REACH Authorisation - Advisory

This Nickel Institute Advisory on the application of the EU's REACH Authorisation Process is intended to assist downstream users of nickel chemicals in addressing their concerns over the impact of the process on their businesses using these chemicals. It is not a definitive position paper of the Nickel Institute or its member companies on the process, its scope or its impact on the use of nickel containing chemicals in the EU.

Background

REACH Authorisation is a process designed to reduce or otherwise substitute Substances of Very High Concern (SVHC) where substitutes that are technically and economically exist. Under the REACH Regulation, a Member State, or ECHA (on request of the Commission), may propose a substance to be identified as a SVHC based on specified criteria (set out in Article…). Following the identification as SVHC, a substance may be included in the Candidate List of substances which will eventually be subject to Authorisation and included in Annex XIV of the REACH Regulation. Once included in Annex XIV, the substance may only continue to be used up to an official "Sun Set" date after which it's continued placing on the market and use is subject to an Authorisation granted by the European Commission. The authorisation itself will specify the precise uses and any conditions of use. Thus far no substances placed on the Candidate list have been the subject of an authorization but 14 substances are already on Annex XIV and first applications will be submitted in the coming months.

The Candidate List – evolution & recent developments

The Candidate List is a list of relevant SVHCs identified to be eventually included in Annex XIV of REACH – the list of substances subject to Authorisation – which would mean their use must be authorised by the regulators (unless the use is exempt from the Authorisation process).

The Candidate List is updated twice a year and is published on the ECHA website at http://echa.europa.eu/web/guest/candidate-list-table. So far, 84 SVHCs have been included in the Candidate list. As to Annex XIV, it was first populated with six substances in February 2011; a further eight substances were added in February 2012. Third and fourth recommendations are under discussion.

In August 2012, the European Commission instructed the European Chemicals Agency (ECHA) to take steps to include 38 substances including 21 lead compounds on the REACH Candidate List. Despite assertions to the contrary, the move was taken to ensure that the 2010 political commitment of Commissioners Tajani (Enterprise) and Potočnik (Environment) to have 136 substances on the Candidate List by the end of 2012 was fulfilled.

The proposing of the 21 lead compounds took the metals industry by surprise given the availability of a detailed Risk Management Options (RMO) analysis on some of them concluding that Authorisation is not the preferred route. An RMO analysis is the assessment of existing risk management options in place and their effectiveness. This analysis may conclude that additional RMOs are needed to address potential remaining concerns. The identification of additional RMOs must take into account the effectiveness of the suggested measures, proportionality, practicality and regulatory consistency.

The Commission's REACH Unit in DG Enterprise, confirmed to industry that the Commission's request to ECHA with regard to the lead compounds and the other 17 substances is only a first step of a

longer term policy of the Commissioners (linked to an objective in the EU Resource Efficiency Road Map[1]) to list all relevant SVHC on the Candidate List by 2020.

What is a relevant SVHC?

The European Commission wants to focus on "relevant SVHCs" and to have all of them on the Candidate List by 2020. However, populating the Candidate List in a liberal way could see a very significant list develop. However, is it not the point of listing an SVHC to ensure that it eventually is subject to Authorisation? In that case "relevant" needs to be interpreted as those substances most likely to require Authorisation. This further implies a "test" for relevance.

Since 2009, the European Commission ECHA and Members States have been promoting RMO analysis – the test of relevance – as early as possible in the process. The Nickel Institute fully supports this and wishes to see it become an integral part of the process instead of being discretionary as it appears from recent behavior. The NI even recommends going a step further promoting that an RMO must always be conducted prior to the proposal of an SVHC to be placed on the Candidate List to ensure that the appropriate option is chosen in due time and decrease the negative economical impact of a non-appropriate listing on the Candidate list.

Key Message

We believe consideration of relevant SVHCs for inclusion in the Candidate List should be subject to a careful Risk Management Option analysis to ensure regulatory efficiency and certainty with respect to the eventual use of authorisation to control, limit and eventually eliminate the use of that substance.

