KEMI
Kemikalieinspektionen
Swedish Chemicals Agency

MEMO

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To
DG Growth and DG Environment
European Commission

Additional comments relevant to the public consultation on the REACH refit evaluation

We find that the REACH regulation, in general, is well designed and is delivering on its main objectives. The legislation has resulted in generation of (eco)toxicological new data, CSAs, SVHC-listing, and production of new general and specific restrictions. These efforts are expected to have contributed substantially to higher protection of consumers, workers and the environment. In addition, the authorisation system has for certain authorised uses led to higher protection of workers than the OSH legislation. Thanks to the harmonised rules, the REACH legislation has created a level playing field for all companies in the EU contributing to free circulation of chemicals on the internal market. Although it is difficult to assess the REACH regulation's impact on innovation, it has been recognised from enforcement in Sweden that instead of applying for authorisation, companies often substitute SVHCs and Annex XIV substances on their own initiative.

The main deficiencies which we have identified are primarily related to the implementation of the regulation (see the points raised below). The shortcomings could be resolved by making the implementation of some of the REACH processes simpler, clearer, more streamlined or even re-designed. In any case, a more efficient REACH should be sought, in our opinion, in the regulation itself. In many instances the legal text of REACH is very clear but its implementation may not have delivered to a full extent (e.g. registration) or may have complicated its processes (e.g. restriction and authorisation).

In 2014 the Swedish Chemicals Agency assessed the functioning of the REACH regulation. This resulted in the report "Developing REACH and improving its efficiency" (see http://www.kemi.se/global/rapporter/2015/report-2-15-REACH.pdf). Although many of the findings are still applicable, we have for the REACH Refit evaluation chosen to focus on the following areas of principal importance:

- Registrations
- Substances in articles
- Drivers for substitution

Swedish Chemicals Agency

Mailing address	*Visit & delivery*	*Invoicing address*	*Phone & fax*	*Internet*	*VAT No*
Box 2 SE-172 13 Sundbyberg Sweden	Esplanaden 3A SE-172 67 Sundbyberg Sweden	FE 124 SE-838 80 Frösön Sweden	Phone +46 8 519 41 100 Fax +46 8 735 76 98	www.kemi.se kemi@kemi.se	SE202100388001

Registrations

Registration dossiers are the cornerstones of the REACH regulation since they constitute a knowledge base for a safe use of chemicals for manufacturers, downstream users (DU) consumers, and the environment. The information gathered in the dossiers including adequate exposure scenarios shall be passed further down the supply chain to the users (as SDS and eSDS) to instruct them how to use the chemicals in a proper and safe way. In addition, these data are also used in other processes where needed, e.g. in applications for authorisation or for harmonised classification, as well as for implementation of other legislations, e.g. OSH, cosmetics, medical devices and the water framework. Therefore, dossiers with insufficient data, data of bad quality or poor safety assessment of chemicals will undermine all REACH objectives and also diminish the usefulness for other legislations.

Already the REACH review 2012 showed that many of the registration dossiers do not comply with the legal requirements. We see this as a substantial drawback which should be minimised as soon as possible. We believe that improving the quality of the registration dossiers is the single most important factor that can positively impact the whole performance of the REACH regulation.

There are a number of possible measures that can be taken to improve the quality of registration dossiers, e.g.

(i) Revoking registration number (according to agreed criteria) if a registration dossier does not fulfil legal requirements (according to the principle "no data no market").

(ii) Communicating clearly to the registrants regarding the requirement for updating of registration dossiers, and to registrants and DU regarding the need for communication in the supply chain.

(iii) Extending the number of the compliance checks done by ECHA.

(iv) Extending support to registrants from ECHA and MSCAs.

(v) Providing further descriptions of what an exposure scenario should include. This measure would contribute to an improvement of the registration dossiers since it would give a hands-on guidance to registrants and DU how to handle their substances safely. We are aware of and strongly support the activities taking place within the remits of CSA/ES Roadmap aiming at delivering better guidance on ES, including practical examples. This work should be, however, intensified (by both industry and MSCAs) and its results implemented as soon as possible.

(vi) Updating of REACH Annexes with information requirements on nanomaterials.

(vii) Pushing for agreement among notifiers of self-classifications on the same substances (many enterprises notified different classifications on the same substances to the C&L inventory).

