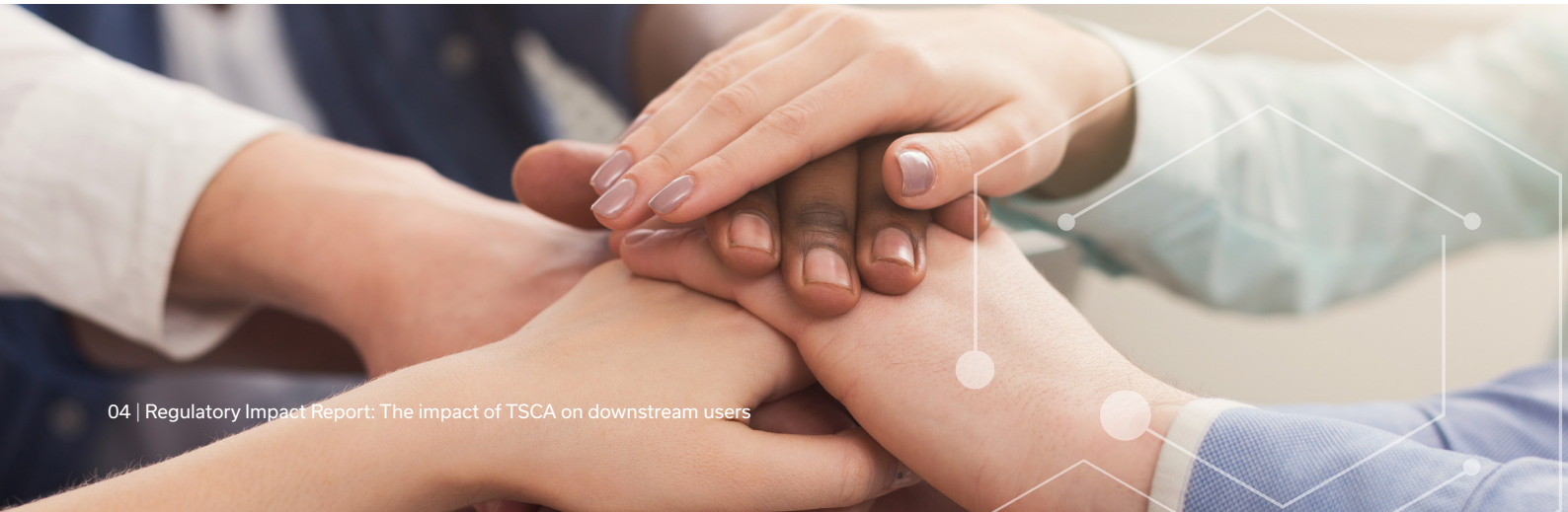
The major impacts on downstream chemical users of the revised TSCA regarding risk assessments may take a while to crystallise. "We are taking a wait-and-see approach as the EPA has just begun risk assessment work on the first ten chemicals," said Jim Cooper, senior policy advisor at American Fuel and Petrochemical Manufacturers (AFPM).

"But what this is going to do in the future is to get the supply chain talking to each other, probably sooner rather than later. We will see more activity where companies get together to exchange information. And in competitive situations, we may see more companies talking directly with the EPA."

Mr Cooper adds: "The transparency in the risk assessment process puts downstream chemical users in the position of having to talk to each other. This creates a more efficient supply chain in the long run, where we have certain types of information transfer that is important for chemical safety."

Brian Sansoni, vice president at the American Cleaning Institute (ACI), agrees that it may be a while before the actual impacts of the revised TSCA on downstream users are fully understood, as the various pieces and parts of the implementation of the LCSA are grinding their way through the process.

"Right now, Mr Sansoni said, "processors are working to confirm that the chemicals they formulate with are on the TSCA active inventory. Processors have until 5 October to update it with their chemicals. Overall concerns for our supply chain membership include the impacts of bringing products to market because of the drawn-out PMN process and Snurs."



