REACH 관련 APEC 질의에 대한 EC측 회신 내용

□ 질의 1: 완제품의 한계치 농도 0.1%

[EC 회신]

ㅇ 화학물질의 한계치 농도 0.1%는 생산, 수입, 공급된 그 자체의 완제품에 대하여 적용하므로 완제품의 동질물질 또는 부품과는 무관함

□ 질의 2 : 고분자의 단량체 등록

[EC 회신]

ㅇ 고분자의 단량체 등록 관련 규정은 EU역내 제조자 및 수입자에게 동등하게 적용되며, EU역내 제조자에게만 부여하는 특혜는 없음

ㅇ 고분자 제조자가 민감한 비밀이라고 생각하는 정보보호와 관련하여, 수입자에게 제품 관련 정보의 유출 없이 EU의 요구사항을 준수하면서 시판할 수 있도록 유일대리인을 선임할 수 있도록 함

□ 질의 3 : 유일대리인

[EC 회신]

ㅇ 다수의 EU역외 제조자를 대리하는 유일대리인은 동일한 물질에 대하여 제조자별로 별개의 등록서류를 제출하는 것으로 최근 변경됨

ㅇ EU역외 화학물질 제조자가 자사의 물질을 혼합물, 고분자 또는 완제품을 생산하는 EU역외 하위사용자에게 판매하고, 그 생산품들이 EU역내에 시판되는 경우, EU역외 화학물질 제조자는 유일대리인이 선임하여 등록서류에 화학물질을 다루도록 하였음

□ 질의 4 : ECHA 지불 비용 및 수수료

[EC 회신]

ㅇ 중소기업을 위한 감액혜택은 Commission Recommendation 2003/361/EC에

의거, 중, 소 또는 극소규모의 업체에 적용됨

ㅇ 유일대리인에 대한 감면도 동일한 정의를 적용하되, 직원수, 총매출, 대차대조표와 같은 기업평가 정보는 유일대리인을 선임한 EU역외 제조자의 것임. 즉, 유일대리인의 감액대상 해당여부는 유일대리인을 선임한 EU역외 제조자의 직원수, 총매출 및 대차대조표를 평가하여 결정됨

□ 질의 5 : 공급망내 정보교류 및 후보목록의 화학물질 포함

[EC 회신]

ㅇ 후보목록의 물질로 포함되는 것은 부속서 XIV의 물질에 포함되는 사전절차에 해당되며, 부속서 XIV의 물질은 허가 없이 시판하거나 사용할 수 없으나, 후보목록의 물질은 별도 허가 없이 시판하거나 사용할 수 있음

ㅇ 공급망내 정보교류 관련 세부요건은 아직 수립되지 않았으며, 업체가 시장 및 공급망의 특성에 가장 적합한 모델을 선택할 수 있음

□ 질의 6 : SIEF 및 협력체 활동

[EC 회신]

ㅇ 동일물질을 사전등록한 업체는 공동 제출을 위한 준비를 같이 하도록 하고 있으므로 동일물질을 사전등록한 모든 업체가 SIEF의 일부가 됨. SIEF 활동은 강제성을 지니며, 동일물질에 대한 특정 사전등록 업체의 참여를 배제하는 SIEF는 REACH 위반임

ㅇ 협력체 구성을 규정하지 않고 있으므로, 이와 관계된 활동은 자발적이며 사전협력체도 마찬가지임. SIEF 구성 전의 협력체/사전협력체의 활동 및 정보는 SIEF에서 공유하여야 하며, 이러한 정보는 협력체/사전협력체에 참여하지 않은 사전등록자도 접근가능하게 될 것임

첨부 : APEC측 질의서, EC측 회신

APEC CHEMICAL DIALOGUE
QUESTIONS RELATED TO THE EUROPEAN COMMISSION REGARDING REACH IMPLEMENTATION

At its February 23-24, 2008 session in Lima, Peru, the APEC Chemical Dialogue Steering Group agreed to develop a series of questions outlining areas of concern and ongoing questions related to the European Commission's ongoing efforts to implement the REACH (**R**egistration, **E**valuation, **A**uthorization and Restriction of **Ch**emicals) regulation. The following questions address the six areas of concern identified by the Steering Group.

1. The European Commission's draft guidance on substances in articles (REACH Implementation Project (RIP) 3.8) included a 0.1% threshold for substances present in an article, applied to the article as a whole in the form imported or manufactured. However, at their December 19-20, 2007 meeting, some Member State Competent Authorities apparently expressed a negative view of the 0.1% threshold for substances in articles.

   Can the Commission clarify that the guidance included in the last RIP 3.8 draft guidance document represents the current position on the applicable threshold? Can the Commission also clarify when the final RIP 3.8 guidance document will be issued?

