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EUROPEAN CHEMICALS AGENCY

GUIDANCE

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

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November 2014

## LEGAL NOTE

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

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# 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 Orientated 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 originally drafted and discussed within the REACH Implementation Projects (RIPs) led by the European Commission services, involving all stakeholders from Member States, industry and non-governmental organisations. The European Chemicals Agency (ECHA) updates these guidance documents following the Consultation procedure on guidance. These guidance documents can be obtained via the ECHA website[1].

This document relates to the REACH Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006[2].

[1] http://www.echa.europa.eu/web/guest/guidance-documents/guidance-on-reach

[2] Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC (OJ L 396 of 30 December 2006, p. 1; corrected by OJ L 136, 29.5.2007, p. 3).

# Document History

| Version | Changes | Date |
|---|---|---|
| Version 1.0 (originally unnumbered) | First edition. | June 2007 |
| Version 1.1 (originally unnumbered; treated as a corrigendum) | Section 1.2.3: Text added at the beginning of 3rd paragraph to insist on the fact that the conditions of use have to be carefully examined especially for those substances on which very little information is available.<br><br>Section 1.2.3.1: 3rd bullet point: clarification on the need to register if the substance used outside the PPORD program and at or above 1 tonne per year.<br><br>Section 1.2.3.1: 4th bullet point: the reference to the possibility to make notifications prior to 1 June 2008 removed.<br><br>Section 2.2.2.2: Identity of the substance: text added to take into account the possible variation of composition.<br><br>Section 2.2.2.2: Classification of the substance: text added to take into account the possible variation of composition. Sentence saying that non-classification should be justified deleted.<br><br>Section 2.2.5: Text added to take into account the possible variation of composition.<br><br>Section 2.6: Text modified to be in line with Regulation (EC) No 1049/2001 (regarding public access to European Parliament, Council and Commission documents).<br><br>Document history: List of changes made during the update added (as Appendix 1 to Version 1.1). | February 2008 |
| Version 2.0 | Full revision of the guidance structure and content.<br><br>The title of the document has been changed to better align with REACH text ("orien**tated**" rather than "orien**ted**" as per Article 3 point 22 and title of Article 9 of REACH)<br><br>The document has been revised in general by removing errors and inconsistencies and particularly to incorporate learnings on best practices developed so far in dealing with SR&D and PPORD substances.<br><br>The main drivers for this update are issues related to the requirements of Article 9(4) of the REACH Regulation:<br><br>– possible conditions that may be imposed by ECHA;<br><br>– scope of information that may be requested by ECHA from a PPORD notifier.<br><br>Furthermore, the expiration of the five-year period for exemption from registration for the first PPORD substances notified as such triggers a need to provide more guidance on how to request the | November 2014 |

| | | |
|---|---|---|
| | extension from exemption and on how to update a PPORD notification dossier.<br><br>Document history: The information in the original Appendix 1 to Version 1.1 has been transferred to the present document history table and expanded with a summary of changes from Version 1.1 to Version 2.0.<br><br>New Appendices added:<br><br>– Appendix 1: Summary of the obligations for substances used in SR&D and PPORD;<br><br>– Appendix 2: Text of Article 9 of REACH. | |

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# 1. Introduction

One of the main objectives of the REACH Regulation is to increase and promote innovation by providing encouragement to innovate for research-orientated companies. To achieve this objective, REACH foresees a number of exemptions. For example, substances used in scientific research and development (SR&D) are exempted from **authorisation and restrictions** which might otherwise apply even to substances manufactured or imported at below 1 tonne per annum.
All substances manufactured or imported at below 1 tonne per annum are in any case exempted from **registration**. However, the REACH Regulation further promotes innovation by also allowing substances manufactured or imported at above 1 tonne per annum to be exempted from registration under certain conditions, *i.e.* when they are used in product and process orientated research and development (PPORD). This PPORD exemption is limited to a specified time and to listed customers. The duration of the exemption may be extended by a further specified period if justified.

This document aims to give guidance on what obligations apply to those seeking to take advantage of the exemptions available for SR&D and PPORD substances and on how to fulfil applicable conditions. The guidance also clarifies the concepts of SR&D and PPORD and explains the tasks and obligations that manufacturers, importers and users of SR&D and PPORD substances have under the REACH Regulation.