These documents serve as an interim step between last June's 'scoping documents' and the final risk evaluations, which must be completed by December 2019. They provide further clarity as to which 'conditions of use' will be evaluated for each substance. They will determine whether the agency must issue regulations that could restrict or even ban the ten. While they have nothing to do with the new chemicals process, they do illustrate how the EPA is seeking to be open, solicit public input and assess risk objectively.

PMNs

Anyone who plans to manufacture or import a new chemical substance for a non-exempt commercial purpose is required by Section 5 of TSCA to provide the EPA with notice before initiating the activity, in the form of a PMN. This must be submitted at least 90 days prior to the manufacture or import of the substance in question.

Exemptions may be applied for with regard to certain chemicals. The EPA website has full information about the R&D, Test Marketing, Low Volume, Polymer and Low Releases and Low Exposure (LoREX) exemptions. It also has a sample form that shows all of the information that needs to be submitted. PMN submissions require all of the available data on:

- chemical identity;
- production volume;
- by-products;
- use;
- environmental release;
- disposal practices;
- human exposure; and
- existing available test data.

Who must submit a PMN?

EPA risk assessors consider all of this information during the new chemicals review process. The agency can take a range of actions to ensure new chemicals do not present an unreasonable risk to health or the environment. Figure 1 shows the steps for determining whether a PMN submission is required.

In cases where the EPA determines that a new chemical or significant new use is not likely to present an unreasonable risk of injury to health or the environment, without consideration of costs or other non-risk factors, including an unreasonable risk to a potentially exposed or susceptible sub-population under the conditions of use, it will notify the submitter of its decision under TSCA Section 5(a)(3)(C) and publish its findings in a statement in the Federal Register pursuant to Section 5(g).

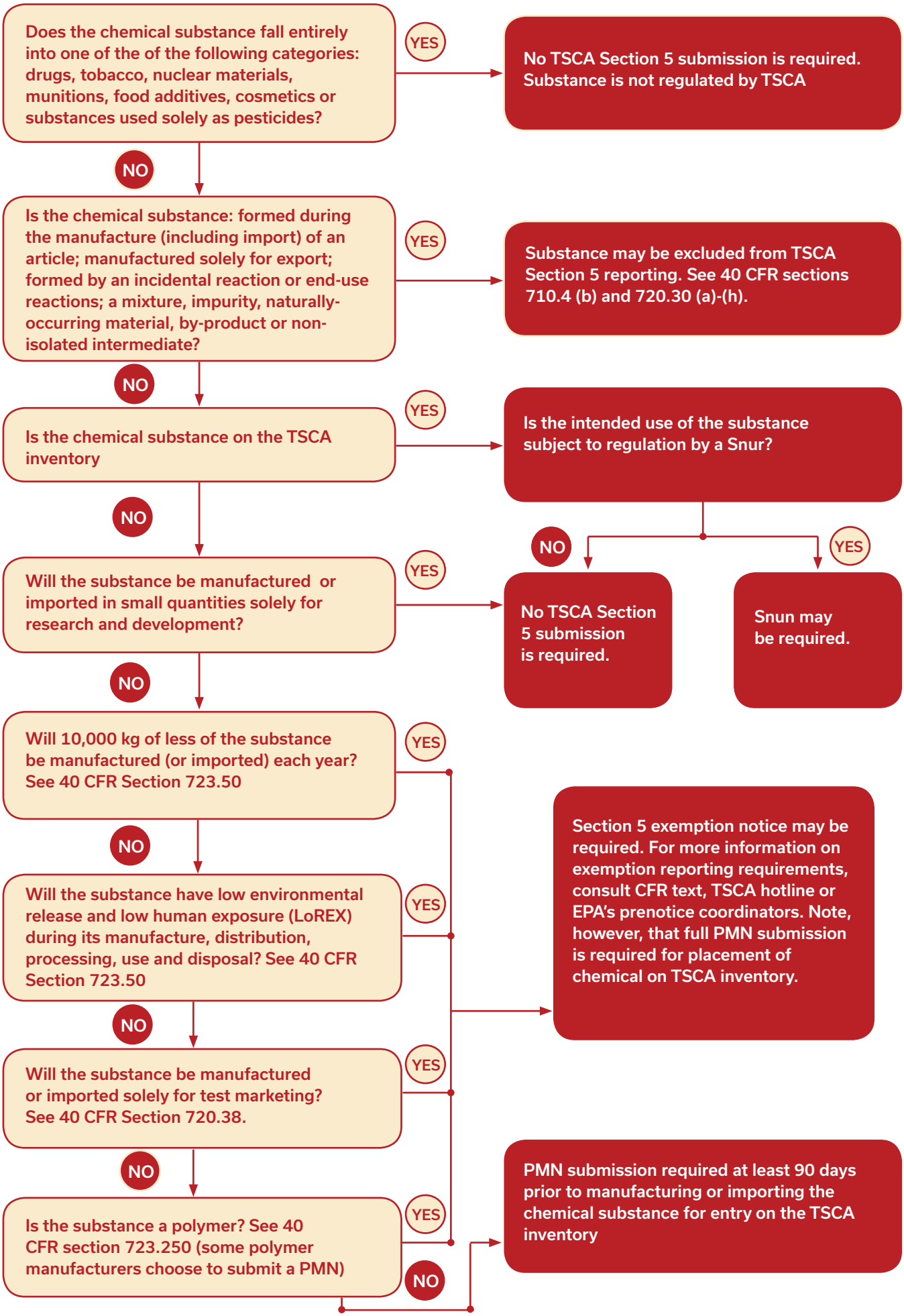
"To expedite approval of a new chemical, now more than ever, it is important for submitters to provide the EPA with as much toxicity and exposure information as possible - and as early in the process as possible," says Ari Lewis of law firm Gradient.

