REFIT Platform Opinion

Date of Adoption: 21/09/2017

REFIT Platform Opinion on the submission by the European Environmental Bureau (EEB) on the REACH authorisation process

The REFIT Platform has considered the submission made by the European Environment Bureau (EEB) on the need to make the REACH Authorisation process more efficient and effective.

The Stakeholder group recommends that the European Commission closely examines means to simplify the procedure for placing SVHC (Substances of Very High Concern) on the Candidate List and to make the Authorisation procedure more effective to ensure that the main goals of REACH are achieved. The Stakeholder group also suggest that additional efforts are made by competent authorities to identify new SVHCs.

The Government group recognises that there is room for improving the REACH authorisation process.

The majority of contributing Member States encourages the Commission – in line with the Better Regulation principles - to identify simplification measures on the basis of the evidence collected through the REACH evaluation.

Detailed Opinion

Contents

1 Submission II.4.a by the EEB (LTL421) 2

2 Policy context 2

3 Opinion of the REFIT Platform 3

3.1 Considerations of the REFIT Platform Stakeholder group 3

3.2 Considerations of the REFIT Platform Government group 4

1 Submission II.4.a by the European Environmental Bureau (EEB) (LTL421)

Since REACH was approved in 2006, substantial progress in the management of chemicals has been achieved in Europe, bringing about many positive changes to companies' competitiveness and their capacity to innovate. The REACH Authorisation process is vital to ensuring the phase out and substitution of SVHC by safer alternatives, the creation of jobs, promotion of innovation and new market opportunities by favouring frontrunners producing and using safer alternatives rather than laggards using or producing hazardous/obsolete chemicals.

As a new report from the European Environmental Bureau (EEB) shows however, in practice, the Authorisation process is not working properly and too slow. It underlines the main flaws of the process and sets out a clear path for reform showing how the Authorisation procedure can be made fully fit for purpose to achieve not only its main goal, namely health and environmental protection, but also its goal of free circulation of substances on the internal market while enhancing competitiveness and innovation.

Our main concern are earlier initiatives by the European Commission to simplify and streamline the process as part of its Better Regulation agenda that have made the process less, not more, effective in achieving these goals.

Please see the attached report for further recommendations (click on the paper clip):

2 Policy context

Regulation (EC) No 1907/2006 on Registration, evaluation, authorisation and restriction of chemicals (the REACH Regulation) is the cornerstone of EU chemicals legislation, setting harmonised rules for the registration, evaluation, authorisation and restriction of chemicals in the EU. In force since 2007, REACH also established the European Chemicals Agency (ECHA), based in Helsinki.

REACH merged the previously different regimes governing so-called new and existing chemicals into one unified systematic registration system, ensuring that the same obligations apply to both groups of chemicals.

REACH aims at improving the control of risks from individual substances while ensuring the good functioning of the EU internal market. In this regard, the authorisation procedure aims to assure that the risks from Substances of Very High Concern (SVHC) are properly controlled and that these substances are progressively replaced by suitable alternative substances or technologies where these are economically and technically viable.

The SVHC Roadmap aims at identifying, by 2020, all known relevant substances for the

Candidate List. To achieve this objective, ECHA, with the collaboration of Commission and Member States, has put in place a system to screen the information present in the registration dossiers to identify the substances that would be relevant for the Candidate List or would need to be regulated with another process, within REACH or outside of REACH.

The screening process is progressing as expected. In the period 2014-2016, 900 substances were selected for screening and 600 were screened by Member States and ECHA. While all currently known SVHCs have been assessed, there are more than 300 substances in the REACH evaluation process to ask industry for further information. Evaluation by authorities of existing and new toxicological information would allow identifying substances fulfilling the SVHCs criteria. In addition, to speed up the process, authorities have now started addressing groups of similar substances instead of individual substances.

Moving to the other steps of the authorisation process, so far, 43 substances have been included in Annex XIV to REACH and are therefore subject to the authorisation requirement. Up to now 39 authorisation Decisions have been adopted by the Commission and 78 are in preparation. Since the start of the process, 117 applications have been submitted in total.

As part of the REFIT programme the Commission has announced the intention to reflect in which specific low-risk cases the authorisation application procedure could be improved and simplified, and how to streamline the process of applying for authorisation in general, while maintaining the REACH goals and objectives. For this purpose a Task Force was set up, with representatives from Member States Competent Authorities, ECHA and the Commission. The possible simplification identified in this context so far consists in specifying the type of data that satisfy the information required in REACH for applications for uses in low quantities and for uses in legacy spare parts. As for streamlining, the Task Force prepared a practical guide, *How to apply for authorisation*, aimed at specifying more concretely the required information in applications for authorisation, in order to ensure that these are fit-for-purpose and do not include more information than necessary.

