chemsec
INTERNATIONAL CHEMICAL SECRETARIAT

Pick Up the Pace

SIN List shows the REACH process is too slow

The REACH Candidate List has proven to be a major driver for innovation. It identifies hazardous Substances of Very High Concern (SVHCs) and gives important incentives to phase these out. Identified SVHCs will eventually be banned, unless for authorised uses. Candidate listing is also followed by an immediate requirement to inform about the presence of these substance in products.

However, for the majority of substances to be added to the list, affected producers strongly oppose SVHC identification. They do this quite effectively by highlighting data uncertainties, the importance of the chemical and by claiming lack of alternatives. To clarify raised uncertainties and increase predictability of the process authorities have set up a number of expert groups to discuss substances upfront. A "roadmap" has also been adopted at EU level to carry out "risk management option analysis" of substances. ChemSec has identified, that while these extra steps have been introduced, the already slow pace of populating the Candidate List has further decreased. In addition substances that are "under scrutiny" in these different processes are regarded as being dealt with and thus escape the political radar for a number of years.

Next year the SIN List will be ten years old. Based on the same criteria as the Candidate List, it has served over the past nine years as guidance to companies on which chemicals to avoid in order to be safe from future regulations. For that purpose it has been increasingly implemented in chemicals management strategies at different levels. At present the SIN List contains 912 chemicals, while the corresponding figure for the Candidate List is 174 substances, represented by 249 CAS numbers.

In order to reach the political target of having all known relevant SVHCs on the Candidate List by 2020 the process needs to speed up. For this, authorities need to start acting on the already available data. For the substances on the SIN List there is already enough information on hazardous properties. We suggest that ECHA, member states and the Commission use the SIN List to speed up population of the Candidate List.

The SIN List and its success

In the early days of REACH, when there were not yet any substances on the official REACH Candidate List, ChemSec was approached by companies asking what we thought the Candidate List would look like in terms of substances. The exercise that followed that question resulted in the launch of the first version of the SIN List in 2008.

To populate the SIN List we used the criteria laid out in REACH for identifying Substances of Very High Concern, SVHCs.

For the classified CMRs, in categories 1A and 1B, and a few PBT/vPvB substances the exercise was relatively easy, as these have already been officially assessed and agreed upon at EU level. The classification criteria and the SVHC criteria are aligned.

For other endpoints, we contracted expert scientists to conduct scientific assessments based on officially available peer-reviewed data. Where we had any doubts about whether the data was sufficient to conclude that substances have SVHC properties those substances were never added to the list.

While the SIN List is purely hazard-based we put the focus on substances that are used, and used in a way that is relevant for REACH authorisation. We therefore exempted CMR-classified pesticides and hydrocarbon distillates, unless they have full REACH registration. When selecting the substances for scientific evaluations, we also ensured that the substance had a relevant use before evaluating it.

The SIN List was in fact an immediate success. Companies greatly appreciate this guidance, based on solid science. In policy discussions the SIN List provides something concrete to relate the discussions to.

Since 2008, the SIN List has had two major updates based on extensive new scientific reviews. There have also been a number of "technical updates" to catch up with developments, such as having newly classified CMRs added to the list.

Today the SIN List has about 13,000 unique visitors a year, most from the US, Europe and China. The users are from large and small corporations, governments, authorities, research institutes, and academia. The SIN List is frequently incorporated in more and more standards for chemicals management, procurement criteria and ecolabel schemes.

In this sense, the SIN List has a life of its own and a value reaching far beyond being a shadow Candidate List. While the process of populating the official Candidate List has gone slowly, there are thankfully plenty of corporate voluntary initiatives and processes to replace hazardous chemicals, and in those the SIN List has a given role.

Why all SVHCs belong on the Candidate List

The Candidate List, introduced with REACH in 2007, identifies "Substances of Very High Concern" (SVHCs). The list has been populated at a slow pace since 2008.

For every substance to be added, there needs to be a unanimous agreement among EU member states that the substance in fact fulfils the criteria for being an SVHC. The criteria are strictly hazard-based; intrinsic hazard alone should decide whether a substance belongs on the Candidate List.

