



ที่ พณ 0304 / ว ๕๗

ถึง สำนักงานมาตรฐานผลิตภัณฑ์อุตสาหกรรม

กรมการค้าต่างประเทศขอแจ้งสถานะล่าสุดของการดำเนินการของสหภาพยุโรป ภายใต้ระเบียบ REACH ตามที่ได้รับรายงานจากสำนักงานพาณิชย์ในต่างประเทศ ณ กรุงบรัสเซลส์ มาเพื่อทราบว่า ภายหลังจากที่ ECHA ได้เสนอปรับปรุงข้อกำหนดเกี่ยวกับ Only Representative (OR) สำหรับผู้ประกอบการนอก EU ในการจดทะเบียนสารเคมีตามระเบียบ REACH ใน 3 ประเด็นหลัก คือ 1) เพิ่มความชัดเจนว่า OR ไม่มีความจำเป็นต้องแต่งตั้ง Third Party Representative 2) เพิ่มความชัดเจนในเรื่องปริมาณสารเคมีที่ครอบคลุมในเพิ่มข้อมูลการจดทะเบียน และ 3) เงื่อนไขกรณี OR จะได้รับประโยชน์จากการจดทะเบียนสารเคมีล่วงหน้าช้ากว่ากำหนดสิ้นสุดระยะเวลาสุดท้าย และเมื่อวันที่ 26 พฤศจิกายน 2551 ECHA ได้ประชาสัมพันธ์ให้ทราบว่า ขณะนี้ได้มีการปรับรายละเอียดข้อกำหนดเกี่ยวกับ OR ตามข้อเสนอทั้ง 3 ข้อข้างต้นและปรากฏในคู่มือการจดทะเบียนเรียบร้อยแล้ว นอกจากนี้ ECHA ได้รวบรวมคำตอบสำหรับคำถามที่มักเป็นข้อกังวลและถูกถามบ่อยในเว็บไซต์มาให้ผู้ที่เกี่ยวข้องรับทราบ รายละเอียดดังเอกสารแนบ

ทั้งนี้ สามารถศึกษารายละเอียดเพิ่มเติมของข้อกำหนด OR ได้ที่ เว็บไซต์ http://reach.jrc.it/docs/guidance_document/registration_en.htm และรายละเอียดของหัวข้อคำถาม – คำตอบ ได้ที่ เว็บไซต์ http://echa.europa.eu/reachit/reachit_faqs_en.asp



สำนักมาตรฐานการทางการค้า

กลุ่มวิเคราะห์มาตรการอื่นๆ

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News Alert:

ECHA/PR/08/50

Helsinki, 25 November 2008

RAPID RESPONSE SERVICE - FREQUENTLY ASKED QUESTION No. 4

ECHA has noted an inaccuracy in the News Alert of 20 November (ECHA/PR/08/47) in the answer to the question 4. The correct answer is below and the original News Alert on the ECHA website has been corrected.

4. Do I have to pre-register a substance previously notified in accordance with Directive 67/548/EEC by other manufacturers?

A notification under Directive 67/548/EC is nominal so that only the notifier benefits from being considered registered. Any other parties manufacturing or importing the substance but who have not notified it, do have (pre)registration obligations unless they may benefit from one of the exemptions in the REACH Regulation.

Previously notified substances are non-phase in substance under REACH. You do not need to pre-register them but you have to inquire and then submit a registration dossier as soon as the quantity of the substance manufactured or imported reaches 1 tonne per year.

For more information on notified substances we would like to refer you to section 6.3.6 of the Frequently Asked Questions on REACH:

http://echa.europa.eu/reach/faq_en.asp

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News Alert:

ECHA/PR/08/49

Helsinki, 24 November 2008

25 November 2008 (Revised text is highlighted)

RAPID RESPONSE SERVICE - FREQUENTLY ASKED QUESTIONS ON REACH AND PRE-REGISTRATION

In addition to the questions highlight in the News Alert of 19 November (ECHA/PR/08/47) ECHA has identified further 7 commonly asked questions for which answers are already available on the ECHA website. During the first week, the rapid response service has answered almost 900 questions. This special service for pre-registrants will be available until 1 December.

1. Can I pre-register on paper, via e-mail or through the Information request web forms on ECHA's website?

Unfortunately, the European Chemicals Agency cannot accept pre-registrations on paper, by e-mail or through the information request web forms on ECHA's website.

In accordance with Article 111 of Regulation (EC) No 1907/2006 the European Chemicals Agency specifies and makes available the formats that can be used by Member States, manufacturers, importers, distributors, or downstream users in their submissions to the Agency. The format for the submission of pre-registrations specified by the Agency is REACH-IT. Therefore, the only channel which can be used for pre-registering a phase-in substance is the REACH – IT system. REACH-IT is a web-based application.

To pre-register, you have to sign up to the REACH-IT portal on the ECHA website at:

http://echa.europa.eu/reachit/portal_en.asp

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5. One of our pre-registration was submitted, but it is not on ECHA's intermediate list of pre-registered substances. Why?

We would like to clarify that the published list is only an intermediate list of pre-registered chemical substances. ECHA decided to release this intermediate list as an additional service to allow Downstream Users of chemicals a possibility to determine whether substances of their interest are already pre-registered. As required by Article 28 of the REACH Regulation the final list will be published by 01 January 2009. The list will comprise all phase-in substances pre-registered within the time period starting on 1 June 2008 and 01 December 2008.

