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Reformed TSCA and REACH: How do they compare?

Daniel Uyesato and Lucas Bergkamp of Hunton & Williams look at how the two key overarching chemical legislation regimes measure up and draw out the main similarities and differences.

Last year, President Obama signed into law the amended Toxic Substances Control Act (TSCA). Congress made substantial changes with respect to how both existing and new chemical substances are regulated. Some of these changes are significant and will have a direct impact on US chemical manufacturers, importers, distributors and users. However, the US did not attempt to mimic the EU's REACH Regulation.

This article provides a high-level comparison of the main building blocks of the two regimes, bringing out the main similarities and differences between them. Of course, these are two different jurisdictions and no direct comparison can be completely valid, but it is worth making the comparison nonetheless, because many companies operate across both regions and because other jurisdictions have mimicked REACH in their regulatory reform, whereas the US has chosen not to.

TSCA as reformed

To get a better picture of chemicals actually in commerce, the TSCA inventory, a list of all chemicals that can be legally manufactured, imported and used for commercial purposes in the US, is to be updated to reflect their status as 'active' or 'inactive'. Many of the 85,000 chemicals estimated to be on the inventory are no longer actively produced.

Whilst this may sound like an administrative formality, the Environmental Protection Agency (EPA) must also evaluate the safety of existing chemicals in commerce, starting with those it identifies as most likely to pose risks, in accordance with statutory deadlines. The agency will evaluate both new and existing chemicals against the new risk-based safety standard of 'unreasonable risk' and must account for particularly exposed or susceptible subpopulations. Clear and enforceable deadlines are intended to ensure timely review of prioritised chemicals and timely action on identified risks.

TSCA now makes it easier for the EPA to regulate chemical risks. Under the new law, the EPA must take measures to eliminate any 'unreasonable risk' that it identifies in its evaluation of a chemical. In determining whether a chemical presents an 'unreasonable risk', no consideration of cost or other non-risk factors is permitted.

Thus, the old 'risk-benefit balancing' standard no longer applies. The EPA is now only required to consider cost and other non-risk factors among available risk management options that it has determined meet the safety standard. The agency also now has the authority to require the development of information necessary to support these evaluations without formal rulemaking - it may issue orders to chemical manufacturers and importers requiring testing.

Risk management action is to be promulgated within two to four years after completing a risk evaluation. So-called 'critical uses' can be exempted from such risk management measures.

A risk evaluation of a high-priority chemical is to be completed in three years, with a possible six-month extension. Ten priority chemicals were identified by the statutory mid-December 2016 deadline. For each high-priority evaluation completed, the EPA must designate a new high-priority chemical. Within 3.5 years, there must be 20 ongoing evaluations of high-priority chemicals and at least 20 chemicals must be designated as low priority.

The EPA must now make an affirmative determination on a new chemical, or on a 'Significant New Use' (SNU) of an existing chemical, before it may be placed on the market. Thus, the old default rule - that a new chemical could be marketed if no EPA action to the contrary was issued within 90 days after submission of such notification - no longer applies. The EPA can make one of three decisions. It may find that:

- the substance or significant new use is not likely to pose an unreasonable risk, in which case the submitter can immediately commence manufacture or import;
- the substance or significant new use does present unreasonable risk, in which case the EPA must take regulatory action to protect against such risk; or
- the EPA itself has insufficient information to make a determination, in which case it must issue an order to protect against risk pending the development of required information, and the submitter may only manufacture, import, process such substances in compliance with such an order.

The EPA must prioritise existing chemicals for assessment and establish a risk-based process to identify 'high' and 'low' priority substances. 'High' means that the chemical may present an unreasonable risk of injury to health or the environment due to the potential hazard and route of exposure, including to susceptible populations; 'low' means that there is no such unreasonable risk.

The statute required that a procedure for this process be set forth in a regulation by June 2017 and the EPA administrator signed this rule on June 22, 2017, for subsequent publication in the Federal Register. A specific fast-track process applies to persistent, bioaccumulative and toxic substances (PBTs).

In terms of downstream uses, 'conditions of use' has been newly defined as an important part of the basis for EPA risk evaluations and resultant regulatory actions. The term is defined as 'circumstances under which a chemical is intended, known, or reasonably foreseen to be manufactured, processed, distributed in commerce, used or disposed of'.

The statute now requires the EPA to notify other federal agencies of releases and exposures governed by other federal laws and to act if those other agencies do not act within 30 days, with a specific reference to the Occupational Safety and Health Administration. The EPA's determination will be important to manufacturers, importers and processors, as well as their downstream users.

