ChemicalWatch
GLOBAL RISK & REGULATION NEWS

REACH & CLP Hub: SVHC authorisation – review report or new report?

3 June 2019 / Europe, REACH, SVHCs

Frederik Johanson of REACHLaw examines company strategies for successful REACH authorisation applications.

REACH authorisation is required for SVHCs included in Annex XIV of REACH (the authorisation list).

This means that companies need to apply for authorisation to continue their relevant uses after the sunset date. Applicants for authorisation can either be the users, commonly referred to as a downstream user application, or the manufacturers and/or importers supplying the Annex XIV listed substance to the users, commonly referred to as an upstream application.

An application may also be a combination of the two (eg, formulators who supply their formulation

for further use downstream). Applications for authorisations may be submitted by a single company (single application for authorisation) or by a group of companies (joint application for authorisation).

To benefit from so-called transitional arrangements, the authorisation application must be submitted before the latest application date given in the authorisation list entry.

Transitional arrangements mean that the applicant(s) as well as their downstream users, where relevant, can continue their use after the sunset date, also given in the authorisation list entry, if their decision is not yet available from the European Commission.

After the sunset date, only companies that benefit from transitional arrangement or have an authorisation in force can continue their use. All others must stop their use effective from the sunset date.

Where an authorisation application is accepted by the Commission, the use covered will be subject to a time-limited review period. At the end of this period, the authorisation holder(s) must submit a review report or cease or substitute the use of the substance. The length of the review period granted is based on several factors, such as the availability of alternatives, the level of certainty that the operating conditions and risk management measures in place for the use minimise exposure and socio-economic arguments such as a long investment cycle.

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Four years is considered a short review period, seven years is considered a standard review period and 12 years is considered a long review period. The length of the review period is ultimately determined by the Commission taking into consideration the Opinions of the Committee for Risk Assessment (Rac) and the Committee for Socio-economic Analysis (**Seac**). The Commission may also reject an application for authorisation, resulting in a ban on the use of the substance by the applicant(s) from the sunset date.

Initial application for authorisation

By 22 May, 142 applications for authorisation had been received by Echa, covering 227 uses by 235 applicants. The Commission has given 203 decisions per use and per applicant. These have been initial applications for authorisation, meaning these have been submitted for the first time for that substance-use-combination.

Review report

If an authorisation holder has not found a suitable alternative during his granted review period, the holder can submit a review report to continue use. A review report is basically a re-application for authorisation and includes updates to all the documents submitted with the original application (Chemical Safety Report (**CSR**), Analysis of Alternatives (AoA) and the Socio-Economic Assessment (SEA) if applicable) an explanatory note describing what has changed as well as any other information that may have been required by the conditions of use given in the Commission decision.

In order to benefit from transitional arrangements, this review report must be submitted at least 18 months before the end of the review period, and the authorisation holder can continue their use even if the Commission has not given its decision on their review report by the end of the review period. There is no limit to the number of times a review report can be submitted. Essentially, as long as the prerequisites for authorisation are fulfilled (ie, on the socio-economic route if there are no suitable alternatives and the socio-economic benefits outweigh the risk to human health or the environment) one can re-apply for authorisation "forever", according to REACH.

As of 22 May, only three review reports have been submitted covering five uses by three applicants. Of these, one applicant has withdrawn the review reports for both uses.

What is a successful application for authorisation?

From the applicant's perspective, the success of an application for authorisation is determined

solely by the length of the review period granted unless it was a bridging application to cover residual time until an alternative can be implemented.

Generally, a review period of seven years is considered a good outcome, while 12 years is considered an excellent outcome providing continuity of use for a substantial period until a decision is taken whether to substitute or phase out the use or submit a review report. Four years or less is considered a poor outcome.

'An important factor for determining success should be the severity or harshness of the given conditions of use as part of the authorisation decision'

However, an important factor for determining success should be the severity or harshness of the given conditions of use as part of the authorisation decision. Harsh monitoring and reporting requirements, especially for upstream applications for complex supply chains, may yield practical problems at the downstream user level in implementing these conditions of use and at the upstream level, in collecting potential monitoring data that has been reported by the downstream users to Echa.

Albeit the final decision is not yet published, based on draft decisions, this seems to be happening for some of the chromium trioxide uses where downstream users would have 12 months from the date of the decision to collect a number of exposure measurements, per supplier, and report it directly to Echa, who in turn will share the information with the upstream authorisation holder to enable them to verify and validate their exposure scenarios.

Therefore, the success of an application for authorisation may be measured as a combination of the length of the review period and the degree of stringency of possible conditions of use imposed on the applicant and the users of the substance.

New, initial application for authorisation or review report

As the first authorisation applications were submitted in 2013 and the first authorisation decisions were published in 2014, it is becoming more relevant for authorisation holders to either discontinue or substitute their use, or re-apply for an authorisation by submitting a review report at the latest 18 months before the end of the review period.

As part of the strategy for re-applying, several factors come into play depending on the type of authorisation. For single downstream users, the options are limited, either:

re-apply; or

substitute/phase-out the use by the end of the review period.

For those that are part of a joint downstream application, the options are not much better, either:

re-apply;

substitute/phase-out the use by the end of the review period; or

submit initial applications for authorisation as a single downstream user, focusing on the single downstream user-specific information in the hopes of having a stronger case resulting in longer review periods and lesser stringent conditions of use by avoiding uncertainties in the assessment reports.

However, in cases where an upstream authorisation holder has covered the downstream uses of the substance, there are more options available for the downstream users. This article will now focus on upstream authorisation holders and their review reports or subsequent new, initial, applications for authorisation.

