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

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LEGAL NOTICE

This document contains guidance on REACH explaining the REACH obligations and how to fulfil them. However, users are reminded that the text of the REACH regulation is the only authentic legal reference and that the information in this document does not constitute legal advice. The European Chemicals Agency does not accept any liability with regard to the contents of this document.

PREFACE

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). It is part of a series of guidance documents that are aimed to help all stakeholders with their preparation for fulfilling their obligations under the REACH regulation. These documents cover detailed guidance for a range of essential REACH processes as well as for some specific scientific and/or technical methods that industry or authorities need to make use of under REACH.

The guidance documents were drafted and discussed within the REACH Implementation Projects (RIPs) lead by the European Commission services, involving all stakeholders: Member States, industry and non-governmental organisations. These guidance documents can be obtained via the website of the European Chemicals Agency (http://echa.europa.eu/reach_en.html). Further guidance documents will be published on this website when they are finalised or updated.

CONTENTS

1 INTRODUCTION

1.1 Research and development activities under REACH

Scientific research and development means *any scientific experimentation, analysis or chemical research carried out under controlled conditions in a volume less than 1 tonne per year* (Article 3(23)).

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, on its own, 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* (Article 3 (22)).

Any scientific development on a substance consisting of, for example, campaign(s) for the scaling-up or improvement of a production process in a pilot plant or in the full-scale production, or the investigation of the fields of applications for that substance, falls under the definition of PPORD irrespective of the tonnage involved.

Examples of PPORD activities include:

- Development and testing of a new process for the manufacture of a substance, as for instance when testing a new catalyst, when changing raw materials or when optimising control or manufacturing parameters for improved quality, implying for instance innovative equipment or significant changes in the mass and heat transfer conditions;
- Testing of a new intermediate for the synthesis of a substance for instance in the manufacturing of an active pharmaceutical ingredient (API);
- Development and testing of a new application for a substance; for example the feasibility for use in a new preparation.

1.2 Tasks and obligations

1.2.1 Scientific research and development

The REACH definition of scientific research and development says that this research is carried out with substances in quantities less than 1 tonne per year. Under REACH, any substance manufactured or imported in a quantity of less than 1 tonne per year does not need to be registered. Consequently, substances manufactured, imported or used for the purpose of scientific research and development are exempted from registration obligations (Articles 3(23), 6 and 7). In addition, the provisions on authorisations and restrictions of substances shall not apply to scientific research and development (see Article 56(3) and Article 67(1) respectively).

Nevertheless, the manufacturer or importer of a substance for the purpose of scientific research and development, who places that substance on the market and who has not already submitted a registration, needs to notify to the Agency the information related to its classification and labelling if the substance meets the criteria for classification as dangerous (Article 113). This has to be done

by the 30th November 2010 or, for substances not yet on the market at that date, as soon as he puts the substance on the market (Article 116).

In addition, suppliers of such substances might need, when appropriate, to provide a safety data sheet or other relevant information to the users of the substance (Articles 31 and 32).

1.2.2 PPORD in quantities below 1 tonne per year

Whenever research and development is related to product development or the further development of a substance, in the course of which pilot plant or production trials are used, this falls under the definition of PPORD. In practice, obligations for PPORD below 1 tonne per year and for scientific research and developments are the same (see **section 1.2.1**), except that authorisation and restriction requirements may apply to PPORD.

For substances subject to authorisation, Annex XIV (list of substances subject to authorisation) shall specify if the authorisation requirement shall apply to PPORD, as well as the maximum quantity exempted (Article 56(3)). In a similar way, Annex XVII (restrictions on the manufacture, placing on the market and use of certain dangerous substances, preparations and articles) shall specify if the restriction on a substance listed in the Annex shall not apply to PPORD, as well as the maximum quantity exempted (Article 67(1)).

It is important to note that when performing research with a substance, it is not only important to check whether it is included in Annex XVII (list of substances subject to restriction) or Annex XIV (list of substances subject to authorisation) but also to identify whether the substance might have properties of very high concern (e.g. being persistent, bioaccumulative and toxic) as those substances might be in the future subject to authorisation. For more guidance on substances of very high concern (SVHC), please read the Guidance on identification of SVHC .

1.2.3 PPORD in quantities of 1 tonne per year or more

In order to promote innovation, Article 9 of REACH specifies that substances manufactured or imported on their own or in preparation, as well as substances incorporated in articles or imported in articles for the purpose of PPORD can be exempted from the duty to register for a period of 5 years. To be exempted a company needs to submit a PPORD notification to the Agency. Upon request, the Agency may further extend this exemption for up to another 5 years, or 10 years for the development of medicinal products (for human or veterinary use) as well as for substances that are not placed on the market.