"To that end, submitters that use the EPA framework to conduct risk assessments proactively using well-supported non-default assumptions will find that their submissions not only more accurately characterise risks, but will be reviewed more expeditiously."

Ms Lewis adds that it is advisable to consult with the EPA throughout the submission process. The agency's staff has a shared interest in ensuring that PMN notifications are processed efficiently and contain well-supported determinations.

"Providing information upfront makes the EPA's life easier when they are trying to do a full evaluation," said Judah Prero of another law firm, Sidley Austin. "Successful PMN submissions are the ones that have enough information provided initially to make an informed decision."

Figure 1 - PMN determination process under revised TSCA



Source: EPA

Snurs

Snurs can be used to require notice to be given to the EPA before chemical substances and mixtures are used in new ways that might create concerns. Under Section 5(a) of TSCA, the agency can determine that a use of a chemical substance is a significant new use. It must make this determination by rule after considering all relevant factors, including those listed in Section 5(a)(2):

- projected volume of manufacturing and processing;
- extent to which a use changes the type or form of exposure of humans or the environment;
- extent to which a use increases the magnitude and duration of exposure of humans or the environment; and
- reasonably anticipated manner and methods of manufacturing, processing, distribution in commerce and disposal.

Once the EPA determines that a use of a chemical substance is a significant new use, TSCA requires persons to submit a significant new use notice (Snun) to the agency at least 90 days before they manufacture, import or process it for that use. The Snun obliges the EPA to:

- assess risks that may be associated with the new use, including risks to potentially exposed or susceptible sub-populations it has identified as relevant under the conditions of use;
- make a determination under the statute; and, if appropriate,
- regulate the proposed activity before it occurs.

Snurs have historically been an important part of the EPA's new chemicals regulatory programme (TSCA Section 5). It has increasingly employed as a means to ensure that uses that have been phased out of an 'existing chemical' of concern to the agency do not resume without prior notice.

When the identity of a substance that is subject to a Snur is not specifically identified in the EPA's significant new use regulation - because it is listed only on the confidential portion of the TSCA inventory - this can make things incredibly difficult for a purchaser and user of the substance or a mixture that contains it.