2. Under the REACH regulation, monomers from which polymers are manufactured or imported into the EU must be registered, even though the monomers are not on the European market. EU polymer producers will have relatively easy access to information on monomers, since the monomers will already be registered under REACH by their respective manufacturers. For non-EU interests, however, the situation is quite different. Polymer importers will be required to determine the monomeric composition of the polymer, and may have considerable difficulty in obtaining that information in light of the interests non-European monomer manufacturers have in safeguarding their trade secrets and confidential business information. Similarly non-EU polymer manufacturers have to disclose the monomeric composition and some related confidential information of their polymers to their EU importers. Non-EU polymer manufacturers may not have any control over who imports their products into Europe. In short, non-EU polymer manufacturers may face a considerable regulatory and business disadvantage compared to makers of EU-origin polymers. Also, while registration of monomers in EU-manufactured polymers may be justified by human health or environmental exposure to the monomers, there is no exposure to the monomers in imported polymers in the EU.

   Will the Commission provide additional guidance to non-EU polymer and monomer manufacturers, and EU polymer importers, on compliance with the REACH monomer registration requirement? Can the Commission clarify how it might address this disadvantage beyond guidance (e.g., an amendment to REACH)?

3. The REACH regulation and subsequent guidance from the Commission on Only Representatives have raised considerable uncertainty and practical concerns. While the Commission's response to comments on registration guidance (RIP 3.1) makes clear that a particular Commission concern is the ability of an Only Representative to accurately aggregate import volumes for the

purposes of a single registration, the scope of Only Representative services remains unclear. For example, it is not clear that a non-EU manufacturer of a monomer or a substance in a preparation sold to another non-EU entity, which subsequently manufactures and exports a polymer or preparation to Europe, can appoint an Only Representative to represent all importers of the preparation or the polymer.

In addition, Section 1.5.3.4 of the guidance on registration indicates that an Only Representative is obliged to submit a single registration representing the total volumes of all non-Community manufacturers he or she represents. This interpretation, however, appears to run counter to the Commission's February 2008 response to comments on registration guidance, in which the Commission indicated that it would not interfere with the right of an Only Representative to enter into appropriate contractual arrangements, as it has the effect of forcing all non-EU manufacturers who happen to use a single Only Representative to provide a single registration, even though the interests of those manufacturers may differ significantly. We understand that recently, representatives of the Commission indicated that an Only Representative must submit an individual registration for every non-EU manufacturer he represents. To date, however, this clarification has not been officially published, and it is not clear what modifications may be made to RIP 3.1, Section 1.5.3.4 as a result. Further, as the Commission is surely aware, many article importers are insisting that their non-EU suppliers certify compliance to the REACH regulation, even in cases where those suppliers do not themselves do business in Europe.

Will the Commission provide additional detailed guidance on the appointment and use of Only Representative services by non-EU entities? In particular, will the Commission further clarify that non-EU distributors, trading companies, and other non-manufacturing entities have no legal obligations or right to appoint an OR under REACH to the extent that they are not importers into Europe?

4. The Commission recently made final its regulation on the fees to be assessed on REACH registration and authorization applications. In this Commission Regulation (EC) No. 340/2008, April 16, 2008, it appears that the term "size" (relative to the potential reduction in fees for SMEs) has changed to the word "reference," and indicates that potential fee reductions shall be determined by reference to the relative headcount, turnover and balance sheet information of a non-Community manufacturer, formulator of a preparation of the non-Community manufacturer, formulator of a preparation, or a producer of an article that is represented by an Only Representative. It is not clear, however, what the Commission means by the term "reference" in this context, as the material quotes Recommendation 2003/361/EC.

Will the Commission further clarify the meaning or definition of "reference" for the assessment of fee reductions for SMEs?

5. It is readily apparent that REACH is having significant distortive effects in global supply chains, particularly as customers attempt to determine whether the products of their suppliers comply with REACH requirements. In many global supply chains, customers are insisting that their suppliers (even if they are not legally obliged to comply with REACH as they are not manufacturers or importers otherwise subject to the regulation) certify compliance with REACH. This effect is all the more remarkable as REACH does not require such certification from

suppliers. In product chains that rely on globally sourced components, such as automotive and electrical products, it is a significant challenge to obtain REACH-relevant information – especially from non-EU entities not otherwise subject to the regulation. In addition to RIP 3.5, several other organizations have developed or are developing guidance on communications through the supply chain, some of which may be inconsistent across different industries or sectors.

The approach to the nomination of substances for the candidate list is another area of concern, as the formation of this list has profound implications for the composition of global supply chains, since manufacturers may feel forced to de-select substances from the articles they produce once these have been named to the candidate list, even if the Commission clarifies that appearing on the candidate list is not itself intended to be a regulatory action.

Will the Commission consider developing guidance on supply chain communications to minimize the potential for unnecessary burden and distortion? Further, will the Commission clarify the methodology used for nominating substances to the candidate list, and specify that naming a substance to this list is not intended as a regulatory/political action?

6. Although REACH does not impose direct requirements for the formation and operation of consortia that may support work in Substance Information Exchange Forums (SIEFs), it is apparent that considerable work is already underway in Europe regarding "pre-consortia" activities. These activities are not transparent to non-EU entities and the ability to participate (or not) in pre-consortia can be a potentially significant competitive issue. **Will the Commission clarify how it intends to assure transparency in pre-consortia activities that may be of interest to non-EU entities, and how it will assure appropriate access to such efforts for all interests?**

APEC CHEMICAL DIALOGUE – QUESTIONS ON REACH

The answers given below do not constitute an official position of the European Commission. The views expressed below are also without prejudice of the interpretation that could be given by the European Court of Justice.