# 2. Definitions

REACH defines **scientific research and development (SR&D)** as *any scientific experimentation, analysis or chemical research carried out under controlled conditions in a volume less than 1 tonne per year* (Article 3(23) of the REACH Regulation).

Examples of SR&D may include any experimental research or analytical activities at a laboratory scale such as synthesis and testing of applications of chemicals, release tests, etc. as well as the use of the substance in monitoring and routine quality control or *in vitro* diagnostics at a laboratory scale under controlled conditions.

The total quantity of the substance to be considered as used in experimental research or analytical activity covered by SR&D definition applies per legal entity that manufactures or imports the substance (not per laboratory or per analysis).

**Product and process orientated 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 mixtures 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) of the REACH Regulation).

Any scientific development of 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. This applies irrespective of the tonnage involved and whether the substance is a new or an already existing substance.
It follows follows from the above definition that the scope of the PPORD definition is very wide

and includes any development and testing of a substance or use[3] of a substance to generate information for example to:

a) develop new substances;

b) develop specific requirements for a substance in a defined process or use;

c) develop new products including mixtures and articles;

d) develop new processes;

e) prove the feasibility of new processes and/or new uses of a substance;

f) improve efficiency and performance of industrial plant operations;

g) improve production efficiency from a socio-economic and environmental point of view;

h) protect the environment by developing (new) technologies including capturing and ameliorating the waste streams and reducing emissions;

i) develop recovering, recycling and reusing technologies of valuable materials from by-products, wastes, etc.

**Please note:** Although the definition of SR&D applies only to volumes below 1 tonne per year, the scope of the activities that can be covered by SR&D is broader than that covered by the definition of PPORD. This is because it is not limited only to research and development "*related to product development or development of a substance (…) 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"* as is the case for PPORD. The definition of SR&D applies more generally to experimentation, analysis and research. Therefore, what would be "PPORD below 1 tonne per year" is also SR&D.

[3] Specific 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 testing the feasibility of its use in a new mixture.

# 3. Tasks and obligations

## 3.1 Substances used in scientific research and development (SR&D)

According to the REACH definition given in Article 3(23) scientific research and development is any scientific experimentation, analysis or chemical research carried out under controlled conditions in quantities of less than 1 tonne per year. In this context, "controlled conditions" can be understood to mean that procedures and measures are in place to minimise[4] or control[5] exposure and potential risks from exposure of humans and the environment to the substance. This may include, for example, limitation of uses to qualified persons having access to the substance, collection and disposal of waste. Member States may also impose specific requirements. The exemption discussed in 3.1.1 below apply to all substances at below 1 tonne per annum, those in 3.1.2 and 3.1.3 apply **only** if the substance is being used for SR&D under the conditions given. The 1 tonne threshold mentioned in the definition of SR&D applies per legal entity that manufactures or imports the substance (i.e. those who would otherwise potentially need to register it) and not per site, laboratory or per analysis.

### 3.1.1 Absence of obligation to register under REACH

Under REACH, **any** substance manufactured or imported in a quantity of less than 1 tonne per year does not need to be registered. Therefore, substances used according to the definition of SR&D that includes "*… in a volume less than one tonne per year…*" are not subject to the registration obligations (Articles 3(23), 6, 7, 17 and 18 of the REACH Regulation).

### 3.1.2 Exemption from authorisation under REACH

If a substance is being used for SR&D any provisions for **authorisation** of the substance do not apply to **this use in SR&D** (see Article 56(3) of the REACH Regulation).

### 3.1.3 Exemption from restrictions under REACH

The provisions for **restrictions** do not apply to the **manufacture**, **placing on the market** or **use** of a substance in scientific research and development (see Article 67(1) of the REACH Regulation). In simple terms: the substance is exempted from restrictions if its manufacture, use or placing on the market falls within the definition of SR&D.