Your substances might be missing from the intermediate list of pre-registered substances as some submissions required further examination by the Agency and potentially, clarification by companies.

6. Do I have to pre-register a substance that has already been pre-registered by another party?

In accordance with Art 6(1) of REACH, a registration shall be submitted to the Agency by all manufacturers or importers established in the European Community for all substances they manufacture or import in quantities of 1 tonne or more per year (unless they are explicitly exempted from the scope of registration by other provisions of the Regulation).

7. What documentation will I need to provide to the REACH Enforcement Authorities to prove my manufacturing/importation tonnage?

In accordance with Article 125 and Article 126 of the REACH Regulation the enforcement of the REACH Regulation lies in the remit of the Member States. Therefore we would suggest that you contact the relevant national authorities of your EU distributors:
http://echa.europa.eu/reach/helpdesk/nationalhelp_contact_en.asp

Further Information

ECHA website: http://echa.europa.eu/reachit/portal_en.asp

REACH Guidance documents: http://reach.jrc.it/guidance_en.htm

Frequently Asked Questions on REACH: http://echa.europa.eu/reach/faq_en.asp

Pre-registration Q&A: http://echa.europa.eu/doc/pre-registration/pre_reg_qa_en.pdf

REACH-IT portal: http://echa.europa.eu/reachit/portal_en.asp

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2. How do I pre-register a substance if I cannot find this substance in EINECS?

We advise you to first verify the phase-in status of your substance as defined in Article 3(20) of the REACH Regulation, since only phase-in substances can be pre-registered.

You can find more information on this issue in Section 1.7 of the *Guidance on registration*

http://reach.jrc.it/docs/guidance_document/registration_en.htm

In case your substance fulfils the definition of phase-in substance, you can pre-register it by using CAS number and CAS name or only its chemical name.

More information is available in Section 1.36 and 1.37 in the Pre-registration Q&A document at

http://echa.europa.eu/doc/pre-registration/pre_reg_qa_en.pdf.

3. I manufacture and import the same substance. I signed up in REACH-IT as a company and pre-registered the tonnage of my substance I manufacture. How can I now pre-register the same substance as importer?

If your company consists only of one legal entity you shall sign up in REACH-IT only one time and when submitting the pre-registration add up the tonnages manufactured and imported when determining the tonnage band and the registration deadline.

In case you decide not to add up the tonnage of the manufactured and imported substance, you may sign up in REACH-IT as company twice. In that case it is not possible to use the same Legal Entity Object (LEO) having the same company UUID for multiple accounts, but you may use the same company identification information (name, VAT, address, etc.). You may consider adding a numerical or other identifier to your company name when signing up in REACH-IT, to facilitate the management of different legal entity accounts.

4. Do I have to pre-register a substance previously notified in accordance with Directive 67/548/EEC by other manufacturers?

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For more information on notified substances we would like to refer you to section 6.3.6 of the Frequently Asked Questions on REACH:

http://echa.europa.eu/reach/faq_en.asp

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News Alert:

ECHA/PR/08/47

Helsinki, 20 November 2008

RAPID RESPONSE SERVICE - FREQUENTLY ASKED QUESTIONS ON REACH-IT AND PRE-REGISTRATION

From 17 November until 1 December 2008, the ECHA Helpdesk is offering a rapid response service to provide enhanced assistance to companies located in the EU/EEA that still intend to pre-register (see News Alert ECHA/PR/08/44). During the two first days, ECHA has received over 500 questions. About half of them are related to REACH-IT. ECHA would like to inform pre-registrants that answers are already available on the ECHA website to some of the questions companies are asking the helpdesk.

The answers to the questions below can be found in the REACH-IT Frequently Asked Questions document or in other documents available on the ECHA website.

Where is my submission/pre-registration number?

If the bulk pre-registration file that a company has submitted complies in format, structure and content with the requirements, **the date of submission is the pre-registration date recognised by REACH-IT**. If the bulk pre-registration file fails, the company is informed by REACH-IT within 3 hours, and must submit a new file for which it will receive a pre-registration date.

For further information please refer to the *REACH-IT FAQ Question 29*. It explains in detail where and when a submission or pre-registration number is sent to the pre-registrant.

How do I modify or delete a pre-registration?

Please refer to the *REACH-IT FAQ Question 19*. It explains in detail how a pre-registration can be deleted and how submitted data such as tonnage band can be modified.

Why can't I perform several operations in the pre-SIEF section?

As mentioned in the *News Alert of 14 November 2008* (ECHA/PR/08/44) the implementation of the performance improvements in the REACH-IT system has required temporary discontinuity of several pre-SIEF functionalities. These functionalities will be available again from 2 December 2008. We apologize for any inconvenience the unavailability of the temporarily discontinued functionalities may cause.

We kindly encourage pre-registrants to take a look at the *Industry User Manuals* that are now available on the REACH-IT portal page of the ECHA website.

We would also like to remind companies that REACH-IT system performance will be constantly monitored and there will be status updates on the ECHA home page and on the REACH-IT portal page each working day until 1 December 2008.

Further Information

The REACH-IT FAQ document can be accessed at:

http://echa.europa.eu/reachit/reachit_faq_en.asp.

REACH-IT Industry User Manuals can be accessed via the REACH-IT portal page at:

http://echa.europa.eu/reachit/portal_en.asp

ECHA press releases and news alerts can be accessed via the Press Office page at:

http://echa.europa.eu/news/press_en.asp

ECHA home page:

http://echa.europa.eu/home_en.asp

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