The exemption from registration for the purpose of PPORD applies provided that the manufacturer, the importer or the producer of the articles carries out the PPORD by himself or in cooperation with listed customers. The Regulation does not impose a limit on the quantities of the substance to be manufactured, imported, incorporated in articles or imported in articles, provided the quantities are limited to the purpose of PPORD.

Although exempted from registration, it is nonetheless important to consider whether the substance is handled in reasonably controlled conditions in accordance with the requirements of legislation for the protection of workers and the environment, and is only made available to selected customers. The Agency may impose conditions to ensure that the principles described in **section 2.3** are respected. The notifier and the listed customers are therefore advised to consider the adequacy of such measures, and implement them accordingly.

For substances subject to authorisation, Annex XIV (list of substances subject to authorisation) shall specify if the authorisation requirement shall apply to PPORD, as well as the maximum quantity exempted (Article 56(3)). In a similar way, Annex XVII (restrictions on the manufacture, placing on the market and use of certain dangerous substances, preparations and articles) shall specify if the restriction on a substance listed in the Annex shall not apply to PPORD, as well as the maximum quantity exempted (Article 67(1)).

When performing research with a substance, it is not only important to check whether it is included in Annex XVII (list of substances subject to restriction) or Annex XIV (list of substances subject to authorisation) but also to identify whether the substance might have properties of very high concern (e.g. being persistent, bioaccumulative and toxic) as those substances might be in the future subject to authorisation. For more guidance on substances of very high concern (SVHC), please read the Guidance on identification of SVHC.

In the following sections, tasks and obligations for the different actors of the supply chain with regard to PPORD are described.

1.2.3.1 Manufacture/import of a substance for PPORD

- A manufacturer or importer or producer of articles is exempted from the obligation to register the quantities of the substance manufactured or imported for the purpose of PPORD, by making a PPORD notification.
- This notification may concern the notifier's own PPORD or a PPORD conducted in cooperation with listed customers.
- If a substance is also manufactured or imported for a purpose other than PPORD, the quantity of the substance covered by the PPORD notification does not need to be taken into consideration in the determination of the quantities falling under an eventual registration obligation (e.g. if a manufacturer manufactures 11 tonnes/year of a substance, of which 2 tonnes/year are for PPORD, the registration information requirement is based on the remaining 9 tonnes/year).
- It should be highlighted that any national PORD exemption for the notification of substance under Directive 67/548/EEC is no longer valid under REACH as from 1 June 2008. Therefore, manufacturers or importers or producers of articles wishing to continue their PPORD activities need to submit a new notification to the European Chemicals Agency. In order to avoid interruptions of such activities, the notification should be made by 16 May 2008 at the latest because, in the absence of an indication to the contrary, PPORD activities may not start earlier than two weeks after the notification. For this purpose, the Agency will allow notification before 1 June 2008. The exact date by when notification will be possible will be communicated at a later stage. Please note also that even if the notification is made more than two weeks in advance of 1 June 2008, any activities covered by the notification can always only start on 1 June 2008, when the PORD rules under Directive 67/548/EEC have expired and the new rules under REACH have entered into force.
- If the substance is listed in Annex XVII, the manufacturer or importer must check whether or not the restriction applies to PPORD. Annex XVII shall specify whether this is the case and, if so, the maximum quantity exempted from the restriction for the purpose of PPORD (Article 67(1)).

- If the substance is listed in Annex XIV, the manufacturer or importer must check whether or not he needs to apply for an authorisation for PPORD. Annex XIV shall specify whether this is the case and, if so, the maximum quantity exempted from the authorisation requirements for the purpose of PPORD (Article 56(3)).

- The Agency may require a manufacturer or importer of a substance, who has submitted a PPORD notification, to provide additional information necessary to set conditions in accordance with Article 9(4)

- A manufacturer or importer has to comply with any conditions imposed by the Agency, as described in **section 2.2** of this guidance.

- The manufacturer or importer must provide his customer(s) with a safety data sheet (SDS) for substances meeting the criteria for classification as dangerous, being PBT or vPvB, and for substances included in the candidate list of substances which may be subjected to authorisation (Article 31). If the SDS is not required, the supplier must nonetheless provide his customer(s) with the following information (Article 32):

    - the registration number of the substance, if available,

    - any eventual authorisation granted or denied in his supply chain,

    - any restriction imposed,

    - any other available and relevant information about the substance that is necessary to enable appropriate risk management measures to be identified and applied.