### 3.1.4 Classification, labelling and packaging

The CLP Regulation does not apply to substances and mixtures used in SR&D which are not placed on the market (*i.e.* supplied or imported), provided they are used under controlled conditions in accordance with the EU workplace and environmental legislation (see Article 1(2)(d) of the CLP Regulation). However, as soon as SR&D substances or mixtures are imported or supplied to third parties (for example by sending samples from a university to another research institute or by importing such samples) this is considered as "placing on the market" (see Article 2(18) of the CLP Regulation and the ECHA frequently asked question FAQ ID=185). In such a situation, the CLP Regulation requires the supplier or importer to classify according to the available information and to label and package hazardous substances or

[4] Where information on the hazards is not available.

[5] When the hazards are known.

mixtures according to the CLP criteria. As a consequence, importers also need to classify and label imported substances even if only for their own use.

Note that the obligation to classify, label and package (Article 4 of the CLP Regulation) applies irrespective of the quantity of the substance. Therefore, it also concerns the small amounts of substances or mixtures that are supplied to a test house or laboratory.

For more information about the application of the CLP criteria for physical, health and environmental hazards, please consult the *Guidance on the application of the CLP criteria*. It is also recommended to view the "Classification" section on ECHA website.

### 3.1.5 Notification to the C&L Inventory

The manufacturer or importer of a substance for the purpose of SR&D, who places that substance on the market and who has not already submitted a registration[6], needs (irrespective of the quantity) to notify to the ECHA Classification & Labelling (C&L) Inventory the information related to its classification and labelling if the substance meets the criteria for classification as hazardous (Article 40 of the CLP Regulation). The same applies to an SR&D substance contained in a mixture, if the mixture is classified due to the presence of this substance. ECHA will publish certain information notified to the C&L Inventory on its website. The information that will **not** be published includes:

- the name of the notifier,
- the IUPAC name where the notifier has justified its confidentiality in IUCLID and provided a public chemical name that can be displayed[7].

For more information please consult Practical Guide 7: How to notify substances to the Classification and Labelling Inventory. It is also advised to view the Notification to the C&L Inventory section on the ECHA website.

### 3.1.6 Information in the supply chain

Manufacturers, importers or downstream users of a substance or mixture for SR&D purposes who place such substances or mixtures on the market are obliged to follow the provisions of Article 31(1) of the REACH Regulation which requires the supplier of substances (or mixtures) to provide the recipient with a **safety data sheet (an SDS)** formatted according to Annex II of REACH, whenever the following criteria apply:

(Until 31 May 2015:)

*"(a) where a substance meets the criteria for classification as hazardous in accordance with Regulation (EC) No 1272/2008 or a mixture meets the criteria for classification as dangerous in accordance with Directive 1999/45/EC; or*

[6] Note that the manufacturer or importer may have registered a substance for identified uses for a certain tonnage band and he may however perform SR&D with additional quantities (even if below one tonne).

[7] For more information on how to derive a public name in the classification and labelling inventory for research substances please follow the technical instructions set out in Data Submission Manual 12 – How to Prepare and Submit a Classification & Labelling Notification Using IUCLID.

*(b) where a substance is persistent, bioaccumulative and toxic or very persistent and very bioaccumulative in accordance with the criteria set out in Annex XIII; or*
*(c) where a substance is included in the list established in accordance with Article 59(1) for reasons other than those referred to in points (a) and (b).”* (where the latter list corresponds to the so called “candidate list”[8] for authorization (list published on ECHA website, see link in the footnote).

As of June 1, 2015 (a) above changes to:

*“(a) where a substance or mixture meets the criteria for classification as hazardous in accordance with Regulation (EC) No 1272/2008; or”*

(and criteria (b) and (c) remain as above).

For more information on for which substances and mixtures SDSs need to be provided and by whom, please consult the *Guidance on the compilation of safety data sheets*.

If the supplier does not have to provide an SDS according to Article 31, he has to provide the recipient with **other information** according to Article 32 of the REACH Regulation. Note however that, in practice, if none of the conditions described in Article 32 (b), (c) or (d) apply (i.e. if the substance is not the subject of authorisation, it is not restricted and no information is necessary to enable appropriate risk management measures to be identified and applied) then no other information is needed under Article 32 for a substance or mixture for which an SDS is not required.

