How might the candidate list change under the REACH revision process?

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Tim Becker
Senior Legal Adviser
REACHLaw

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Since its inception in 2008, the REACH candidate list of substances of very high concern (SVHC) has evolved from a regulatory novelty to a cornerstone of SVHC management for authorities and industry. The future role of the candidate list is now being re-evaluated as part of the ongoing REACH revision under the EU's chemicals strategy for sustainability (CSS).

A European Commission paper for the Competent Authorities for REACH and CLP (Caracal) on the reform of the authorisation and restriction systems (CA/03/2022, 17 January 2022) has provided ideas for a significant expansion of the candidate list scope and obligations.

Steady growth in numbers and relevance
When introducing the REACH Regulation back in 2006, the candidate list of SVHCs for authorisation was one of the key novelties. In October 2008, the first 15 substances were included in the list. Ever since, the list has grown steadily following Echa's biannual updates. Today it has 450 substances, grouped in 223 entries (the last update was on 17 January 2022).

The role of the candidate list has been further enhanced through the introduction of the substances of concern in products (Scip) database under the revised waste framework Directive adopted in 2018. The Scip database already contains several million articles which are on the EU market and contain candidate list substances. The number shows the importance of the candidate list, both as a regulatory tool for authorities and as a reporting trigger for industry, indicating the continued broad relevance of listed SVHCs in products.

Candidate list: the current role

Looking at the REACH legal text as it currently stands, the candidate list is the first step in the REACH authorisation process. Substances fulfilling the REACH Article 57 criteria – ie substances which are carcinogenic, mutagenic or reprotoxic category 1A or 1B, persistent, bio-accumulative and toxic (PBT), very persistent and very bio-accumulative (vPvB) or those giving rise to an equivalent level of concern

(for example, endocrine disruptors) – are formally identified on the candidate list as SVHCs for eventual inclusion in the REACH authorisation list.

In this regard, the candidate list is seen as an 'antechamber' to be used by Echa for prioritising SVHCs for authorisation based on the criteria in REACH Article 58(3) (ie PBT/vPvB properties, wide dispersive use, high volumes). However, the decision on whether to include in the authorisation list SVHCs recommended by Echa, lies with the Commission, which takes into account additional aspects such as the socio-economic consequences of including a substance in Annex XIV.

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Furthermore – and outside of the authorisation process – the candidate list has become a trigger for reporting obligations for SVHCs in substances, mixtures and articles in the supply chain in the following cases:

- provision of a safety data sheet (SDS) for substances and mixtures, if not already required (REACH Article 31(1)(c) and (3)(b)), and 31(9)(a));
- certain disclosure requirements in the SDS, such as for endocrine disruptors, including in mixtures at a concentration equal to or greater than 0.1 % by weight (REACH Annex II); and
- the duty to communicate safe use information on articles supplied that contain candidate list substances above 0.1% weight by weight (w/w) (REACH Article 33).

REACH Article 33 reporting has had a big impact on producers and importers of assemblies of articles (complex objects) in various sectors. The 2015 judgment of the European Court of Justice (ECJ) in case C-106/14 (see link below) which confirmed the requirement of component-level reporting ('once an article, always an article'), further added to the impact on producers and importers.

With regard to candidate list updates, suppliers of articles continue to struggle with the biannual rhythm and the absence of a grace period. The addition of broad and unspecific group entries (more than 1,000 CAS numbers correspond to perfluorobutane sulfonic acid (PFBS) and its salts, including all existing, and even future salt forms unknown today) poses another challenge. In practice it is therefore often impossible to be fully compliant (and timely) with the strict reading of the Article 33 obligation in complex global supply chains.

In addition, a notification obligation to Echa is foreseen for articles produced or imported into the EU/EEA that contain candidate list substances above 0.1% w/w and which are present in those articles in quantities totalling over one tonne per producer or importer per year (REACH Article 7(2)). Given the one tonne threshold and exemption possibilities, the practical relevance of this reporting obligation has always been limited.

Candidate list: a broadening role

In recent years, the role of the candidate list has gone beyond the REACH legal text as outlined above.

Even though no legal requirement for substitution is associated with the inclusion of a substance in the candidate list, listing has, in practice, had a substitution effect in many cases. Hence, the candidate list has already become a kind of substitution list in practice, where alternatives are technically, and economically, feasible for companies.

This substitution pressure is expected to increase further through the new reporting requirement to Echa for articles placed on the EU/EEA market and containing candidate list substances above 0.1% w/w, based on Article 9(1)(i) of the revised waste framework Directive 2008/98/EC. While these Scip notification and database requirements are designed to inform waste treatment operators about the presence of SVHCs in articles after becoming waste, their most obvious practical function today, based on Echa's implementation, is to provide public transparency on SVHCs. This includes information on non-waste articles being available to the public, something which could not be achieved through the REACH reporting provisions (Articles 7(2) and 33).

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For example, a number of polar aprotic solvents including n-methyl pyrrolidone (NMP), dimethylformamide (DMF) and n,n-dimethylacetamide (DMAC) have been, or are, in the process of being included in Annex XVII of REACH after a late risk management option analysis (RMOA) by the Commission in collaboration of Echa concluded on restriction (binding derived no-effect levels (Dnels) relating to exposure of workers) as the most appropriate RMO. These substances had previously been successively recommended for authorisation by Echa in 2013 (DMAC), 2014 (DMF) and 2018 (NMP).