1.2.3.2 Downstream use of substances for PPORD.

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

- A DU of a substance, who is listed as one of the selected customers with whom the manufacturer or importer cooperates in a PPORD notification submitted by the manufacturer or importer has to use the substance for the purpose of PPORD and within any conditions set in accordance with Article 9(4) and communicated to him by his supplier, as described in **section 2.2**. If the DU stops using the substance for the purpose of PPORD and, by this, ends the cooperation with his supplier, he needs to inform his supplier, as the tonnage covered by the PPORD notification will change and the supplier might need to register the substance or update his registration dossier for his substance.

- On the other hand, if a 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**, as described in the Guidance for Downstream Users with the following exception. Normally, a DU would need to produce their own Chemical Safety Report when a substance is used outside of the conditions in an exposure scenario communicated to him in a Safety Data Sheet or used in a way his supplier advises against. However, provided the risks to human health and the environment are adequately controlled, the DU is exempted from preparing a Chemical Safety Report for the use under PPORD (Article 37 (4)(f)).

The DU of a substance for the purpose of PPORD has otherwise the same obligations under REACH as for any standard substance. The general rules on information down the supply chain

therefore apply. The authorisation and restrictions provisions apply if Annex XIV and XVII respectively specify so. Detailed information on these obligations is presented in the Guidance for Downstream Users.

2 PPORD NOTIFICATION

2.1 Considerations before making a PPORD notification

Prior to an eventual submission of a PPORD notification for a substance to the Agency, the potential PPORD notifier needs to figure out whether the activity he carries out alone or in cooperation with listed customers is within the scope of the definition of product and process oriented research and development (Article 3(22)).

In addition, it is important to figure out, based on the hazardous properties of the substance and the conditions of manufacture and use, whether the substance is effectively handled in reasonably controlled conditions for the protection of human health and the environment. In particular it is useful to take the following considerations into account:

1. Is the substance effectively manufactured and used for the purpose of PPORD?
    - What are the objectives of the research program?
    - What is the scale of the program: who will be exposed to the substance (workers, selected customers?)
2. What are the conditions for the manufacture, use and disposal of the substance?
    - What is the process (including batch sizes, identification of any potential losses (e.g. process emissions to waste water, reactor washings and residual material left in containers))
    - Information regarding any treatment of wastes and waste disposal practices for all potential waste streams.
    - Guidance on risk management measures and use description is available in the Guidance on Chemical Safety Report.
3. What is the research program?
    - Description of the program including timelines and quantities used

It should be reminded that the Agency may impose some conditions as described in **section 2.3** and that these should also be taken into account. The above considerations should make it easier for the PPORD notifier and his listed customers to comply with most of the conditions that the Agency may impose.

2.2 PPORD notification dossier

2.2.1 Information requirements

In accordance with Article 9(2), the manufacturer or importer or producer of articles must notify the Agency of his intention to carry out PPORD by himself or in cooperation with listed customers on a substance. For that purpose, the notifier has to submit an electronic notification providing the Agency with the following information:

(a) the identity of the manufacturer or importer or producer of articles as specified in section 1 of Annex VI: the information to be submitted is detailed in the Guidance on registration;

(b) the identity of the substance, as specified in section 2 of Annex VI: the information to be submitted is detailed in the Guidance on registration;

The notifier has to ensure that possible variations in the composition of the substance (that may be foreseen under the scientific experimentation) are taken into consideration in the information to be reported in accordance with section 2 of Annex VI.

(c) the classification of the substance as specified in section 4 of Annex VI, if any: the information to be submitted is detailed in the Guidance on registration;

(d) *the estimated quantity as specified in section 3.1 of Annex V*: the information to be submitted consists of the estimated quantity of the substance to be manufactured or imported for the purpose of PPORD for the calendar year of the notification.

(e) the list of customers with which the PPORD cooperation is carried out, including their names and addresses.

2.2.2 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 web-site (REACH IT) or using IUCLID 5. The notification prepared through REACH IT only allows the notifier to submit the information requested in Article 9(2). The notification prepared using IUCLID 5 allows more flexibility, and the possibility to attach additional information to the dossier, where the notifier so wishes.

Once the notification has been submitted to the Agency, the Agency will issue a submission number and an invoice for the notification. The notifier must only carry out a payment for the notification after the invoice has been received, as the invoice will contain the reference number to be quoted for the payment.

2.2.2.1 Using REACH IT

To be completed later

2.2.2.2 Using IUCLID 5

A PPORD notification dossier can be elaborated with the IUCLID software (International Uniform Chemical Information Database). IUCLID 5, for which specific guidance is available (see the

Guidance on IUCLID), will be downloadable from the IUCLID website (http://iuclid.eu) for free by all parties, if used for non-commercial purposes. Preparation and submission of a PPORD notification dossier using IUCLID 5 is described below.

