13 February 2012

AmCham EU position on the REACH authorisation and restriction processes

Executive Summary

The American Chamber of Commerce to the EU (AmCham EU) speaks for European companies of American parentage that invest in Europe and contribute substantially to European economic growth. We promote and are committed to a coherent and balanced approach to environmental legislation, based on sound science and the better regulation approach.

REACH has entered into a new phase with the application of the authorisation and restrictions processes and it is important to ensure that each of these processes are applied with full respect to the fundamental principles underlying these processes, such as sound science and due process.

In particular, it is important to ensure that the Authorisation and Restrictions processes under REACH, which represent different risk management options, are used alternatively, possibly successively, but not simultaneously, safe in exceptional circumstances.

Background

In January 2009, the European Chemical Agency (ECHA) organised a workshop on the Candidate List and Authorisation as Risk Management Instruments, which served to compare the respective merits of the different risk management options (RMO), including the Authorisation and Restrictions processes. The first recommendation made at the workshop was to ask ECHA to 'develop a "framework" for the analysis of the best RMO option (authorisation, restriction, other RMO, or combination)'. To the best of our knowledge, this work remains to be done.

With the first authorisation processes having now been instigated, it is important that ECHA and the European Commission adopt the necessary policies to ensure that RMO are selected and applied consistently and in such a way that each process is applied in full respect of its fundamental underlying principles, including those of sound science and due process.

In particular, AmCham EU is concerned about the possible overlap and duplication that may result in the simultaneous application of the Authorisation and the Restriction processes for the same substances and requests the European

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Commission to fully analyse this situation and adopt a policy that ensures due process.

Interface between restrictions and Authorisation

REACH contains several articles that address the relationships between the Authorisation and the Restriction processes (articles 56(1); 58(5); 58(6); 60(6) and 69(2)) and it is important that these articles are interpreted and applied in such a way that ensures legal certainty and prevents duplication and overlaps.

AmCham EU is particularly concerned about the application of article 58(6) of REACH. This article indeed allows new restrictions for substances subject to Annex XIV if limited to the risks to human health or the environment from the 'presence' of those substances in articles. But this article has to be read and applied in conjunction with articles 58(5) and 69(2), which seek to prevent duplicative processes.

In particular, article 69(2) specifies that the ECHA must consider the risks from authorised substances (after their sunset date) and should prepare an Annex XV dossier only if the risk of their use in articles is not adequately controlled. This provision would have no effect if a restriction should be adopted before the Authorisation process is completed for the same substances.

AmCham EU is also particularly concerned that a prior decision in the Restriction process may prevent companies from having their authorisation requests duly considered. Indeed, pursuant to article 60(6) of REACH, a use shall not be authorised if this would constitute the relaxation of a restriction set out in Annex XVII. For all uses that would be restricted, therefore, no authorisations could be granted.

In addition, an adopted restriction would have a determinative influence on the final outcome of the authorisation process even for uses that would not be directly affected by the restriction. The adoption of a prior restriction would therefore *de jure* or *de facto* prevent the authorisation process to be carried out, a situation that would certainly trigger legal challenges, as well as confusion in the supply chain.

In AmCham EU's opinion, it would be much more effective and efficient use of the REACH processes -- and of available regulatory and industry resources -- to allow Authorisations to proceed (if Authorisatrion is the selected RMO) and to then put in place restrictions for non-authorised uses only if necessary in the conditions set forth in article 69(2) of REACH.

AmCham EU believes that article 58(6) should only be used in exceptional circumstances to avoid duplication of efforts, legal uncertainty and confusion in the supply chain, and suggests that the Commission elaborates a policy as to the circumstances that may justify the application of this article, such as for example, in case where restrictions must be adopted on articles containing

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Annex XIV listed substances that cannot wait for the completion of the Authorisation process.

Conclusion

To conclude, AmCham EU is concerned about the proper application of RMO under REACH and asks that ECHA and the Commission adopt a suitable policy that avoids unnecessary and damaging overlaps and duplications between several RMO, in particular the REACH Authorisation and Restrictions processes.

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AmCham EU speaks for American companies committed to Europe on trade, investment and competitiveness issues. It aims to ensure a growth-orientated business and investment climate in Europe. AmCham EU facilitates the resolution of transatlantic issues that impact business and plays a role in creating better understanding of EU and US positions on business matters. Aggregate U.S. investment in Europe totalled €1.4 trillion in 2009 and currently supports more than 4.5 million jobs in Europe.

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