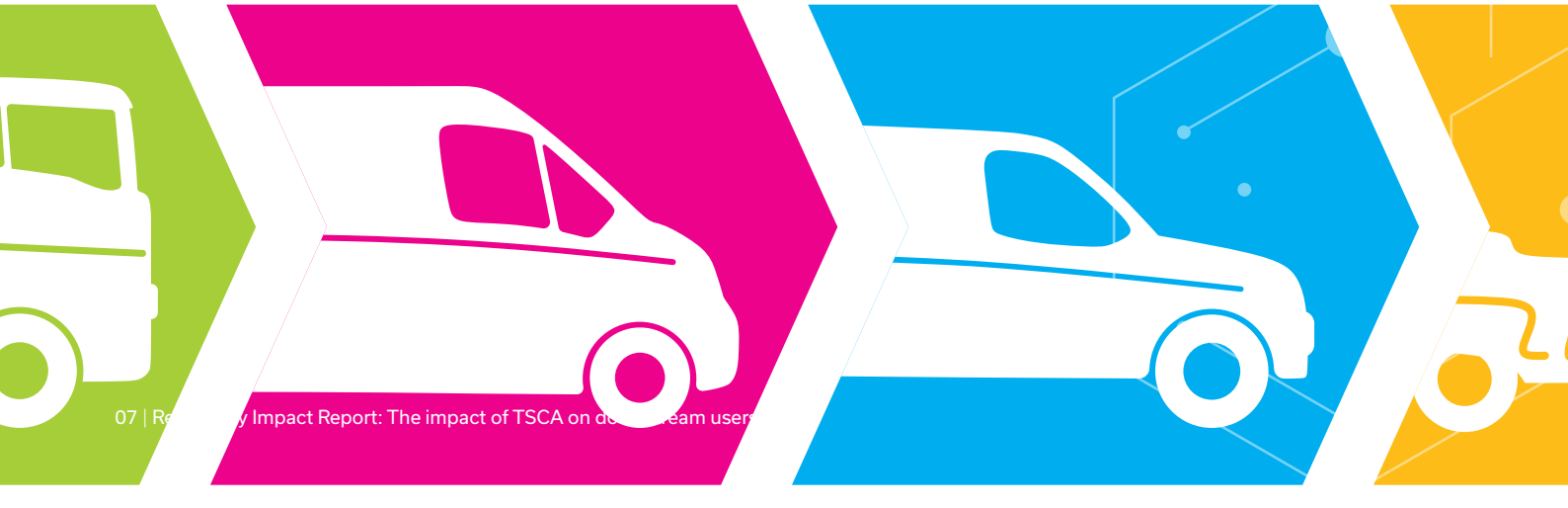
A purchaser, who is a user of a substance that is the subject of a Snur, can have obligations as a 'processor' under the regulation. Thus, compliance becomes difficult for such entities in situations where the specific identity of a substance subject to a Snur is not known to the general public, unless the supplier is careful to advise the customer of the Snur and its terms.

Substances on the inventory that are subject to Snurs are designated as such by an 'S' flag in the listing. If your substance is subject to a Snur and your intended manufacture, processing or use of it is a significant new use, you would be required to submit a Snun 90 days prior to manufacturing or importing it.

It is always the obligation of the manufacturer or processor selling a chemical substance to notify the user of the Snur status of that substance. Buyers of a substance whose identity is confidential, and thus not disclosed to them, should seek certification from the sellers that their intended use is not a significant new use.

CBI

CBI claims under TSCA made during the initial filing of a PMN now require additional substantiation *(see box)* and the EPA is required to review a certain percentage of claims. For claims to keep the specific chemical identity confidential,



the agency will review all claims and a suitably descriptive generic name must be provided. One quarter of other claims will be reviewed, and all claims must be substantiated in order to show that:

- companies have acted to protect the CBI;
- the information is not publicly known or readily discoverable; and
- CBI disclosure would cause commercial harm.