It is also important to check whether a substance (as such or in a mixture) used in SR&D might be identified as substance of very high concern (SVHC) and placed on the Candidate List of Substances of Very High Concern for Authorisation. Please note that inclusion of a substance on the Candidate List may result in legal obligations for suppliers of substances on their own or in mixtures, namely:

- EU and EEA[9] suppliers of a **substance** on the Candidate List have to provide their customers with an SDS from the date of inclusion of the substance on the Candidate List;
- Each EU and EEA supplier of a **mixture** not classified as dangerous according to the Dangerous Preparation Directive (DPD)[10] have to provide the recipients, at their request, with an SDS if the mixture contains at least one substance on the Candidate List and the individual concentration of this substance in the mixture is ≥ 0.1% (w/w) for non-gaseous mixtures, if the substance has been included in the candidate list for reasons other than posing human health or environmental hazards[11].

Furthermore, for SVHC substances contained in articles, the provisions of Article 33 of REACH (*Duty to communicate information on substances in articles*) may also apply.

[8] http://echa.europa.eu/web/guest/addressing-chemicals-of-concern/authorisation/substances-of-very-high-concern-identification/candidate-list-of-substances-of-very-high-concern-for-authorisation

[9] European Economic Area

[10] Until 1 June 2015, the mixtures can be classified according to the DPD. However after 1 June 2015 (at latest) mixtures must be classified, labelled and packaged according to CLP.

[11] Legal reference: Article 31 (3) (a) and (b) of the REACH Regulation.

For more information about communication obligations for SVHC substances contained in articles, please consult the *Guidance on requirements for substances in articles*.

**A summary of obligations for substances used in SR&D (and comparison with those for PPORD) is provided in Appendix 1 to this guidance document.**

## 3.2 Substances used in product and process orientated research (PPORD)

### 3.2.1 Exemption from registration obligation for PPORD substances 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 mixtures, as well as substances incorporated in articles or imported in articles for the purpose of PPORD can be exempted from the registration obligation for a period of five years. A manufacturer or importer of a substance (on its own or in a mixture) or producer of articles containing a substance (that would otherwise need to be registered) is exempted from the obligation to register the quantities of the substance manufactured or imported only for the purpose of PPORD according to Article 9(1) of REACH. To benefit from the exemption a company needs to submit a PPORD notification to ECHA according to Article 9(2) (see 3.2.1.1 below).

Upon request, ECHA may extend the exemption period for up to a further five years (or ten years in case of medicinal products for human or veterinary use or substances that are not placed on the market). The notifier needs to present the research and development program to demonstrate that such an extension is justified (see section 6 of this guidance document).

The exemption from registration for the purpose of PPORD applies only to the quantity of substance manufactured or imported for the purpose of PPORD by a manufacturer, importer or a producer of the articles. It requires that the notifier carry out the PPORD himself or in cooperation with **listed customers** referred to under Article 9 (1) of REACH). The REACH Regulation does not impose a limit on the quantities of the substance to be manufactured, imported, incorporated in articles or imported in articles, provided that the quantities are limited to the purpose of PPORD.

Importantly, the quantities of a substance that have been notified for PPORD must not be made available to the general public[12] at any time on their own, in a mixture or in an article. The notifier must also ensure that remaining quantities are recollected after the end of the exemption period. Any other quantity of the same substance not used for PPORD is subject to the registration obligations.

Substances used for PPORD must be handled in reasonably controlled conditions, in accordance with the requirements of the applicable legislation[13] for the protection of workers

[12] Note that the "general public" is not limited to the general public within the EU market, since any "general public" would be inconsistent with the concept that the substance "is not yet intended to be placed on the market to an indefinite number of customers because its application in mixtures or articles still requires further research and development" in Recital 28 of the REACH Regulation.

[13] This covers all applicable, EU, national, regional or local legislation on environmental protection or health and safety at work. It includes the REACH and CLP Regulations and, for example, the following:

- Directive 89/391/EEC on the introduction of measures to encourage improvements in the safety and health of workers at work, as amended by Regulation (EC) No 1882/2003, Directive 2007/30/EC and Regulation (EC) 1137/2008;

and the environment[14]. Thus, REACH exempts PPORD notifiers from registering the substance for a limited period of time, but not from complying with the legislation on protection of workers and the environment. ECHA may impose conditions to ensure that these requirements are respected. The notifier is advised to consider the necessary measures and to implement them accordingly.

