ECHA
EUROPEAN CHEMICALS AGENCY

GUIDANCE IN A NUTSHELL

# Scientific Research and Development (SR&D), Product and Process Orientated Research and Development (PPORD)

The document aims to explain in simple terms the obligations for applicants for exemptions available for SR&D and PPORD substances

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This document contains guidance on REACH and provides useful key elements to facilitate compliance with specific requirements under the REACH Regulation. 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.

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# 1. Introduction

This Guidance in a Nutshell provides a concise and simple introduction to the specific obligations under REACH for substances manufactured or imported or used in Scientific Research and Development (SR&D) and Product and Process Orientated Research and Development (PPORD), according to the REACH Regulation (EC) No 1907/2006.

In order to provide encouragement to innovate for research-orientated companies, REACH allows exemptions from authorisation and restrictions for substances used in scientific research and development (SR&D) at tonnages <1 tonne/year. REACH further encourages innovation by allowing substances manufactured or imported at tonnages >1 tonne/year to be exempted from registration for a period of 5 years (or longer) when they are used in product and process orientated research and development (PPORD) or exported for the purpose of PPORD.

This document aims to give an overview of the obligations for applicants for exemptions available for SR&D and PPORD substances and to clarify the concepts of SR&D and PPORD. However, it is recommended to read the full *Guidance on Scientific Research and Development (SR&D) and Product and Process Orientated Research and Development (PPORD)* to confirm that you fullfil possible requirements and obligations.

# 2. Definitions

**Product and process orientated research and development (PPORD)** is any scientific development related to product or process development and/or application of a new or already existing substance, irrespective of the tonnage. Please note, that PPORD notification exempts the quantities above 1 tonne imported or manufactured for the purpose of PPORD only from the obligation to register.

**Scientific research and development (SR&D)** is any scientific experimentation, analysis or chemical research carried out under controlled conditions in a volume <1 tonne/year/legal entity (e.g. company). The scope of the SR&D applies more generally and therefore, what could be “PPORD at <1 tonne/year” is also SR&D. There is in any case no obligation to register quantities of a substance at below 1 tonne/year under REACH, but substances used in SR&D are potentially additionally exempted from authorisation or restriction requirements which might otherwise apply. See sections 3.1.2 and 3.1.3 of the full Guidance for more information on this; **SR&D is not further discussed in this document after the summary table below.**

# 3. Summary of obligations

| Type of obligation | Substance used in **SR&D** | Substance used in **PPORD** |
|---|---|---|
| **Registration** | **Not required**. All substances at tonnages <1 tonne/year/legal entity are exempted from registration. | **Not required** – temporarily for 5 years, but the company must submit a PPORD notification to ECHA. |
| **Authorisation** | **Not required**. | **Required** for a substance listed in Annex XIV (unless exempted in Annex XIV). |
| **Restriction** | **Does not apply**. | **Applies**, unless it is exempted in Annex XVII. |
| **Classification,** | **Required**, if a substance or mixture is | **Required** for **substances** used in |

| Type of obligation | Substance used in **SR&D** | Substance used in **PPORD** |
|---|---|---|
| **labelling and packaging (CLP)** | placed on the market (i.e. supplied or imported).<br><br>**Not required** if not placed on the market. | PPORD, irrespective of whether these substances are made available to any listed customers or not. For a **mixture** containing a PPORD substance, classification (and labelling and packaging according to CLP) is only required if the mixture is placed on the market (i.e. sent to any listed customer(s)). |
| **Notification to the C&L Inventory** | **Required**, if the substance or mixture is classified as hazardous and placed on the market. | **Required**, if the substance or mixture is classified as hazardous and placed on the market. |
| **Information in the supply chain** | **Requires safety data sheet** (SDS), if a substance or mixture is hazardous (dangerous), persistent, bioaccumulative and toxic; very persistent and very bioaccumulative; or is included in the list according to Article 59(1) of REACH for other risk management reasons.<br><br>If SDS is not required, other information is required for certain substances (see sub-section 3.1.6 of the full Guidance). | **Requires safety data sheet** (SDS) (to be sent to listed customers), if a substance or mixture is hazardous (dangerous), persistent, bioaccumulative and toxic; very persistent and very bioaccumulative; or is included in the list according to Article 59(1) for other risk management reasons.<br><br>If an SDS is not required, other information is required for certain substances (see sub-section 3.2.6 of the full Guidance). |
| **Downstream user (DU) obligations** | **Apply**. Normal obligations apply as for any standard substance. | (a) **If DU is a listed customer in supplier's PPORD notification**, DU must use the substance only for PPORD and implement the conditions communicated by the supplier.<br><br>(b) **If DU uses the registered substance for his own PPORD**, normal obligations apply as usual for any substance. |
| **Compliance with conditions imposed by ECHA** | **Not applicable**. | **Required**, or any conditions imposed by ECHA. |