After having specified his legal entity profile in IUCLID, the notifier has to create the substance dataset, where the information on the substance can be entered. 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, such as the identity of the substance, its classification, the estimated quantity and the list of selected customers, are highlighted. It is however possible for the notifier to also report in the PPORD notification dossier any additional information on the substance. For clarity, links between the requested information as listed in Article 9(2), Annex VI (containing guidance on fulfilling the information requirements) and IUCLID 5 are summarised in Table 1.

Table 1: Links between Article 9(2), Annex VI and IUCLID5 sections

Article 9(2)	Annex VI	IUCLID 5
(a) identity of the manufacturer or importer or producer of articles	Section 1: General registrant information	Legal identity section and Substance dataset : 1.1 Identification
(b) identity of the substance	Section 2: Identification of the substance	Substance dataset: 1.1 General information 1.2 Composition 1.4 Analytical information
(c) classification and labelling	Section 4: Classification and labelling	Substance dataset: 2 Classification and Labelling
(d) estimated quantity	Section 3.1	Substance dataset: 1.9 Product and process oriented research and development
(e) Listed customers		Substance dataset: 1.8 Recipients

Identity of the notifier

Information regarding the notifier identification as specified in Article 9(2)(a) and Annex VI (section 1) must be reported under the IUCLID 5 Legal identity section. All fields and all information specified in section 1 of Annex VI have to be entered in IUCLID 5 for the notification to be complete. Note however that the information in sections 1.2 and 1.3 of Annex VI are not relevant for the purpose of PPORD notification, since the concepts of joint submission and third party appointed under Article 4 referred to in these sections only apply to registration.

Identity of the substance

The notifier needs to submit in section 1 (in particular 1.1, 1.2, 1.4) of the IUCLID 5 Substance dataset all the information dealing with the identification of the substance as referred to in Article 9(2)(b) and section 2 of Annex VI.

A substance is identified by its chemical identity, molecular and structural formula, chemical composition and content of each constituent in the substance. Required information listed in *section 2 of Annex VI* must be documented as far as possible including the information on the substance, its composition, degree of purity, nature of impurities and information on the analytical methods. The notifier is advised to consult the Guidance on substance identification in order to clearly identify and name his substance in the notification dossier.

The classification and labelling

The notifier has to specify in section 2 of the IUCLID 5 Substance dataset the classification and labelling of his substance for physico-chemical properties, human health and the environment, if available. The information on classification and labelling should be documented within section 2 of IUCLID 5. Note also that when a substance is not classified, this needs to be justified, in particular it should be stated whether the non classification is due to lack of data. Further information on the documentation of the classification and labelling within IUCLID is provided in the Guidance on registration, section 8.2.2.4.

Estimated quantity

The notifier must report the estimated quantity of the substance to be manufactured, imported or used for the purpose of PPORD for the calendar year of the notification. This estimation, to be documented in section 1.9 of the IUCLID 5 Substance dataset, can be provided as an exact or approximate tonnage, or as a tonnage range.

Listed customers

Unless the notifier undertakes the PPORD activity exclusively by himself, the notifier must identify in IUCLID any direct or indirect DU of the substance, with whom the cooperation in the context of the PPORD notification is (to be) established. The information should be reported in section 1.8 under the IUCLID 5 Substance dataset and must include as a minimum the name and address of the customer(s).

Additional information

In addition, the notifier has also the possibility to include in his notification dossier any further information he regards as relevant for the PPORD notification dossier, such as for instance the Research and Development programme to be followed. This documentation is to be attached in section 1.9 of the IUCLID 5 Substance dataset.

2.2.3 Completeness check

The Agency shall undertake a completeness check of the notification within 2 weeks of the submission date (Article 9(3) and (5)). The completeness check verifies whether all the required information elements have been submitted and the payment of the fee has been received.

If the notification dossier is incomplete and/or the fee payment is missing, the Agency shall inform the registrant before expiry of the 2-week period, as to what further information is required in order for the notification to be complete, and set a reasonable deadline for this (Article 20(2) and Article 9(3)).

The notifier must complete his notification accordingly. If the information submitted to the Agency within the set deadline is still not complete, the Agency shall reject the notification. This also applies when the fee is not received at the Agency within that deadline.

Only once the notification is complete, the Agency shall assign a notification number to the notification and a notification date, which shall be the date of receipt of the complete notification dossier at the Agency. The notification number and notification date shall be immediately communicated to the notifier. This information shall also be forwarded to the competent authority of the Member State(s) in which the manufacture, import, production or product and process orientated research takes place.