Certain details can be claimed as CBI without substantiation (for example. specific information on manufacturing processes), but some types of information, such as the results of health and safety studies, cannot be claimed as confidential at all. The EPA provides several CBI substantiation templates to help CBI claim submitters provide adequate detail and justification.

Imports and exports

The EPA has also laid down rules about importing and exporting chemicals under TSCA. All chemical imports must be accompanied by a TSCA Import Certification Form. However, this only applies when you are the ultimate consignee for the chemical.

If a chemical distributor is importing the chemical and then selling it to you, the distributor must complete the form. The form must be available to the carrier and the customs officer at the time of import. This requirement can be satisfied by having the sender include a copy of this form with the import documents for the shipment.

Some chemicals fall under the Department of Commerce (DOC) or State Department export control regulations. Chemicals subject to export control regulations require an export permit to legally export from the US. Export permits take weeks to obtain, so you should plan ahead. The EPA's Extremely Hazardous Substances (EHS) list should be checked to determine if a chemical is subject to restrictions.

If your chemical is not subject to DOC or State Department controls, you must determine if it is subject to TSCA exporting requirements. Chemicals listed on the EPA's trigger list require notification prior to export. If your chemical is on this list you must notify the EPA using the TSCA Section 12(b) Export Notification Form. The form must be postmarked within seven days of forming the intention to export or the day of the export, whichever is earlier.

EPA rules for CBI claims

The ACC has highlighted the following as key rules that companies should be aware of when claiming CBI:

- all claims for CBI other than specific chemical identity must be reasserted and substantiated at the time of PMN submission;
- all claims for CBI for specific chemical identity must be reasserted. Mandatory substantiation is not required as part of the revised TSCA for these claims, but the EPA will allow companies to submit substantiation for specific chemical identity at the time a Notice of Activity Form A (EPA Form No. TBD-1) is filed for retrospective reporting; companies that elect to do so will be exempt from the subsequent substantiation requirement to be imposed under the separate CBI review plan rule, authorised by the TSCA amendments to be substantiated under a process determined by EPA in the future;
- submitters can assert and maintain a CBI claim for specific chemical identity even if they were not the original claimant; and
- Notice of Activity Form B (EPA Form TBD-2) submitters for forward-looking notifications under the Inventory Reset Rule will also be allowed to submit substantiation at the time of notification if they so choose.

Users are also warned not to send CBI to the EPA, as the agency's email system is not secured to protect CBI.

Domestic shipments

When sending chemical substances within the US, it is the responsibility of the shipper to communicate all known or suspected hazards of the substances to the receiver. EPA inspectors may ask for documentation to verify that a shipper has done this. The Domestic Chemical Shipment Form (3520-1), a standard form the agency uses for any kind of shipment, can fulfill the hazard communication requirement and provide a means of documentation.

Manufacturers and processors of chemical substances subject to TSCA are exempt from the notice requirements of Section 5(a) if they manufacture or process the substances "only in small quantities solely for the purposes of scientific experimentation or analysis, or chemical research on, or analysis of such substance, or another substance, including such research or analysis for the development of a product".

To be in compliance with TSCA regulations under this R&D exemption, you must communicate the hazards of a chemical to your recipient when shipping with the US. The form ensures compliance by indicating any known or suspected hazards.

Conclusion & further resources

In this report, we have attempted to present an overview of some of the key elements of TSCA important for the downstream chemical user. We have tried to provide an explanation of the TSCA Chemical Substance Inventory, risk-based versus hazard-based assessments, the PMN, Snurs and more.

Chemical manufacturers are also generally willing and able to assist their downstream users in meeting the new TSCA requirements. The American Chemistry Council (ACC) has created the Center for Chemical Safety Act Implementation to serve as a scientific, technical and advocacy hub that will assist ACC members and non-members with the implementation of the new TSCA.