A recent example of this is contained in a rule proposed in January 2017, in which the EPA proposed to find that the risks associated with the use of two chemicals, methylene chloride and N-methylpyrrolidone (NMP), in paint or other coating removers, are unreasonable and to adopt certain restrictions to mitigate those risks, including prohibitions on their manufacture (including importation), processing and distribution in commerce for all consumer and most types of commercial paint and coating removal. For the latter, the EPA proposed that:

- commercial users of NMP for paint and coating removal should establish a worker protection programme for dermal and respiratory protection and should not use paint and coating removal products that contain greater than 35 wt% NMP, except for product formulations destined to be used by the US Department of Defense (DoD) or its contractors performing work only for DoD projects; and
- processors of products containing NMP for paint and coating removal should reformulate products such that these products do not exceed a maximum of 35 wt% NMP, identify gloves that provide effective protection for the formulation and provide warning and instruction labels on the products.

In addition, TSCA's confidential business information (CBI) provisions were made more stringent. TSCA now requires upfront justification and periodic re-substantiation of CBI claims, including the reassertion of claims after ten years.

Articles, broadly defined to include all manufactured products formed to a specific shape or design whose end-use functions depend on its shape or design and whose chemical composition does not change during such use, are still largely exempt. However, the EPA may require SNU notifications for the import or processing of a chemical as part of an article if it makes an affirmative finding by rule that a reasonable potential for exposure to the chemical through the article justifies notification.

The agency may restrict chemicals contained in articles 'only to the extent necessary to address the identified risks from exposure' to such chemicals. Replacement parts for 'complex durable goods and complex consumer goods' are exempt, unless the EPA finds that they contribute significantly to the risk in question.

Preemption was also addressed in the reform of TSCA. As a general rule, individual US states retain the power to act on chemical risk if the EPA has not acted, although there are exceptions. If the EPA does act, state action is not preempted if it:

- was taken before April 2016;
- was taken pursuant to a state law enacted before 31 August 2003 (such as California's Proposition 65);
- is incidental to the implementation of other federal environmental laws;
- constitutes co-enforcement of identical requirements; or
- relates to a 'low priority' chemical.

State law is preempted if the EPA determines that a chemical is safe or takes final action to address chemical risk. Further, state SNU rules are preempted if the EPA imposes a comparable requirement. New state action is put on hold during EPA assessment of a high-priority chemical substance. If the EPA misses a deadline, however, this hold (or 'pause') is lifted. If risk is identified, only temporary measures are permitted.

In addition to these waivers, a state may seek a waiver from preemption. Under the 'pause' preemption regime, EPA must grant an exemption if a state has enacted a prohibition or restriction or state action meets certain requirements. Under the general preemption regime, the EPA may grant an exemption if certain criteria are met, such as that 'compelling conditions' necessitate a waiver, there is no undue burden on interstate commerce and the EPA supports the state's scientific judgment.

REACH

A key part of the REACH Regulation - the 'R' - is registration. This involves the submission of extensive data on existing and new substances by manufacturers and importers of chemicals. Staggered, phased deadlines apply to existing chemicals based on hazard and volume, in 2010, 2013 and 2018. Other components of REACH are:

- the evaluation of dossiers and substances (the 'E');
- the identification and listing of substances of very high concern (SVHCs), defined to include carcinogenic, mutagenic and reprotoxic (CMR) and PBT substances;
- authorisation (the 'A') of substances listed on Annex XIV; and
- restrictions on the manufacture and use of substances listed in Annex XVII.

The general objective of REACH is to control chemical risk over a substance's entire life cycle. REACH is intended to address chemical risk from manufacture to disposal. Its scope is broad, as it covers chemicals in bulk and chemicals in articles. It covers consumer as well as environmental exposure.

REACH is an umbrella regulation that combines multiple loosely connected regulatory regimes. The coordination between REACH's various regimes is weak, however. The European Commission tries to remedy this lack of coordination through so-called risk management option analysis (RMOA), a loose process that is intended to produce an evaluation of the available regulatory instruments to address a risk.

Authorisation, which applies only to uses of listed chemicals within the EU, raises specific problems, since imported articles are not subject to it. Such imports are supposed to be targeted through directly applicable restriction, but the link between authorisation of domestic uses and restriction of imported products reflecting such uses is weak.

The Classification, Labelling and Packaging (CLP) regulation operates alongside the REACH regulation. It deals with the classification and labelling of hazardous substances. Harmonised classification of a substance often is a trigger for further measures under REACH.

In the opinion of some authorities, this process can be initiated for any substance, even if the evidence of hazard is questionable, as long as some formalities are met. This has resulted in the process being triggered for substances that do not show the hazard for which classification is sought.

In CLP and REACH procedures, the Commission, Echa and the member states all play roles and have certain powers. This provides opportunities to member states for political maneuvering and pursuing anti-chemical strategies.

The safety standards under REACH vary. The standard for registration and chemical safety assessment requires that 'risks arising from the substance they manufacture or import are adequately controlled during manufacture and their own use(s) and that others further down the supply chain can adequately control the risks'.