Placing of a substance on the REACH Candidate List provides a strong signal that this substance should be substituted; it will eventually be added to the Authorisation List and be given a sunset date, after which it can only be used under authorised conditions. Candidate listing also entitles consumers to be informed about the presence of the substance in products upon request – the Right to Know principle. This information must also be made available in the supply chain. For these reasons it is crucial to have all Substances of Very High Concern on the Candidate List.

That Candidate Listing really drives substitution and innovation has been shown in several studies, including 2017 ECHA report, here in the context of investors:

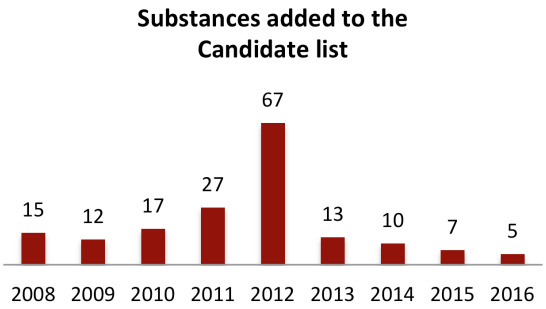
In parallel to the Candidate List and the authorisation process there is also a process for restriction of substances. These processes are complementary. While restriction is based on authorities proving an unacceptable risk following a specific use of a substance, the authorisation process instead requires evidence of why an SVHC should be granted ongoing use. The burden of proof lies with industry to make its case.

"Many investors are looking at the evolution of R&D to sales ratios as part of their analysis. Due to regulatory pressure, long-term use of hazardous chemicals is not considered viable. All companies noted that they pay attention to the Candidate List and to ChemSec's SIN list."

As restriction also covers imported articles it makes good sense to tackle the same substances in both the restriction and the authorisation processes, to level the playing field for EU and foreign producers, and to provide consistency. It is becoming increasingly common that the same substances are tackled in both processes.

At the beginning of 2010 Vice-President Tajani and Commissioner Potočnik set an interim target to have 136 SVHCs on the Candidate List by the end of 2012, and this was reached

in December 2012 when the Candidate List contained 138 substances. Since then the pace of adding substances has however been much slower. The last addition to the Candidate List, in July this year, was only one substance. Prior to that, in January 2017, four new substances were added to the list. Today the Candidate List contains 174 substances, or 249 CAS numbers.



A roadmap – but to where?

In 2013, the member states, Commission and ECHA agreed on the objective to have all relevant currently known Substances of Very High Concern identified and included on the Candidate List by 2020. To do so, an SVHC Roadmap was designed and agreed upon.

It aims to improve "planning, predictability, communication and to define responsibilities and deliverables". There are two major steps envisaged: Screening of registration dossiers and Risk Management Option Analysis (RMOA).

In practice, however, there are so many road bumps, parking lots and even stop signs included in this map that it's hard to see how the roadmap will eventually take us to our destination.

The idea of RMOA was to provide brief summaries of options to help define the way forward. However some of these "briefs" are 150 pages long, obviously violating the whole idea of moving speedily to conclusions, and creating a clear paralysis by analysis instead of adding speed.

Interestingly, one can actually see a clear decrease in substances added per year after 2013, when the Roadmap was introduced.

Too costly for member states to nominate substances

The addition of substances to the Candidate List is largely a political process. There is no system for deciding which substance is nominated next, so the process is unpredictable. As mentioned earlier, the decision to place a substance on the Candidate List must be taken unanimously by all member states. While only hazardous properties should be the basis of nomination, the dossiers submitted by member states have become extensive reports that also include information related to socioeconomic aspects, such as use and availability of alternatives. Compiling all this information is very costly and time consuming.

In an interview from October 2017, ECHA's director, Geert Dancet, said:

"Regarding substances of very high concern, it's not easy to get them on the Candidate List and the Authorisation List. As you are aware, the number of substances that got on this list up until now is lower than originally predicted. Every time ECHA or an EU member state puts a substance forward for the Candidate List and in particular for the Authorisation List, there is huge pressure from industry to block that. Because they exaggerate the fact that they cannot substitute. And it takes a lot of convincing in order to get member states to vote in favour of adding substances on the Authorisation List.

Over the years the process of nominating substances to the Candidate List has also become less and less straightforward. Member states are now hesitant to nominate substances that have not already been concluded as having SVHC properties in either the substance evaluation process (CoRAP) or in any of the expert groups.