1. Concentration threshold for articles.

The guidance of substances in articles is already available from ECHA's website (http://reach.jrc.it/docs/guidance_document/articles_en.pdf). The guidance states that the substance concentration threshold of 0.1 % (w/w) applies to the article as produced, imported or supplied and that it does not relate to the homogeneous materials or parts of an article, as it may in some other legislation.

The guidance is intended to assist stakeholders in the understanding of their obligations under REACH. Nevertheless, we note that only the text of the REACH Regulation is legally binding and that the interpretation of Community legislation lies with the European Court of Justice.

2. Registration of monomers in polymers.

Article 6, which requires the registration of monomers in polymers under certain conditions, applies equally to manufacturers and importers established in the EU. There is not any more favourable treatment granted to manufacturers established in the EU.

Guidance on the interpretation of the obligation to register monomers in polymers is available from ECHA's website:
(http://reach.jrc.it/docs/guidance_document/polymers_en.pdf).

Regarding the concerns expressed in your note about the protection of information that manufacturers of polymers may regard as sensitive confidential information, REACH provides for the possibility to appoint an only representative so that manufacturers established outside the EU can make sure that the products they sell in the EU comply with the EU requirements without having to disclose information about their products to the importers.

3. Only representatives.

The section on only representatives in the Guidance on Registration has been recently updated. The update explains the principle that an only representative acting on behalf of more than one non-EU manufacturer must submit separate registration submissions for the same substance. A new update will be published soon and will explain the possibility for a non-EU manufacturer of a substance that is sold to a downstream user outside the EU to make a preparation, a polymer, or an article that is later sold in the EU to cover also those substances in the registration dossier submitted by his only representative.

We note that the appointment of an only representative is not an obligation, but a facility. The REACH Regulation is worded in very clear terms: the obligation to register falls upon manufacturers and importers that are established in the EU. Also the Guidance on Registration is very explicit in this regard:

> 'The *"non-Community manufacturer"* or supplier who is exporting a substance or preparation has no responsibilities under REACH.' (section 1.5.3.3)

4. Fees and Charges payable to ECHA.

The reduction for SMEs applies to all entities that are medium, small, or micro companies within the meaning of Commission Recommendation 2003/361/EC. Further information on how to assess whether a specific company is an SME can be found at the SME User Guide (http://ec.europa.eu/enterprise/enterprise_policy/sme_definition/sme_user_guide.pdf.)

Regarding the application of the SME reduction to only representatives, we note that the same definitions apply. However, the headcount, turnover, and/or balance sheet information that must be considered for the purposes of assessing the SME status are those of the non-EU manufacturer that is being represented by the only representative. Specifically, the section on Questions and Answers on the Regulation on Fees and Charges (http://europa_eu.staging.entr.cec.eu.int/enterprise/reach/reach_fees_en.htm), explains that:

> If you are an only representative, the determination of whether the SME reduction applies to your submission should be done by reference of the headcount, turnover, and/or balance sheet information of the non-EU manufacturer that you represent.

5. Communication of information down the supply chain and inclusion of substances in the "candidate list".

Substances of very high concern will be identified and included in the candidate list according to the procedure established in Article 59 of the REACH Regulation. The inclusion of a substance in the candidate list is a pre-requisite for the inclusion of a substance in Annex XIV. If the substance is included in Annex XIV, it may not be used or placed on the EU market unless an authorisation has been granted. Substances that are in the candidate list may, however, be marketed and used in the Community without any authorisation.

It should be pointed out that the process to identify a substance as a substance of very high concern and to include it in the candidate list allows for comments of any interested third party, including third country stakeholders. The opportunities to comment are set out in the REACH Regulation (Title VII, Chapter I). The draft guidance on inclusion of substances in Annex XIV has been finalised and should be handed over to ECHA and published shortly. Moreover, the Guidance for the Competent Authorities on to the preparation of Annex XV dossiers is already publicly available at ECHA's website: (http://reach.jrc.it/docs/guidance_document/svhc_en.pdf).

Regarding models of communication down the supply chain, REACH has not established specific requirements. Consequently, companies are free to choose the model that best fits the characteristics of the market and supply chain at stake.

6. SIEFs and (pre-)consortia activities.

REACH requires that companies that pre-register the same substance work together to prepare a joint submission. Specifically, all companies that pre-register the same substance are part of the same substance exchange information forum (SIEF) under REACH. This is mandatory and therefore any SIEF that excludes the participation of a pre-registrant of the same substance would be in breach of REACH.

REACH does not regulate the formation of consortia; any such activity is a voluntary action that is not regulated under REACH. The same goes for pre-consortia. However, we note that work that may have been developed in a consortium or a pre-consortium before the SIEF is formed will be part of the information that must be exchanged within the SIEF and, consequently, would also be accessible to pre-registrants that did not participate in the consortium (or pre-consortium).