A REFIT evaluation of the REACH Regulation was included in the Commission Work Programme 2016 and the results of the evaluation are expected to be reported in 2017.

3 Opinion of the REFIT Platform

3.1 Considerations of the REFIT Platform Stakeholder group

The REFIT Platform Stakeholder group considered the submission and concluded that there is sufficient evidence to support the claim that the REACH Authorisation process is not working effectively, and is made unnecessarily slow and inefficient.

The authorisation process should be improved and different stakeholders have submitted their comments and proposals during the REACH REFIT consultation of the Commission early this year.

The EU White Paper *Strategy for a future Chemicals Policy* (2001) estimated that 1,400 substances had hazardous properties giving rise to very high concern and should therefore be

progressively phased out and substituted with safer alternatives.

The *SVHC (Substances of Very High Concern) Roadmap 2020* (2013) laid out a work plan to identify all relevant, currently known SVHC and to include them in the Candidate List by the end of 2020. The objective stated in the Roadmap has been to screen 440 substances by 2020.

Today, the Candidate List includes 173 substances and the authorisation list (REACH Annex XIV) 31 substances. No new substances have been added to the authorisation list since August 2014. However, in December 2016 the REACH committee supported a draft Commission regulation for inclusion of 12 additional substances that have gone through the scrutiny process and should be published in the Official Journal of the EU soon.

At the same time the Candidate Listing process is widely considered to be one of the main drivers for innovation in the chemicals sector. An evaluation conducted in 2012 for the European Commission on Impact of the REACH regulation on the innovativeness of EU chemical industry states that "*The candidate list is a, if not the, major driver for change at present. But attention to unintended consequences tends to distract firms from their planned innovative activities, as for example when retailers or DUs request greater levels of SVHC absence than required within the Regulation, it generates excessive paper/administrative work, and there is uncertainty about which substances may in future appear on the candidate list.*"

Also, downstream users from many different sectors, including textiles, electronics, retailers, etc. have identified the Candidate List as an important driver for innovation and substitution (http://ec.europa.eu/environment/chemicals/reach/pdf/studies_review2012/report_study5.pdf Click on the paper clip

The avoidable delays faced in this process are therefore not only adversely impacting human health and the environment, but are also adversely impacting innovation in the industry.

The REFIT Platform Stakeholder group therefore **recommends** that the European Commission services examine closely how to simplify the procedure for placing SVHC on the Candidate List in order to achieve the original goal of placing **all known relevant** substances on the candidate list by 2020, and how to improve the Authorisation procedure for it to be fully fit for purpose and to achieve the main goals of REACH, to '*ensure a high level of protection of human health and the 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*'(REACH Directive Art. 1). Finally, additional efforts should be done by authorities to identify new SVHCs on the basis of new and existing information.

3.2 Considerations of the REFIT Platform Government group

The 19 Member States who contributed to this draft Opinion consider that there is potential to simplify and further develop the REACH authorisation process.

Most contributing Member States broadly support the recommendations of the Stakeholder group, noting however that the issue to be tackled is the speed at which substances are placed on Annex XIV (the authorisation list). Regarding the recommendation of the Stakeholder group towards competent authorities in Member States, one member of the Government group points towards the differences in contributions amongst Member States and recommends that the emphasis is placed on those Member States which have not yet contributed much and to prioritise a sound monitoring and effective enforcement of the recently introduced.

Some Member States further recall that – in light with the Better Regulation principles- future simplification measures should be informed by the evidence collected in the context of the REACH evaluation.

Individual contributions from Member States

Member State 1 agrees with the REFIT Platform Stakeholder group. Although ECHA has done great work in building up and initiating the REACH-authorization process, it needs to be accelerated and further developed. This can be carried out by e.g. streamlining the process itself, and also by ensuring that all relevant substances are identified as SVHCs as soon as possible. The identification requires that enough information on the intrinsic properties of substances is received in registration dossiers, which means that also compliance checks need to be intensified.

Member State 2 supports in principle the recommendations made by the EEB relating to the authorization procedure for substances of very high concern. ECHA, together with the EC and Member States, take initiatives to improve the quality and consistency of Application for Authorisation, including but not limited to streamline and simplifying procedures for authorisation and restrictions, including accelerate the process of replacing dangerous substances. MS2 notes that additional financial and human resources for Member States involved in the process would pose a challenge for small countries.

