Guidance on Scientific Research and Development (SR&D) and Product and Process Oriented Research and Development (PPORD)

I. Introduction

This document describes specific provisions under REACH for substances manufactured, imported or used in Scientific Research and Development (SR&D) and Product and Process Oriented Research and Development (PPORD). **Scientific Research and Development (SR&D)** is defined as any scientific experimentation, analysis or chemical research carried out under controlled conditions in a volume less than 1 tonne per year; **Product and Process Oriented Research and Development (PPORD)** is defined as any scientific development related to product development or the further development of a substance in preparations or in articles in the course of which pilot plant or production trials are used to develop the production process and/or to test the fields of application of the substance. Examples of PPORD activities include: (a) Development and testing of a new process for manufacture of a substance implying for instance innovative equipment or significant changes in the mass and heat transfer conditions; (b) Testing of new intermediate for synthesis of substance; and (c) Development and testing of new application for a substance.

II. Tasks and obligations

1. Scientific Research and Development (SR&D)

- Any substance defines as scientific research and development substance (manufactured or imported in a quantity of less than 1 tonne per year) does not need to be registered.
- The provisions on authorizations and restrictions of substances shall not apply to scientific research and development.
- Manufacturer/importer of substance for purpose of scientific research and development needs to notify to Agency its classification and labeling information if substance classifies as dangerous. And this has to be done by 30/11/2010 or as soon as he puts the substance on market.
- Suppliers of such substances might need to provide a safety data sheet or other relevant information to the users of the substance.

2. Product and Process Oriented Research and Development (PPORD)

2.1 PPROD in quantities below 1 tonne per year

Same Obligations as scientific research and developments (SR&D), but authorization and restriction are required to PPORD. When performing research with a substance, it is important to identify whether substance might have properties of very high concern (SVHC) as those substances might be subjected to authorization.

2.2 PPORD in quantities of 1 tonne per year or more

REACH specifies that substances manufactured/imported on their own or in preparation can be exempted from the duty to register for a period of 5 years. (Note: For exemption, submit PPORD notification to the Agency is required.) Exemption from registration for purpose of PPORD applies provided that manufacturer/importer/producer of articles carries out PPORD by himself or in co-operation with listed customers. In addition, REACH does not impose a limit on quantities of substance to be manufactured, imported, incorporated in articles or imported in articles, and provided quantities are limited to purpose of PPORD.

Notified and listed customers are therefore advised to consider the adequacy of such measures, and implement them accordingly. Again, when performing research with a substance, it is important to identify whether the substance might have properties of very high concern (SVHC) as those substances might be subject to authorization.

2.3 Manufacture/Import of a substance for PPORD

- Manufacturer/importer/producer of articles is exempted from obligation to register quantities of substance manufactured or imported for purpose of PPORD, by making a PPORD notification (the notification should be made by 16/5/2008 at the latest.). This notification may concern the informer's own PPORD or a PPORD conducted in co-operation with listed customers.

- The Agency may require manufacturer or importer of a substance to provide additional information necessary to set conditions, and manufacturer or importer should be complied with all conditions imposed. Noted that manufacturer or importer must provide his customer(s) with a safety data sheet (SDS) for substances classifying as dangerous and for substances subjecting to authorization. (If SDS is not required, supplier must provide his customer(s) with following information: (a) Registration number of substance, if available, (b) Any authorization granted or denied in his supply

chain, (c) Any restriction imposed, and (d) Any other available and relevant information about substance that is necessary to enable appropriate risk management measures to be identified and applied.

2.4 Downstream use of substances for PPORD

Obligations under REACH for a downstream user (DU) using a substance for purpose of PPORD may differ, depending whether or not the PPORD activity is covered by a PPORD notification:

- DU of a substance, who is listed as one of the selected customers with whom manufacturer or importer co-operates in a PPORD notification submitted by manufacturer or importer has to use the substance for purpose of PPORD and within any conditions set in accordance with Article 9(4) and communicated to him by his supplier. If DU stops using the substance for purpose of PPORD and ends the co-operation with his supplier, DU might need to register the substance or update his registration dossier for his substance.

