Next step on REACH – How the non-EU manufacturers and suppliers should prepare
非歐盟製造商和供應商應如何作出準備

Video-conference 25 March 2009

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ECHA Working plan 2009-12
歐洲化學品管理局的工作計劃（09 –12年）

- List of pre-registered substances published
  已公佈成功進行預註冊的化學物質表
- Recommendations for substances subject to authorisation 物質授權的建議
  - 14 January draft proposal out for comments
    於一月十四日提供草擬建議書作公眾諮詢
  - 14 April close of comments
    諮詢期於四月十四日結束
  - 1 June proposal to Commission
    於六月一日向委員會提交建議書
- CLP regulation enters into force 20 January
  《分類、標籤及包裝》法規於本年一月二十日正式實施
  - First proposals for harmonised CLP
    公佈第一份有關分類、標籤及包裝建議書
- Title VIII Restrictions enters into force 1June (but takes over restrictions from old legislation)
  目錄八內的限制物質將於在六月一日生效(將取代舊有指令)

ECHA Working plan 2009-12
歐洲化學品管理局的工作計劃（09 –12年）

- Registration of non-phase-in substances
  為非現存物質進行註冊
  (200-400 expected annually) 大約每年200-400種物質
- Preparing for first registration deadline 30 November 2010
  準備首次的註冊期限 - 2010年11月30日
- Manufacturer or importer may make a late pre-registration for a substance manufactured or imported by a company for the first time after 1 December 2008
  於2008年12月1日後，製造商或入口商可為首次製造或入口的物質進行 “Late pre-registration”

ECHA Working plan 2009-12
歐洲化學品管理局的工作計劃（2009–12）

- Establish a C and L inventory (建立分類及標籤資料庫)
- Notification from industry to the inventory by 1 December 2010 of
  (2010年12月1日前，商戶應為以下物質進行通報)
  - All substances subject to registration (所有已進行註冊的物資)
  - All other substances classified as dangerous (已列入為危險的物質)
- Dossier evaluation starts, peak 1 after 1 Dec 2010
  (審查技術檔案會在2010年12月1日後開始實施)
  - Testing proposals (測試建議)
  - Compliance checks (守法檢查)
- First Community Rolling Action Plan for Substance Evaluation 1 December 2011
  (第一個歐盟物質評估實行計劃將於2011年12月1日公佈)
- From 1 June 2011 obligation to notify SVHC in articles
  (含有高度關注物質的成品有責任在2011年6月1日後進行通報)

Authorisation process – steps
受權的程序

1. Identification of Substances of very high concern
   界定高度關注物質(SVHC)
2. Inclusion in Candidate list (物質會被列入為候選名單)
3. Draft Recommendation on Priority substances for authorisation (優先考慮列入授權物質的建議草案)
4. Commenting period (3 months, 1st round until 14 April)
   公眾咨詢期 (3個月，第一階段訴本年4月14日結束)
5. ECHA Recommendation to Commission
   歐洲化學品管理局向歐盟委員會提供建議
6. Commission decision = inclusion in Annex XIV
   歐盟委員會進行表決，將被建議物質納入附件14之內
   - application date (申請日期)
   - sunset date (結束日期)

Information obligations

From the **date of inclusion** on the Candidate list of Substances identified as being of Very High Concern (SVHC),

Information Obligations regarding the use of these substances in articles **come into force**

當物質被列入為候選高度關注物質名單，其製造商或入口商已有責任提供該物質在其成品的使用資料

1st list containing 15 substances adopted 28 October 2008

2008年10月28日已有15種物質被列入為高度關注物質

Information obligations

Any supplier of an article which contain substances on the Candidate List in a concentration above 0.1% (w/w) have to provide sufficient information, available to them,
如成品內含有的物質是已被列入為候選名單內，而該物質按重量比例計算濃度高於 0.1% ，該製造商或入口商有義務提供所足夠的資料給：

- to the recipients (professional and industrial users, distributors) and
要求者(專業和工業用戶、分銷商)
- on request, to a consumer - free of charge - within 45 days of the receipt of the request
因應要求在45天內向要求者免費提相關資料

This information must ensure safe use of the article including as minimum the name of the substance.
提供的資料要確保成品能被安全使用，而該資料至少要包括物質的正確名稱。

Other obligations for substances in articles linked to the Candidate list
含有被列入候選物質的成品之其他責任

As from 2011 *Notification of substances in articles*
(2011年要為物質進行通報)

- Art. 7(2) – **notification** of SVHC substance in an article is required if both two following conditions are met:
(第7(2)章－成品內的高度關注物質如符合以下兩個條件，須完成通報方可進入歐盟)
  - The substance is present in those articles in quantities totalling over one tonne per producer or importer per year (物質每年入口超過1噸或以上)
  - The substance is present in those articles above a concentration of 0.1% w/w (物質按重量比例計算，濃度高於 0.1%)
    - For substances included in the candidate list before 1 December 2010 the notifications have to be submitted not later than 1 June 2011 (如物質已在2010年12月1日前已被列入在候選名單內, 那物質通報程序必須在2011年6月1日前完成)
    - For substances included on the candidate list on or after 1 December 2010 the notifications have to be submitted no later than 6 months after the inclusion (如物質在2010年12月1日後才被列入在候選名單內, 該物質必須在6個月內完成通報的程序)

Obligations linked to the candidate list
被列入候選名單的物質之責任

- A notification is **not required** when
通報是不需要，當:
  - The producer or importer of an article can exclude exposure of humans and the environment during the use and disposal of the article. In such cases, the producer or importer shall, however, supply appropriate instructions to the recipient of the article
(成品的製造商或入口商能排除該成品在使用和棄置時，不會接觸人類和環境。製造商或入口商需提供使用指引)
  - The substance has already been registered for that use up the same supply chain or any other supply chain
(物質已完成註冊的程序，而其資料已於該供應鏈或任何供應鏈流通)

To sum up
總結

- Obligations for supplying (提供資料的責任)
  - the (professional) recipient of an article (成品的用戶)
  - a consumer, on request free of charge, within 45 days of the receipt of the request
(在45天內免費提交該物質的相關安全數據表給對該成品作出提問仁的人士。)

  with information on certain hazardous substances in articles have been in force since 28 October 2008 in the EU
(必須提供有害物質資料的要求已於2008年10月28日在歐盟生效)
- The obligation applies to imported articles as well as those manufactured within the EU
(入口商或製造商必須遵行以上的責任和義務)

How to identify a SVHC in an article
怎樣於成品內找出高度關注物質

REACH does not specify how to find out if an article contains a SVHC
(REACH法規沒有清楚列明應如何在成品內找出高度關注物質的方法)

- If a well functioning supply chain, information on the occurrence should be possible to get via documentation from the different production steps
(如供應鏈運作良好，物質資料可從不同的供應商獲得)
- In some cases it might be easier to analyse the article, e.g. if complicated supply chain.
(在某些情況下可更容易獲得成品內的物質資料，例如：在複雜的供應鏈)

ECHA contacts with countries outside the EU (歐洲化學品管理局與歐盟以外的國家聯絡)

- No official links to non EU countries
(與非歐盟國家沒有正式的官方聯繫)
- ECHA Helpdesk important contact point
(ECHA的咨詢平台是重要的聯絡方式)
- ECHA Website
(ECHA的官方網站)
- In certain cases meetings with ECHA or ECHA makes presentations for larger audiences in other countries
(與ECHA的會面或在不同的國家進行大型演講)
- The Commission delegation one contact point
(該委員會的代表團也是一個重要的聯絡點)