Looking at the substances that are up for discussion for inclusion on the Candidate List in January 2018, one can wonder if these are really "substances that matter the most", or if these are rather examples of substances that member states can easily agree upon?

We have three cadmium compounds, suggested with the motivation that other cadmium compounds have already been Candidate listed. Two substances, benzanthracene and chrysene, are part of a group that has already been recognised as an SVHC. In addition, two compounds have been nominated for the reason that they respectively contain more than 0.1% of two substances already on the Candidate List.

It has also been proposed that BPA is registered with an additional hazardous property. Only one substance, dechlorane plus, seems to be an actual newcomer. We do not oppose the addition of these important substances to the Candidate List, but it illustrates in our opinion how difficult and expensive it is to convince all member states to support a new SVHC nomination. This is a way to play it safe and still increase the number of substances on the Candidate List.

Substance evaluation and expert groups – analysis or paralysis?

One part of REACH is substance evaluation. This process is guided by a Community Rolling Action Plan, or CoRAP. Under CoRAP, member states are assigned to evaluate substances for which there is reason to suspect a concern. Depending on the outcome of the evaluation a substance could then be subject to regulation, including Candidate listing. However, in most cases (80%), the conclusion is that more data should be required from industry in order to further clarify the concern. Interestingly, a number of classified CMRs are also evaluated in the CoRAP process, but for other properties and if a risk can be expected from their use, while the CMR classification alone would have qualified them as SVHCs to start with. Regarding conclusions of CoRAP we are concerned about the difficulty to follow up what exact actions these have initiated.

Expert groups now exist for Persistent, Bioaccumulative and Toxic compounds (PBTs) and Endocrine Disrupting Chemicals (EDCs). There is also an authority-industry group discussing the way forward for petroleum and coal stream substances (PETCO).

The outcome of the expert groups is also not very impressive. 107 of the 145 (75%) substances discussed in the PBT expert group during 2012-2015 are still not identified as PBT or non-PBT. 31 substances have been concluded as not having PBT properties and 7 have been identified as having PBT properties. The result of the EDC expert group is similar, 32 of the 33 substances discussed during 2014-2015 are still not identified as EDC or non-EDC due to lack of information or postponement. Only one substance has been concluded to have ED properties by the group.

When the conclusion from CoRAP or an expert group is that more data is needed, industry gets a few years to complete the tasks. However, about 20 percent of these requests are questioned by industry and taken to the Board of Appeal. Again, a few years are added during which the substance can continue to be used.

We need to have a “good enough” evaluation base to make sure the system moves forward. More information can always be useful, but to get a complete picture is almost impossible and we tend to get stuck in a “paralysis by analysis” situation. Using the precautionary principle it is possible to take decisions even when some question marks remain.

It lies within the nature of science to always ask more questions and keep investigating, but this must not be used as an excuse for authorities not to act on substances for which we have enough data.

The slower the process, the happier chemical industry lobbyists

It's not surprising that parts of industry are working to keep the process as slow as possible (and in some cases even blocking it). It is in their economic interest as it keeps their substances on the market. The longer the better. Pushing for more information, more studies to be done and focusing on inconsistencies in the current data is an efficient way to prolong processes and prevent any conclusions.

Ironically, to provide information on chemicals is the responsibility of the chemical industry. In the ECHA report from 2016 ECHA writes "More than 90% of compliance checks on REACH registration dossiers during 2016 required further information, compared with 82% the year before".

Registrants are legally required by the REACH Regulation to update their dossiers "whenever there is a material change, or where new information comes to light". Last year the ECHA proposed that supplementary legislation is passed to strengthen the Regulation's provisions regarding this obligation. Most 2010 and 2013 REACH registration documents have never been updated, according to ECHA.

The ECHA, member state competent authorities and other experts working within the REACH process need to put the blame for lack of information on the industry and not take responsibility for this themselves by doing the research work for industry. Once again: we need to find a "good enough" evaluation base to make sure the system moves forward.

How are the SIN List substances being dealt with?