Member State 3 considers that the introduction of the REACH Regulation in 2006 brought about significant change in how chemicals are dealt with by regulators and by industry. The regulatory goals of REACH, namely to provide a high level of protection of human health and the environment and reduce animal testing as well as the free circulation of substances on the internal market while enhancing competitiveness and innovation, are as important today as they were in 2006 and REACH has increased consumer and worker safety, environmental protection, and confidence in chemicals and sustainability throughout Europe. In the meantime MS3 notes that the results of the Commission's REFIT evaluation of the REACH Regulation - 10 years on from the introduction of REACH –are expected shortly.

Member State 4 acknowledges the concerns addressed to the Commission with a view to speeding up the authorisation process. However, in light of the ever increasing time and effort for the identification and authorisation of SVHC, practical experience shows that the scope for such acceleration is limited.

As for the wish of the Stakeholder group that authorities make additional efforts, it may be mentioned that the amount of contributions has varied considerably from Member State to Member State; for example, this Member State (one of the smaller ones) has nominated 15 substances to the candidate list since 2007 – which amounts to (disproportionally high) 9 %, while other Member States have not yet taken part in the nomination process.

After a thorough evaluation of the REACH authorisation process between August 2014 and December 2016, the EC decided to launch an additional public consultation once a substance is suggested for regulation by REACH authorisation. In 2017 seven new substances were added to annex XIV, the "REACH authorisation list".

MS4 supports ECHA to intensively continue work to identify further substances that could be relevant for inclusion and the EC to invite Member States, which have not contributed much so far, to dedicate more resources for this task. In particular, to support Member States in their work the coordination of work and cooperation is fostered by different means like IT-tools as for example the PACT (Public Activities Coordination Tool) and regular workshops.

Furthermore, SMEs need special attention, especially when taking into account the importance of this sector for this Member State's economy. These companies seem to be affected the most negatively by the REACH-regulation including authorisation. The process of applying for an authorisation is already burdensome for large industry, but it is even more problematic for SMEs. The main aspects are costs for the elaboration of a dossier, short review-periods, language regime, lots of administration, and high fees.

Therefore, MS4 deviates from the recommendations of the REFIT Platform Stakeholder group as specifically those Member States, which have not contributed much so far, should be invited to dedicate more resources for this task and that a sound monitoring and effective enforcement of the recently introduced changes should also be a priority.

Member State 5 does not apply any objections towards this draft opinion.

Member State 6 considers that authorisation is an important instrument to encourage substitution of hazardous substances, and there are strong indications that the process, including the preceding step of placing substances on the Candidate List, indeed is an important driver for such substitution.

There is, however, room for improvement to address some weaknesses. One of these is the speed at which substances are placed on Annex XIV (the authorisation list). The process from the first screening of a substance until its addition on Annex XIV takes about five years. This not only compromises the health and environment objectives of REACH, but also gives uncertainties for businesses. One of the reasons is the number of steps, each of them combined with a public consultation:

- on placement on the Candidate List (after a Member State submitted a proposal);
- on the intrinsic properties of substances and extra information on uses (after ECHA's recommendation for inclusion on Annex XIV);
- on socio-economic aspects (as a separate step organised by the Commission, also after

ECHA's recommendation for inclusion on Annex XIV);
- after application for authorisation.

It is important that stakeholders have the opportunity to provide information and comments on different aspects of authorisation. However, the current process has the risk of over-representation of the voice of stakeholders with resources to participate in all these consultations, as well as the risk of submission of the same information in several consultations. Therefore, it is useful, in the context of the REACH evaluation, to streamline (and where possible to shorten) the procedure and at the same time make sure that essential information, including about socio-economic aspects, is brought forward early in the process.

To achieve the objective of the SVHC Roadmap it is also important that companies improve the quality of their registration dossiers and keep them updated. In addition, a grouping approach, which considers a group of similar substances rather than single substances, is increasingly being pursued and this helps to increase predictability.

Member State 7 is currently in the process of developing an elaborate position regarding the REACH authorization process. As this development is still ongoing MS7 cannot comment on the submitted opinion for the time being.

Member State 8 agrees that the REACH authorisation procedure may need to be reviewed in order to ensure greater efficiency. However, MS8 believes that the mere simplification of the process does not necessarily lead to the desired output as currently the processes identified by the Regulation are supported by several legally not defined actions (soft measures), like the RMOA or simplified decision-making.

In MS8's, view the REACH authorisation process should be examined as a whole considering all experiences gained in the past years and integrating, where necessary, the motivations to develop these legally not defined processes.