The EPA wants to help businesses satisfy the requirements of the new TSCA and provides a number of guidance resources. It has, for example, has published a Chemistry Assistance Manual for Premanufacture Notification Submitters under TSCA.

For downstream users, chemical manufactures and suppliers are generally familiar with the new TCSA structure and submitting inventory information to EPA through the chemical data reporting system.

The e-PMN software enables manufacturers (including importers) of TSCA chemical substances to submit Section 5 notices online through the agency's central data exchange (CDX), which requires registration for the Chemical Safety and Pesticides Programme (CSPP) service. These notices include:

- PMNs;
- *bona fide* Intent to Manufacture or Import notices:
- Biotechnology Notices for genetically modified microorganisms;
- Notices of Commencement of Manufacture (NOCs);
- support documents for Section 5 notices (such as correspondence, requests for suspensions of the notice review period, amendments, letters of withdrawal, transfer of ownership and test data); and
- alternative control measures for Snurs.

Key points for downstream users

Here are some of the key points to remember, if you are a downstream chemical user with obligations under TSCA:

- The **TSCA inventory**, which currently lists about 68,000 substances, plays a central role in the regulation of most industrial chemicals in the US. The EPA has published detailed information on how you can access the inventory.
- The revised TSCA requires the EPA to conduct **risk-based assessment** of new chemical substances. The EPA is also required to designate all substances on the inventory as either 'active' or 'inactive' in US commerce.
- If you plan to manufacture or import a new chemical substance for a non-exempt commercial purpose, you are required by Section 5 of TSCA to provide the EPA with a **PMN**. You can find the information that needs to be submitted in a sample form on the EPA website. If you are not sure whether a PMN is required, use the diagram provided by the EPA (Figure 1).
- **Snurs** are used to notify the EPA that chemical substances and mixtures are used in new ways that might create concerns. If your substance is subject to a Snur and your intended manufacture, processing or use of it is a significant new use, you would be required to submit a Snun 90 days prior to manufacturing or importing it.
- **CBI claims** made during the initial filing of a PMN now require additional substantiation. The EPA provides several CBI substantiation templates to help you provide adequate detail and justification.
- There are new rules about **importing and exporting chemicals** under TSCA – all chemical imports must be accompanied by a TSCA Import Certification Form, while chemicals subject to export control regulations require an export permit to legally export from the US (which take weeks to obtain).
- When **sending chemical substances within the US**, it is the responsibility of the shipper to communicate all known or suspected hazards of the substances to the receiver. You can do this with a Domestic Chemical Shipment Form.

The PMN form should also be used to submit:

- Snuns;
- test market exemption applications (TMEAs);
- low volume exemption (LVE) notices and modifications;
- LoREX exemption notices and modifications; and
- mock PMNs

The EPA has also made available other helpful resources online, including: an assistance manual for PMN submitters; and information on assessing and managing chemicals under TSCA. For nanomaterials, information is available both from the agency's guide to control of nanoscale materials under TSCA and from the ACC.

Finally, if you prefer the low-tech route, the EPA also has a telephone and email hotline for general questions on TSCA at +1 202 554 1404 and tsca-hotline@epa.gov.

Further assistance from Chemical Watch

For the latest news on TSCA, make sure you bookmark our TSCA coverage highlights page. It contains all our latest TSCA-related news in one place, allowing you to easily monitor developments relating to this complex regulation.

Chemical Watch also runs a regular series of conferences and training courses throughout the year, in the US, Europe and Asia, bringing together expert speakers to discuss key regulatory developments, with TSCA being a key area of focus. Visit our events website to browse all our upcoming events.

If you're a downstream user and need information on REACH as well as TSCA, make sure you download your free copy of our *Regulatory Impact Report: The impact of REACH on downstream users*. And if your business is a user of biocides, our *Regulatory Impact Report for businesses using biocides* contains everything you need to know about the EU biocidal products Regulation (BPR).