- If DU intends to use a substance for PPORD without being listed as one of the selected customers in a PPORD notification, **he has the same obligations as any other DU.** DU would need to produce their own Chemical Safety Report (CSR) when a substance is used outside of the conditions in an exposure scenario communicated to him in a Safety Data Sheet (SDS) or used in a way his supplier advises against. Provided the risks to human health and environment are adequately controlled, DU is exempted from preparing a Chemical Safety Report for use under PPORD.

The DU of a substance for the purpose of PPORD had the same obligations under REACH as for any standard substance (General rules on information down supply chain may therefore apply).

III. PPORD Notification

Considerations before making a PPORD notification

- Prior to an eventual submission of a PPORD notification for a substance to the Agency, potential PPORD informer needs to figure out whether the activity he carries out alone or in co-operation with listed customers within the scope of definition of product and process oriented research and development.

- It is important to figure out whether the substance is effectively handled in reasonably controlled

conditions for protection of human health and environment.

- It is useful to take following considerations into account:
  - **a.** Is the substance effectively manufactured and used for purpose of PPORD?
    - What are the objectives of the research program?
    - What is the scale of program: who will be exposed to the substance?
  - **b.** What are the conditions for manufacture, use and disposal of substance?
    - What is the process?
    - Information regarding any treatment of wastes and waste disposal practices for all potential waste streams.
  - **c.** What is the research program?
    - Description of the program including timelines and quantities used

The above considerations should make it easier for PPORD informer and his listed customers to comply with most of the conditions that the Agency may impose.

PPORD notification dossier

1. Information requirements

The manufacturer/importer/producer of articles must notify the Agency of his intention to carry out PPORD by himself or in co-operation with listed customers on a substance. For that purpose, the informer has to submit an electronic notification providing the Agency with the following information:

- Identity of the manufacturer/importer/producer of articles as specified in section 1 of Annex VI;
- Identity of substance, as specified in section 2 of Annex VI;
- Classification of substance as specified in section 4 of Annex VI, if any;
- Estimated quantity as specified in section 3.1 of Annex V: the information to be submitted consists of estimated quantity of the substance to be manufactured or imported for purpose of PPORD for the calendar year of the notification.
- List of customers with which PPORD co-operation is carried out, including names and addresses.

2. Preparation of the PPORD notification dossier, IT submission and invoicing

In practice, a PPORD notification dossier can be prepared either on-line through the Agency website (REACH-IT) or using IUCLID 5. Notification prepared through REACH-IT only allows the informer to submit the information requested in Article 9(2); while notification prepared using IUCLID 5 allows more flexibility, and the possibility to attach additional information to dossier, where informer so wishes. And once notification submitted to the Agency, the Agency will issue a submission number and an invoice for notification (invoice will contain the reference number to be quoted for the payment).

3. Using IUCLID 5

A PPORD notification dossier can be elaborated with the IUCLID software (International Uniform Chemical Information Database). It is possible to select the appropriate REACH template (REACH PPORD) in which the sections to be filled in for fulfilling the minimum requirements for a PPORD notification are highlighted. it is however possible for the informer to also report in the PPORD notification dossier any additional information on the substance.

4. Completeness check

The Agency shall undertake a completeness check of the notification within 2 weeks of the submission date. Completeness check verifies whether all required information has been submitted and payment of fee has been received. If notification dossier is incomplete and/or fee payment is missing, the Agency shall inform registrant before expiry of 2-week period. Noted that if information submitted to the Agency within the set deadline is still not complete, the Agency shall reject the notification (this also applies when fee is not received within that deadline).

Only once the notification is complete, the Agency shall assign a notification number to the notification and a notification date. The manufacture or import of the substance may start at the earliest two weeks after the notification date.

5. Fees

Fees for notification of a substance shall be specified at latest one year after entry into force of REACH.

6. Confidentiality

The Agency and the competent authorities of the Member States concerned shall always keep confidential any information submitted by the manufacturer, importer or downstream user. Such

information shall therefore not be published in the Internet, and requests for access to that information will not be granted.

For more information, please visit:

http://www.echa.europa.eu

http://www.gma.org.hk

Date of issue: February 2008