Avoid the Candidate List becoming an EU "Black List"

The purpose of REACH is to ensure a high level of protection of human health and environment, including the promotion of alternative methods for assessment of hazards of substances, as well as the free circulation of substances on the internal market while enhancing competitiveness and innovation.

Despite attempts to play down the importance of listing of substances on the REACH Candidate List as "not a ban", the practical effect is the same as a black list**.** Blacklisting is extremely damaging for industry and is triggering initiatives from Original Equipments Manufacturers (OEMs) to restrict or ban their use or relocate their production and R&D outside EU. Additionally, assessment of substance importance in meeting other EU policy goals needs to be carefully assessed as several SVHCs currently on the Candidate List are critical to achieving objectives of policy goals in areas such as the low carbon economy, resource & energy efficiency and innovation.

Key Message

Including substances on the REACH Candidate List without consideration of impact on other EU policy objectives improves neither the protection of human health nor the environment. The Candidate List must not become an official "Blacklist".

[1] http://ec.europa.eu/environment/resource_efficiency/pdf/com2011_571.pdf

List only those substances that will eventually be subject to Authorisation

It is worth underlining that only substances identified as meeting **the criteria for Authorisation** (SVHC criteria and prioritization criteria) should actually be included in a Candidate list for eventual inclusion in the Authorisation procedure.

The listing of SVHC on the Candidate list must be based on a fair and transparent process as recommended by the Regulation, the guidance document and the recent studies performed under the REACH review.

Concerning all known substances meeting the CMR SVHC criteria, it cannot be practical, efficient or proportional that all eventually have to be included on the Candidate List. The latest action by the European Commission implies that this will be the case despite the fact that there is more than sufficient Community legislation in place to manage CMRs in industrial situations.

The metal-based chemicals currently targeted by the authorities play a critical role in innovative technologies. These substances are very well known substances, having already undergone an extensive EU Risk Assessment including a Risk Reduction Strategy which is implemented and monitored. They are also extremely well regulated throughout the EU.

Key Message

CMRs used in industrial processes or in products with no direct consumer exposure are not automatic candidates for inclusion in the Candidate List. It is important to look at all existing risk management options before deciding to include them on the candidate list, just because there is already ample legislation and regulations to manage them.

Regulatory process must be efficient and proportionate

It is disappointing to see the European Commission listing substances solely to meet political targets. This sends the wrong message to all stakeholders and is confusing Member States. For industrial uses of substances – often critical for their businesses – it creates additional risk in an economic climate hardly conducive to confidence.

The Commission action is not at all consistent with OECD Recommendation of the Council on Regulatory Policy and Governance which was adopted in March 2012 and subscribed by all OECD members, with the aim to "promote better regulatory policies for better lives". The impact of this poor regulatory approach will be especially felt by SMEs who will bear the brunt of supply chain switching, displacement of industrial processes and loss of raw materials or significant hikes in prices to cover the authorisation risk. Finally, the approach having taken completely neglects the "Think Small First" principle developed and defended by the Commission since 2011.

Key message

Politicizing regulatory processes with complete disregard for science or existing EU risk management measures to control risks from substances will lead to disruption of the internal market, loss of competitiveness, loss of product quality and hence loss of value for the society.

Conclusions

The REACH Authorisation process is clear in its intent. To ensure that substances of very high concern are progressively substituted with less harmful alternates provided they are technically and economically feasible. It should therefore be approached with scientific and technical rigor following the Regulation and guidance developed by the European Chemicals Agency. The goal should be authorisation of substances, not populating an official "blacklist" which is another objective entirely.

The Nickel Institute firmly supports the prior assessment of risk management options for potential substances of very high concern before their inclusion in the REACH Candidate List. This is consistent with the spirit of the REACH Regulation which foresees only those substances that eventually would be subject to authorisation being included.