## 4. PPORD notification dossier, its update and cessation

In order to be exempted from the obligation to register a substance used in PPORD, a PPORD notification must be made. To do this, the notifier must create a PPORD notification dossier using the IUCLID software and submit it to ECHA using the REACH-IT portal. The notifier must pay the relevant fee after the invoice has been received. The notifier may only start the manufacture or import (of the substance or mixture) or production (of an article) two weeks after the notification date communicated by ECHA after the receipt of the notification dossier.

### 4.1 PPORD notification update for new information

The notified information about a PPORD may change over time. However, the notifier need not submit a new PPORD notification for which he would have to pay a new fee every time one of the elements contained in the notification of his PPORD changes. Instead, he may choose, if he so wishes, to update the notification.

### 4.2 Cessation of the PPORD

When the notifier ceases the PPORD activity he should inform ECHA (using REACH-IT). When the activity has ceased (or the exemption has expired), the notifier must re-collect the remaining quantities of the substance for disposal (if he does not intend to continue manufacturing or importing it) or register the substance (if he intends to keep manufacturing or importing it).

## 5. Extension of the exemption from the obligation to register

The exemption period ends after 5 years. However, the PPORD notifier may request an extension of maximum 5 years (or ten years in case of medicinal products for human or veterinary use or substances that are not placed on the market). The request for extension needs to be indicated as a IUCLID notification update and submitted to ECHA via REACH-IT. A document describing a research and development programme that justifies the extension must be attached to this request.

Upon the request submission, the notifier receives an invoice for the extension fee. ECHA must await the payment before it can assess if the extension is justified for the period requested. Therefore, it is recommended to make the payment of the fee as soon as possible, but at latest within 30 days after the request submission.

Note that since the extension period starts after the last day of the initial five-year exemption period, the notifier is recommended to submit the request for an extension at least 4 months in advance to allow enough time for processing of the request.

## 6. Request for information and conditions that may be imposed by ECHA

If the information provided in the PPORD notification does not allow ECHA to conclude that the legal requirements of Article 9(4) are fulfilled, ECHA may request additional information.

After this information is evaluated, ECHA may decide to impose conditions on the PPORD activity to ensure that the substance is handled only by the staff of the notifier and of the listed customers in reasonably controlled conditions for the protection of workers and the environment, is not made available to the general public and is recollected for disposal after the exemption period has expired.

All the submitted information about a substance used for the PPORD is treated as confidential.

# 7. Where to find further guidance and other relevant information

It is recommended to consult the full *Guidance on Scientific Research and Development (SR&D) and Product and Process Orientated Research and Development (PPORD)* in order to meet your requirements and possible obligations.

Additional information is available by consulting the following documents (via the hyperlinks below):

- Guidance on Scientific Research and Development (SR&D) and Product and Process Oriented Research and Development (PPORD)[1]
- Data Submission Manual 1: How to prepare and submit a PPORD notification[2]

[1] http://echa.europa.eu/guidance-documents/guidance-on-reach
[2] http://echa.europa.eu/support/dossier-submission-tools/reach-it/data-submission-industry-user-manuals

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