The manufacture or import of the substance may start, in the absence of any indication to the contrary, at the earliest two weeks after the notification date.

2.2.4 Fees

The fees for the notification of a substance in accordance with Article 9(2) shall be specified in a Commission Regulation at the latest one year after entry into force of the REACH Regulation.

2.2.5 PPORD notification update

The notifier of a substance manufactured or imported for the purposes of PPORD is responsible on his own initiative for updating his notification whenever a change has occurred in the information submitted in accordance with Article 9(2) and listed in **section 2.2.1**. Any change in the identity of a PPORD notifier, the tonnage band specified in the PPORD notification, the classification and labelling or in the list of customers is considered relevant.

The update is to be submitted to the Agency. Upon submission of the updated notification, the notifier may continue the manufacture or import of the substance, if there is no indication to the contrary from the Agency in accordance with Article 9(4), within the exemption period.

An update of the PPORD notification shall have no consequence on the period over which the exemption from registration is valid.

2.2.5.1 Using REACH IT

To be completed later.

2.2.5.2 Using IUCLID5

The notifier may update his PPORD notification by submitting a new PPORD notification dossier, wherein reference to the PPORD last submission number is specified under the dossier creation wizard.

2.3 Conditions imposed by the Agency

As detailed in Article 9(4), the Agency may decide to impose conditions on the PPORD at any time during the exemption period, with the aim of ensuring that the following conditions are fulfilled.

- The substance will be handled only by staff of a number of listed customers;
- The substance will be handled in reasonably controlled conditions in accordance with the requirements of legislation for the protection of workers and the environment, including the Directives referred to in Article 2(4);
- The substance will not be made available to the general public at any time, either in the form of the substance on its own, in a preparation or in an article;
- Remaining quantities of the substance will be re-collected for disposal after the exemption period.

The Agency may therefore ask the notifier to provide additional information that is necessary to either document that the conditions are fulfilled, or assess the need for eventual conditions to be imposed. The information requested may relate to the PPORD programme, the total quantity of the substance expected to be manufactured or imported during the 5-year period, the intrinsic properties of the substance, etc. The Agency may utilise this information for drafting a decision. The draft decision shall be submitted for commenting without delay to the Competent Authority of each Member State (MSCA) in which the manufacture, import or product and process oriented research takes place. The Agency shall take into account the comments received from the MSCA(s) in its final decision. The decision shall be forthwith communicated to the manufacturer or importer of the substance, who has to comply with any conditions imposed by the Agency and to inform any customers involved in the PPORD.

2.4 Manufacture/import of the substance

The notifier may start the manufacture, import or production of the article for the purpose of PPORD two weeks after the notification date communicated by the Agency upon receipt of the notification dossier, in the absence of any indication to the contrary (see Article 9(5)). Such an indication may be based as a result of the Agency's completeness check, for instance in the cases where some required information or the payment of the fee is missing. It may also be the consequence from the Agency's considerations regarding imposing conditions. In that respect, further information may be requested to assess the need for imposing conditions.

The exemption from registration of the substance under PPORD applies for a period of 5 years starting from the notification date communicated by the Agency.

2.5 Extension of the exemption from the obligation to register

According to Article 9(7), the PPORD notifier has the possibility to request an extension of the 5-year exemption period by a further maximum of 5 years, or by a further maximum of 10 years in the case of substances to be used exclusively in the development of medicinal products for human or veterinary uses, or for substances that are not placed on the market.

The request for extension needs to be justified by the research and development programme. For this purpose it is advised to document the research and development program (including objective,

timelines and quantities manufactured or used). To justify the request for extension, the following considerations can be taken into account:

- What are the improvements and achievements obtained during the first 5 years of exemption?
- Why has the previous research program not been completed over the 5 years exemption period?
- What result is expected to be achieved during the duration of the extension requested?

The application is made via the Agency web-site or via a IUCLID 5 dossier.

After examination of the request, the Agency shall draft a decision, and submit it without any delay for comment to the Competent Authority of each Member State (MSCA) in which the manufacture, import or product and process oriented research takes place. The Agency shall take into account the comments received from the MSCA(s) in its final decision on the request (see Article 9(8)).

The extension period starting after the last day of the initial 5-year exemption period, the notifier must therefore submit his request for an extension of the exemption from the obligation to register so far in advance that the Agency can manage to examine the request and draft a decision, consult the relevant MS(s) and, eventually, revise the decision. A precise deadline will be announced in due time.

2.6 Confidentiality

As underlined in Article 9(9), 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 of a substance for the purpose of PPORD. Such information shall therefore not be published in the Internet, and requests for access to that information will not be granted.