Risks from SVHCs are to be 'properly controlled,' with SVHCs to be 'progressively replaced by suitable alternative substances.' Restrictions are to be imposed on chemicals posing 'unacceptable risk to human health or the environment, arising from the manufacture, use or placing on the market of substances, which needs to be addressed on a Community-wide basis'.

REACH's safety standard under authorisation is inconsistent with the standard under registration, because the registration process does not permit the registrant to consider benefits (under the 'adequate control' standard), whereas the authorisation process permits consideration of benefits during socio-economic analysis of specific uses.

REACH emphasises information throughout the supply chain and regulates supply-chain communications. A key instrument is the safety data sheet, which is required for all substances classified as hazardous, but information on nonhazardous substances may also be required. Further, customers and consumers have a right to SVHC-related information, while workers have a right to information on the chemical substances to which they are exposed.

Preemption is also addressed, as an additional motivation behind REACH is to establish an internal market in chemicals. Member states therefore have only limited powers to regulate independently. As REACH is to ensure 'the free circulation of substances on the internal market,' as a general rule, member states may not enact more stringent measures. They may require notifications of imports and the like, however, provided they are mere administrative formalities. Under the safeguard clause, they may also impose emergency measures based on new information about chemical risk.

Until 1 June 2013, member states were allowed to 'maintain any existing and more stringent restrictions in relation to Annex XVII on the manufacture, placing on the market or use of a substance, provided that those restrictions have been notified [to the European Commission]'.' Currently, no such further restrictions may be applied. Member states may not impose their own authorisation programme, unless it is for purposes other than REACH purposes and does not violate the European treaties. This would appear to be an unlikely scenario, however.

REACH

The reformed TSCA and REACH have many things in common. Both are intended to reduce chemical risk through direct 'command and control' and other types of regulation. Both cover a substantial portion (or nearly all) of a substance's life cycle and apply to both existing and new substances. Both attempt to phase in or prioritise requirements for existing substances.

Like REACH, reformed TSCA applies to domestic manufacture and imports, as well as uses of chemicals. Both apply to chemicals in bulk (substances and mixtures) and substances in articles (that is, products), and, in principle, cover consumer exposure. Under both regimes, restrictions on substances and their uses can be imposed. Both address preemption. Both are worked out in regulations.

There, of course, are further commonalities. It is more illuminating to focus on the dissimilarities, however. Even after its substantial reform, TSCA remains relatively simple and does not attempt to do as much as REACH. Conversely, REACH provides for extensive control over chemicals in commerce. TSCA is more systematic and sequential, while REACH is an umbrella for several stand-alone regimes.

Reformed TSCA also strikes a different balance between government and industry tasks and obligations. With REACH, the EU shifted much of the responsibility for chemical risk management to industry. Under REACH registration, manufacturers and importers have to report information without any order from Echa; reformed TSCA, however, obliges manufacturers and importers to report data on existing substances only if so required by the statute, by rule or if ordered by the EPA.

As a related matter, unlike REACH, TSCA requires the EPA to demonstrate 'unreasonable risk' if it is to regulate a chemical. REACH registration requires that manufacturers and importers demonstrate that chemical risk is adequately controlled. TSCA permits a more targeted imposition of the burden of production of safety information through EPA orders.

Unlike REACH, TSCA focuses more systematically on prioritising substances for assessment and regulation; REACH registration, disregarding the delayed deadlines for some phase-in substances, turns mainly on volume. In other regimes (evaluation, SVHCs, etc.), REACH uses various prioritisation criteria. For REACH Annex XIV listing for authorisation, prioritisation criteria include PBT or very Persistent and very Bioaccumulative (vPvB) properties, wide dispersive use or high volumes.

Unlike REACH, specific prioritisation criteria are not set forth in reformed TSCA; it requires the EPA to establish by rule within one year of enactment a risk-based process for the prioritisation of existing chemicals for assessment. The agency has now done so and the rule became effective on 18 September 2017.

In addition, reformed TSCA mandated a specific schedule for initiating risk evaluations of high-priority chemicals; the EPA has already initiated the statutorily-required ten initial risk evaluations. Further risk evaluations are required to proceed along a mandated schedule, with the EPA required to have at least 20 high-priority chemicals under evaluation by the end of 2019

Another important difference is that, unlike TSCA, REACH imposes authorisation requirements, which effectively impose applicant-specific prior permitting of any uses of listed chemical substances. The role of authorisation under REACH is still the subject of debate: should authorisation be mandatory for all SVHCs, or is it an option among other risk management measures?

As authorisation applies only to chemical uses within the EU, moving manufacturing to outside the EU and shipping the final products back in is an option. Restrictions are supposed to address this issue, but this is not always straightforward. Extending authorisation to uses outside the EU has been proposed, but doing so would raise issues under international trade law. TSCA avoids these problems because it does not provide for authorisation of chemical uses.