Member State 9 considers that the authorisation application procedure should be simplified in certain uses cases. MS9 supports the REFIT Platform Stakeholder group recommendation, that the European Commission services should examine how to simplify the procedure for placing SVHC on the Candidate List. Slow progress in procedure for placing SVHC on the Candidate List adversely impacts development in the European industry.

The European Environmental Bureau (EEB) calls for the accelerated inclusion of substances (SVHC) into Annex XIV. At the same time, the EEB argues that the rapid process of substance authorization leads to an increase in the innovation and competitiveness of the chemical industry in the EU. Such approach raises serious concerns of the industry.

MS9's Industry Associations does not agree with the arguments that the phasing out of chemicals is the driving force behind innovation.

The substance authorization process involves incorporating substances into the candidate list and withdrawing them and replacing them with safer substitutes. Any regulation leading to the limitation and withdrawal of essential chemicals should be based on a well-founded

verification that is founded on a fact-based approach, a reliable and credible substantive assessment rather than a rush. The decision to include substances in Annex XIV should take into account the impact assessment and the availability of an alternative that is capable of replacing a fully withdrawn substance. These actions indicate the prudence and deliberation of decision-making, also in the interest of the entrepreneur, the consumer and the environment.

Better Regulation assumes that EU action is based on facts and understanding, and that the resulting law is designed to deliver maximum benefits at a minimum of costs and with respect of the principle of proportionality. Accelerating the inclusion of a substance on the Candidate List cannot be based, for example, on the application of the precautionary principle in place of a substantive substance assessment and an impact assessment. The costs of substance withdrawal, changes in recipes, etc. are borne primarily by the entrepreneur.

Innovation in the industry cannot be understood primarily as a search for alternatives to existing and recalled components. Innovation is primarily the search for untapped substances with new directions of action and responding to consumer expectations and market trends.

There are a number of examples where legal constraints or enforcing certain practices through prohibitions have led to innovation hindering and enormous costs (including employment costs).

Member State 10 agrees with the submission suggestion. It is important to identify ways to streamline the process of Substances of Very High Concern (SVHC) identification, simplify the procedure for placing SVHC on the Candidate List, and improve the Authorisation procedure for it to be fully fit for purpose and achieve the main goals of REACH.

Member State 11 is supportive of the Stakeholder group recommendations.

Member State 12 supports the Stakeholders group opinion but recognizes that the timeframe (2020) proposed is too short. Every effort must be made by the European Commission, the European Environmental Bureau, businesses and mainly by the national authorities to identify new SVHCs. MS12 also fully supports that the SVHC´s Roadmap should include RMOAs to evaluate RMOs alternatives to Authorization to control the risks in a more cost-effective way in the real world.

Member State 13 agrees with the EEB and that the REACH authorisation process is not working properly and is too slow. However MS13 states that it is important to add substances in Annex XIV at the rate that allows new permit applications at a reasonable rate.

Member State 14 considers that the authorisation process globally works but also supports the conclusion of the Refit Platform Stakeholder group which considers that the authorisation process should be improved to better cover its ambitious goals. MS14 shares the specific concerns that the authorisation process is too slow and agrees that the European Commission should examine how to simplify the authorisation procedure for placing SVHC on the Candidate List in order to achieve the original goal of placing all known relevant substances on the candidate list by 2020. MS14 also supports the improving of the efficiency

of the process e.g. for the authorisation application.

MS14 would also underline the importance to achieve these goals under the current review/refit already initiated by COM under regulatory review of REACH.

Member State 15 has been following the discussions for the 2017 REACH review. The document submitted reflects the conclusions reached during the previous discussions between the Commission, Member States and the European Chemicals Agency (ECHA), so that the REACH regulation could be reviewed. The major challenges are to reconfirm the political commitments, improving data availability and use, improving substitution, innovation, and also to introduce alternative technologies. These measures promote the use of safer chemicals. MS15 supports these initiatives.

Member State 16 in general agrees with the recommendation of the REFIT Platform Stakeholder Group and supports in principle the recommendations from the EEB regarding to the authorization procedure for Substances of Very High Concern (SVHC).

With regard to registration term in 2018, the authorization procedure for the SVHCs is expected in 2020. MS16 is not convinced that a fee reduction will lead to speeding up the authorization process. It is important that enterprises improve the quality of their registration dossiers and keep them updated. Small, medium and micro enterprises do not have to stay at the same business category for next 2 years.

Member State 17 agrees with the suggestion of the Stakeholder group; but considers that the issues raised should be examined under the framework of the REFIT evaluation of the REACH Regulation.

Member State 18 supports the recommendation of the Stakeholder group.

Member State 19 supports the recommendation of the majority of contributing Member States.