On the other hand, occupational exposure limits (OELs) under the EU occupational safety and health (OSH) legislation have been, or are being, introduced or revised for several candidate list substances used at workplaces, such as cadmium, cobalt salts, and lead and its compounds. This has reflected a tendency away from the authorisation process after the complex experience with chromates, with many workplace chemicals recommended for authorisation by Echa, whereas the Commission decided to 'postpone' Annex XIV inclusion.

Thus, in practice the candidate list has become a pool of SVHCs to be prioritised for further regulatory action in a broader sense – and a trigger for reporting obligations, especially regarding the presence of candidate list SVHCs in industrial and consumer products.

Candidate list: the role under revised REACH

There is no doubt that the candidate list will continue to exist following the CSS REACH revision. Reflecting on the outcome of November's member state and stakeholder workshops on REACH authorisation and restriction reform, the Commission said there was "a general agreement to maintain the candidate list, and to use it for prioritising substances for further regulatory action as well as to gather more advanced information linked to uses of substances of very high concern (SVHC) (exposure, emissions) and to their alternatives" (Commission doc CA/03/2022 of 17 January 2022).

One development already prescribed in the CSS communication is the expansion of the list of SVHC categories in REACH Article 57 to include endocrine disruptors, persistent, mobile and toxic (PMT) substances or very persistent, very mobile (vPvM) substances. Through their future recognition as hazard classes, and the possibility of harmonised classification under the CLP Regulation (revision proposal also underway), as well as for PBTs and vPvBs, the process of candidate listing could be simplified and accelerated in a similar way as for CMR Category 1A/1B today, where the hazard is already confirmed in the CLP process. A dynamic link of candidate list entries with CLP Annex VI Part 3 (harmonised classification and labelling table) is also being considered.

Another question is how the future role of the candidate list will evolve as a priority tool and in relation to industry duties. This will depend to some extent on which of the three options tabled by the Commission for the planned reform of the authorisation (and restriction) process will prevail, or which will crystallise as the 'preferred option', taking up elements from different options:

- option 1: keep authorisations with clarifications and simplifications;
- option 2: merge authorisations and restrictions; and
- option 3: remove the authorisation title from REACH.

In its papers on the reform of the REACH authorisation and restriction system (29 October 2021 and 17 January 2022) (CA/03/2022) the Commission considers that even under options 2 and 3 – which imply an abandonment of the authorisation system as we know it – the candidate list could remain as a tool to prioritise substances for regulatory action, in particular for restrictions but also, for example, for OSH legislation or the Industrial Emissions Directive 2010/75/EU (IED).

The Commission also acknowledges that the list could remain useful for identifying substances to be tracked under Articles 7(2) and 33, as well as a tool for future instruments that might be developed under the sustainable products initiative (SPI), seemingly referring to the new instrument of a digital product passport considered under the SPI.

What appears more open at this point, and surely subject to controversy, is the further option raised by the Commission to introduce a new legal obligation for downstream users regarding candidate list substances. The idea is to gather more advanced information on uses of substances on the list, amounts used, exposure, emissions and waste management, as well as on possible alternatives and substitution activities. This information could be maintained and published by Echa to facilitate substitution.

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Such reporting could even be regularly, for example, annually, and in the view of the Commission improve the information basis. as well as speeding up the priority assessment for further regulatory measures, and for applicants to obtain authorisation or derogations under the revised REACH.

It is unclear, as of today, who should be obliged to provide such advanced information, what specific data are to be provided and how any such requirement would relate to the REACH registration provisions. This is to be explored as part of another Commission study on increased information on uses and exposure for registration, and in the impact assessment for the REACH revision.

What is more, the possibility of initial and annual 'fees' linked to such notification for candidate-listed substances to cover resources required by Echa, and to incentivise substitution, is being considered by the Commission. Downstream users might have to provide proof of their notification compliance to the national enforcement authorities.

It should be noted that affected companies and industry bodies already provide use-related information voluntarily in response to the call for information on the possible socio-economic consequences of the authorisation requirement – which is managed by Echa for the Commission – at the time of Echa's public consultation on its draft Annex XIV recommendation.

Outlook

We should expect that the role of the candidate list as a pool of SVHCs to be prioritised for further regulatory action – and as a reporting trigger – will be maintained. This will likely be clarified beyond authorisation, and thus further enhanced.

However, there will be a need for clarity as to how the hazard classes for candidate listing will relate to the planned extension of hazard classes for restrictions following the generic approach to risk management under REACH Article 68(2). The hazard classes in both cases partly overlap. If restrictions based on an extended use of REACH Article 68(2) could be imposed without prior candidate listing (which is the case today), the predictability offered by the candidate list could be jeopardised.

Additional reporting duties associated with candidate listing could conflict with the Commission's objective to reduce the administrative burden on companies and authorities. This is expected to be further analysed as part of the Commission's impact assessment for the REACH revision.

Further assessments and discussions around the evolution of the candidate list under a renewed REACH are going to take place as part of the ongoing study for the Commission on revising the authorisation and restriction provisions, and the study on increased information on uses and exposure for registration. Interested stakeholders are advised to closely follow these studies and the discussions in Caracal (next meeting is on 27 January 2022), and look to participate in the relevant consultations and workshops.

The views expressed in this article are those of the author and are not necessarily shared by Chemical Watch.