TSCA applies an 'unreasonable risk' standard across the board, whereas REACH applies inconsistent safety standards under its various constituent parts that are trying to achieve different ends. In this respect, the TSCA standard, if applied evenly, would appear to be better suited to ensure consistency in safety levels.

Reflecting different constitutional doctrines and traditions, REACH addresses preemption in a more fundamental way, while TSCA applies a less categorical approach. Under REACH, member states have a role in implementation but their ability to apply more stringent national measures addressing chemical risk are severely restricted. In the US, individual states are not involved in TSCA implementation but they can participate in rulemaking and can make their own laws.

REACH

Depending on one's perspective, reformed TSCA and REACH each have their strengths and weaknesses. Any such assessment, of course, cannot be entirely objective. In some cases, weakness and strength are flip sides. TSCA reform was adopted after the REACH regulation had been operating for some time. Thus, the drafters of TSCA reform had the advantage of being able to avail themselves of the experience and practice under REACH.

REACH's comprehensive and broad scope is both a strength and a weakness. It enables chemical risk to be regulated no matter where and when it arises, but it tends to frustrate prioritisation and draws resources away from the most serious risks. REACH defines several regulatory regimes, thus boosting the arsenal available to combat chemical risks arising from substances. At the same time, this has resulted in the same chemicals being subjected to multiple regulatory procedures - in some cases consecutively, in others simultaneously.

REACH has created a large chemical information database for all chemicals that can be used for further regulatory action, much of which can also be accessed by the general public. Furthermore, REACH encourages the substitution of SVHCs through the authorisation programme. It is an open question, however, whether individualised authorisation offers any advantages over directly applicable restrictions.

REACH gives member states a role in implementation, but not all view this as a strength, because it can introduce bias into the regulatory processes. Some member states that do not have a chemical industry, tend to be 'chemophobic' and push for regulation of substances on the basis of perceived hazards.

Quite unlike REACH, reformed TSCA establishes a targeted programme for addressing chemical risk based on prioritisation. It applies a more limited number of regulatory tools to reduce chemical risk: authorisation (that is, individualised permitting of uses of listed substances) is not part of its regulatory arsenal. While this limitation could be viewed as a shortcoming, it might in time result in superior overall risk management. Reformed TSCA manages chemical risk chiefly by imposing generally binding requirements, thus avoiding the burdens associated with individualised authorisations.

TSCA's uniform safety standard offers the advantage of consistency across regulatory decisions, but much depends on how it is applied in specific cases. Further, reformed TSCA avoids giving a significant role to states, but allows for preemption. Compared to REACH, this may result in state preferences not being pushed to the federal level.

In stark contrast to REACH enforcement by the member states, TSCA enforcement, with some very limited exceptions, can only be undertaken by the EPA, not states. The agency may either bring civil administrative enforcement actions under TSCA before EPA administrative law judges or refer criminal enforcement actions to the US Department of Justice to be filed in federal district court.

Indeed, it is worth noting in this context that amendments to TSCA in 2016 were predicated on a compromise. Both the regulated community and environmental groups realised that this was needed to restore public confidence in the federal chemical regulatory process; it was the lack of public confidence that had led to increased regulatory activity by the states, especially California. If the reformed process does not work, the end result might be a patchwork of inconsistent regulations with which neither the regulated community nor the public would be happy.

Conclusions

Reformed TSCA has introduced substantial changes, but, in terms of scope and regulatory burdens, TSCA is not REACH, at least not yet. As much of reformed TSCA's provisions need to be worked out in EPA regulations, which then need to be interpreted and applied to specific cases, much of TSCA's bite is yet to be defined.

Compared to REACH, reformed TSCA is more targeted and applies prioritisation more generically. It does not reverse the safety burden of proof but arguably achieves an equivalent goal through the application of a uniform risk-based safety standard. It also avoids the pitfalls of a prior use authorisation regime, which in effect requires a permitting process for each user, and thus is more burdensome from a regulatory perspective

While the new TSCA prioritisation approach seems to have advantages over REACH, its implementation is as yet in its early stages and its success as a risk management programme will depend on just exactly how it is implemented. At any rate, it is too early to doubt the EPA's ability to carry out its statutory mandate using the prioritisation approach set forth in the newly reformed TSCA and the Trump administration plans to increase funding for TSCA implementation in its 2018 budget, even while cutting back most other EPA programmes drastically.

How REACH and TSCA evolve and perform will determine to how effective their programmes will be. More important than regulation, however, these laws may spur innovative forces in the chemical industry. Under the influence of 'green chemistry,' Responsible Care and similar initiatives, chemicals and their uses may become safer, independent of the specifics of the applicable regulatory programmes.