As part of ECHA's work to screen substances of potential concern, the presence of SIN List substances in different regulatory processes has been investigated. ECHA concludes that the majority of the substances on the SIN List "are under regulatory scrutiny or already regulated, but more work still needs to be done".

ChemSec welcomes the recognition of the SIN List as an important source of information for ECHA, and strongly agrees with the notion that more work needs to be done. ChemSec is concerned, however, that the analysis may give a false impression that the use of SIN List chemicals in the EU is under control. While the views of ECHA and ChemSec align on many issues,

the dividing opinion seems to be around which chemicals should be on the Candidate List.

The SIN List aims to identify SVHCs of relevance for the Candidate List. It contains 912 CAS numbers, while the Candidate List contains 174 substances (249 CAS numbers), and ChemSec therefore urges member states and ECHA to accelerate the process. The target of having all relevant SVHCs listed by 2020 is not likely to be met.

We believe that SIN substances in the following categories, even if filtered out by ECHA's screening, need attention and should be added to the Candidate List.

Substances in CoRAP or in expert groups

These are the substances referred to as "under regulatory scrutiny". ECHA has done a very thorough job in identifying SIN substances that are taken up in any of

- CoRAP evaluation
- EDC expert group
- PBT expert group
- PETCO

ChemSec thinks it is very good that substances are being evaluated under REACH, however, so far substances that enter any of these instances tend to get stuck there for many years, and the outcome of the exercise is often a request for new data, further prolonging the process. In our opinion, the substances on the SIN List are well enough investigated to qualify for the Candidate List and we gladly share our background data with member states and ECHA.

Substances that are classified according to CLP

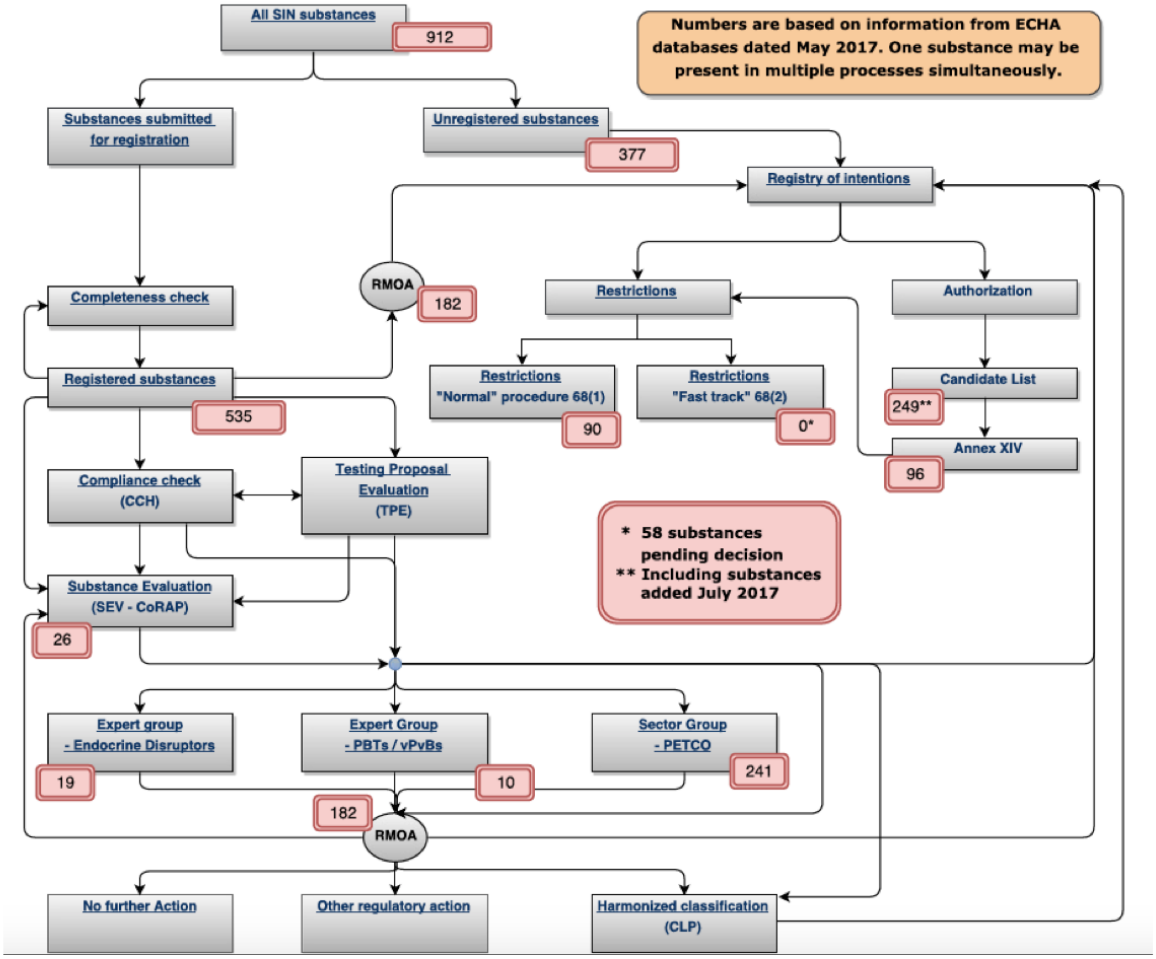
Substances officially classified as CMRs in categories 1A and 1B, by default fulfil REACH SVHC criteria. The vast majority – around 85 percent of SIN List chemicals – have such a classification. While not all classified CMRs are relevant for REACH authorisation, this is still a large group of chemicals which fulfil SVHC criteria. For a number of substances ECHA finds the official classification enough, since it triggers certain legal obligations and argues that inclusion on the Candidate List will not be useful. On the contrary, we believe Candidate listing is crucial as this is such a strong driver for substitution and is followed by the important right to know principle. Many stakeholders see information on the chemicals that a product contains as a key for sustainable chemicals management.