Upstream authorisation holders

In situations where the upstream holder is considering renewing the existing authorisation by submitting a review report, downstream users essentially have the option of:

being covered by the upstream review report, assuming the upstream actor wishes to continue coverage of the use; or

submitting their own downstream user initial application for authorisation.

This can further be done as a single downstream user or group of downstream users as part of a joint application for authorisation.

Therefore, from the downstream users' perspective, the benefits and drawbacks of submitting a new, initial downstream user application for authorisation need to be considered.

Pros and Cons

When determining the benefits and drawbacks of submitting an own (single/joint) application for authorisation it is also worth looking beyond the mere technical aspects of the application to other potential strategic risks, such as political and reputational risks.

 For example, some NGOs have taken an interest in certain rather weak and wide-ranging upstream applications for authorisation, exerting pressure on the decision-making process in favour of short review periods or even not granting the authorisation at all.

Therefore, the unfortunate negative press or stigma attached to an upstream application may also be a reason enough to submit the company's own (single/joint) application for authorisation to break the "vicious" circle by starting from a clean slate.

Therefore, the following pros and cons can be identified for new, initial applications of authorisation instead of relying on the upstream review report, taking into account technical, business as well as reputational aspects.

The pros of submitting a new, initial application instead of relying on the upstream review report include (note that some of the pros also generally apply to downstream user applications for authorisation) include:

gain independence from the upstream authorisation holder supplier(s). The company is no longer subject to their authorisation but can, for example, source the substances from any supplier inside and outside of the EU/EEA, provided the substance complies with the other requirements of REACH such as the registration requirement, where applicable;

only cover the use(s) relevant for the company. – Obtain focus with the application by covering

only the relevant use(s) applicable to the company

The company is not bound by review report conditions of use. – There are no previous conditions of use for the company's new, initial application for authorisation albeit, where applicable, the company will have to comply with the conditions of use of the application for authorisation until the Commission decision has been given on the new application;

less stringent conditions of use are likely given to more specific applications. Downstream user applications for authorisation tend to be more specific and thus more robust. Looking horizontally across applications submitted to date, downstream user applications have better outcomes as the information submitted will generally be more case specific and relevant for the use which is favoured by both the Rac and Seac;

no association with "stigmatised" upstream applications for authorisation, where applicable and avoid the reputational risks associated with those applications. Even if the upstream applicant submits a better review report, it is likely the association with the previous application will remain, at least to some degree;

applicants can be changed. As part of the review reports, the applicant must be one of the named current applicants of the upstream application for authorisation;

adopt a strategy to group substances, where applicable/relevant. The substance scope of the review report cannot change whilst for new, initial applications for authorisation, the scope is to be determined by the downstream user(s); and/or

freedom to redefine use description (broader/different beyond scope). The use scope of the review report cannot go beyond the original application while for new, initial applications for authorisation, the use scope is as to be defined by the downstream user(s).

Cons of submitting a new, initial application instead of relying on the upstream review report include:

transitional arrangements do not apply. The biggest drawback by far is that no transitional arrangements apply for initial application for authorisation as they do for review reports that are submitted at least 18 months before the end of the review period; and

costs. The cost of applying for authorisation, especially in small groups or submitting individually, will likely be higher than relying on the upstream application for authorisation. The costs originate from the development of the authorisation dossier as well as the Echa fees, however, these can be mitigated if submitting a joint application for authorisation whereby all the applicants share the costs.

Transitional arrangements only apply to review reports and not to the initial applications for authorisation. Therefore, transitional arrangements reduce the risk of having to cease the use waiting for the decision of the initial application for authorisation.

'Downstream users should seriously consider applying for authorisation for their own uses, either individually or by forming groups'

However, recognising the drawbacks and mitigating the related effects by sharing costs and submitting initial applications for authorisations in good time, at least 24 months before the end of the review period of the upstream application, it could be argued that the benefits of an initial application outweigh the drawbacks. Therefore, downstream users should seriously consider applying for authorisation for their own uses, either individually or by forming groups for the purpose of a joint application for authorisation.

Brexit considerations

One additional twist to determining a sound strategy – whether to rely on a review report or to submit an own new, initial application for authorisation – is **Brexit** and its implications.

The next key Brexit date is 31 October, when the UK is scheduled to leave, and there is still no certainty on what kind of exit deal will be agreed.

If companies are a UK downstream user, currently relying on an upstream authorisation where the authorisation holder is located in the EU-27/EEA, the company will be covered until the end of the review period of that application.

However, it is still not entirely clear what will happen after that review period ends and whether the company will be covered by the (potential) upstream EU-27/EEA review report or not.

Furthermore, even if a downstream user will be (or can be) legally covered in the UK by an EU-27/EEA review report in the future, the upstream applicant must take UK socio-economic aspects into consideration in the review report. If not, it is likely that UK downstream users would not be covered by such review reports. Therefore, UK downstream users should consider submitting a new, initial, downstream user application for authorisation to mitigate risks and gain control over their use of the substance.

Therefore, the list of pros given above should also include the following (for UK downstream users):

in case of Brexit as a UK downstream user, companies should get coverage by an own authorisation post-Brexit, allowing the continued use of the substance in the UK after the review period of the EU-27/EEA application for authorisation is over.

The final outcome of Brexit will, of course, determine whether UK-REACH applications for authorisation need to be submitted or not and much of the practical details of UK-REACH authorisations are still not available and may change closer to the new **Brexit** deadline.

Conclusion

For those who require use of an **SVHC** to be covered by an authorisation, having an authorisation in place is usually a business-critical issue.

Taking into account the available information, in the case of being dependent on the re-application of the upstream applicant, the recommendation is to seriously consider applying for authorisation as a downstream user, either as a single or joint applicant, by analysing the benefits versus the drawbacks of such actions.

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

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