Substances in articles

For substances in articles REACH includes provisions mainly on substances of very high concern (SVHC) through notification to ECHA (REACH Art.7) and communication in the supply chain of articles that contain above 0.1% of SVHC (REACH Art.33). In addition, Article 68(2) is aimed to provide a fast track for restriction of CMR cat 1 substances in articles for consumer use. These provisions establish a system which so far has not been fully operating due to a number of factors, e.g. disagreement regarding the interpretation of the 0.1% threshold and discussions on how to apply Article 68(2). Thus, the full potential of the system is still to be shown.

The court judgement regarding the interpretation of the 0.1% rule, the coming updated ECHA guidance on SVHC in articles, and the entry into force of the first restriction according to art 68.2 will certainly contribute to the performance of the system. Also, since the information requirements are dependent on the identification of SVHC substances, a higher rate of identifying new substances of concern would have a positive impact. The potential of the system is, however, diminished by the provisions in Article 7. According to which, notification from only one supplier of similar articles is needed to comply with the regulation. Consequently, information about the presence of SVHC substances in articles collected as a result of Article 7 is not sufficient to allow development of appropriate risk management measures. Furthermore, the enforcement of Article 7 is difficult. Results from the Swedish enforcement also show that the implementation of Article 33 by industry is far from completed.

The requirement in Article 33 to inform about safe use apply to articles supplied to professionals and on request to consumers. However, this information does not reach the waste and recycling sectors, which creates difficulties when establishing circular economies. Possible solutions to this shortcoming could also be included in other legal frameworks (e.g. ecodesign or waste legislation).

In general, we agree with the benefits of focusing on SVHC substances but the possibility to restrict other hazardous substances by specific restrictions is necessary as well. From our experience, suppliers of articles call for more action concerning restrictions of hazardous substances in articles. To achieve this, a considerably more efficient and effective restriction process is needed.

We also believe that specific provisions in product legislation, as a complement to the general provisions on articles in REACH, are important for the protection of human health and the environment.

A consequence of the provisions on the authorisation of SVHC substances in relation to articles is a disturbance of the level playing field. EU companies producing articles containing substances included in Annex XIV have to apply for authorisation, while importers can place the same type of articles on the European market without authorisation. It should be examined how imported articles containing substances listed in Annex XIV and articles produced in the EU could be treated equally by EU legislation. A legal analysis of a possible solution was recently

presented by the German Environmental Agency (UBA) and could be a starting point for further analysis.

Drivers for substitution

Authorisation

The authorisation is meant to be a driver for substitution of SVHC with less hazardous alternatives where available. Its first phase, listing of substances on the candidate list has already shown that the candidate list itself seems to have had a positive effect on substitution, partly caused by expectations from producers on future measures as authorisation. If these expectations disappear due to generous authorisations of broad and unspecific uses the positive effect of the candidate list is also at risk to decrease. Although the process is starting to deliver, there are still several issues that make it inefficient and controversial. The main factors hampering its performance are:

(i) Lack of clarity regarding the scope of the applications mainly caused by improper guidance on the description of "use".

(ii) Processing of the applications by ECHA, including among others ECHA's engagement in the interpretation of the legislation; unclear and inefficient opinions on authorisation applications from RAC and SEAC mainly expressed in vague standard wordings regardless of the specificity of the uses and substances applied for.

(iii) Difficulties in assessing the availability and feasibility of alternatives and the poor response on alternatives in public consultations.
It may be useful to examine whether the assessment of alternatives for authorised and restricted substances should be made by independent consultants (cf. assessment of exemptions in RoHS and ELV directives).

We are of the opinion that the provisions in REACH are adequate when it comes to the main objectives and provisions of the authorisation. The problems specified above can be derived, to a certain degree, from the procedures developed for implementation of the various legal requirements. The outcome from these sometimes inappropriate procedures in combination with unclear opinions generate substantial problems in the decision making process resulting in unnecessary prolongation of the time to finalise the decisions.

Lack of coherence regarding the level of evidence required in Authorisation vs Restriction

There is a lack of coherence in implementation when processing authorisation applications compared to restriction proposals regarding the level of evidence required. The experience gained from both processes clearly shows that all authorisation applications (regardless of their quality) have been found compliant and lead to approval, while for the restriction proposals there is a tendency to require

further evidence from authorities even when available data give scientifically based reasons for concern and action.

The shortcomings of the authorisation applications have so far never lead to any rejection of the application but are, at a later stage, penalised by giving a shorter review period and inclusion of additional conditions. Putting such a low standards on the level of evidence required for authorisation applications will reverse one of the objective of REACH which puts a requirement on the industry to ensure that their substances do not adversely effects human health and the environment.

An unintended consequence of the different standards applied may be a decreasing number of restriction proposals.