Substances that are restricted

Substances restricted under REACH are rightfully seen as regulated. However, again, we believe Candidate Listing has important added value. We also see the current trend of having complementary, mirrored authorisation and restrictions as the most efficient way to handle SVHCs under REACH.

Non-registered substances

According to the SVHC Roadmap, non-registered substances are of lower priority, as their use needs further investigation. This is understandable from a prioritisation perspective, but to conclude that a majority of the SIN List chemicals are under scrutiny, while the non-registered ones are excluded at different steps in the process, is misleading in our view. Half of the substances on the SIN List have not yet been registered. We still think they are of importance as they can enter the EU in imported articles, they may be registered at the next registration deadline or they may be considered as substitutes for Candidate listed/agreed SVHCs. With these arguments non-registered substances are also regularly included on the Candidate List.



This is an overview of the workflow for substances in REACH. The numbers refer to the SIN substances in each process. Two processes/instances clearly stands out in this flowchart. The expert/sector groups (ED/PBT/PetCo) and RMOA - where very few substances has passed through but instead remain on hold for various reasons. For RMOA, only little more than 10% of the substances have been concluded. Please note that one substance may be present in multiple processes simultaneously.

Candidate Listing must be speeded up

The aims of REACH are very clear: to improve the protection of human health and the environment and to enhance innovation and the competitiveness of the EU industry. The Candidate List was set up to list the most hazardous chemicals, the worst of the worst. The ones we do not want on the market at all, which we as a society want to move away from.

The Candidate List has also proven to be a strong driver for innovation, providing clear incentives to companies for phasing out, at the same time requiring information flow in the supply chain and to consumers.

The REACH criteria for Substances of Very High Concern have been used to populate the SIN List. Regardless of the slow forward pace of REACH and the paralysis by analysis momentum in the EU, the SIN List is still a peek into the future that reveals what the REACH Candidate List eventually will encompass. What's lacking for the moment is the political will to make it happen.

The SIN List is today more relevant than ever. It has a life beyond its initial EU and REACH focus. It represents the substances considered as relevant by corporations, financial investors, UN bodies, scientists and institutions.

The SIN List is free of charge for anyone to use. The scientific background data is available on request. While few companies could probably yet claim to be completely "SIN-free" the SIN List represents the direction and the target. For us, and for many with us, the official Candidate List will never be complete until it matches the SIN List.

We ask member states and Commission to revisit the aims of REACH and to support each other in the work of generating a more complete Candidate List by 2020.

www.chemsec.org

chemsec
INTERNATIONAL CHEMICAL SECRETARIAT

ChemSec November 2017