In the following sub-sections, the guidance describes tasks and obligations for the different actors of the supply chain with regard to PPORD.

#### 3.2.1.1 Information that needs to be notified to ECHA in order to benefit from an exemption for PPORD

To benefit from a PPORD exemption the manufacturer or importer of the substance or producer of the articles must submit to ECHA information according to Article 9(2) of the REACH Regulation (see Appendix 2). This information may concern a PPORD activity carried out by the notifier alone or in cooperation with listed customers.

**Calculation of the volume in case of PPORD exemption**

If a substance is also manufactured or imported for a purpose other than PPORD, in quantities of one tonne or more per year, then it has to be registered in the same way as any other substance (see the Guidance on registration). The quantity of the substance covered by the PPORD notification does not need to be included into calculations to determine the volume that needs to be registered.

**Example:** If a company manufactures 11 tonnes per year of a substance, of which 2 tonnes are for PPORD, the registration obligation is defined by the 9 tonnes per year, which are not used for PPORD. The company will have also to submit for that substance a PPORD notification dossier for 2 tonnes.

### 3.2.2 Authorisation under REACH

The provisions on authorisation also apply to the **use** of a substance for PPORD purposes (irrespective of the tonnage used). Annex XIV can specify if the authorisation requirement does not apply to PPORD and, if not, the maximum quantity exempted from the authorisation provisions (see Article 56(3) of the REACH Regulation). In simple terms: an authorisation is required for a substance listed in Annex XIV and used for PPORD, **unless** it is exempted. Information on exempted uses can be found in the column "*Exempted (categories of) uses*" in

- Directive 2010/75/EU on industrial emissions (Integrated Pollution Prevention and Control);
- Directive 98/24/EC on the protection of the health and safety of workers from the risks related to chemical agents at work, as amended by Directive 2007/30/EC;
- Directive 2000/60/EC establishing a framework for Community action in the field of water policy (Water Framework Directive), as amended by Decision No 2455/2001/EC, Directive 2008/32/EC and Directive 2009/31/EC;
- Directive 2004/37/EC on the protection of workers from the risks related to exposure to carcinogens or mutagens at work.

[14] Thus, "reasonably controlled conditions" refer to the requirements for the protection of workers and the environment.

Annex XIV[15].

For more information on the authorisation process, please consult the *Guidance on the preparation of an application for authorisation* and Questions and Answers on application for authorisation. It is also advised to visit the "Authorisation" section on ECHA website.

### 3.2.3 Restrictions under REACH

Restrictions under Annex XVII to the REACH Regulation apply to PPORD by default. Annex XVII shall specify in Column 2 ("*Conditions of restriction*") if the restriction shall **not** apply to PPORD and, if so, the maximum quantity exempted from the restriction (see Article 67(1) of the REACH Regulation). In simple terms: a restriction applies to the PPORD use of a substance, **unless** it is explicitly exempted in Annex XVII[16].

For more information about restriction, please consult the *Guidance for the preparation of Annex XV dossiers for restrictions*. It is also recommended to visit the "Restriction" section on the ECHA website.

### 3.2.4 Classification according to CLP

If a **substance or a mixture containing the substance** used for PPORD is going to be **placed on the market** it must be classified (Article 4(1) of CLP).
In addition, for **substances not** placed on the market which need either to be registered (Article 4(2) (a) of CLP) or notified for PPORD (Article 4(2)(b) of CLP) a classification is also required. Therefore, the classification obligation **always** applies to **substances** used for PPORD. The obligation to classify **a mixture** containing a PPORD substance **only** applies if it is placed on the market.

The supplier or importer of a substance used for PPORD or a mixture containing it must classify the substance or mixture according to the available information. He must classify label and package hazardous **substances** according to the CLP criteria and (until 1 June 2015) can classify, label and package **mixtures** according to the DPD[17]. After 1 June 2015 (at the latest) mixtures must also be classified, labelled and packaged according to CLP.
For more information on application of the CLP criteria for classification, please consult the Guidance on the application of the CLP criteria. It is also recommended to view the "Classification" section on the ECHA website.

### 3.2.5 Notification to the C&L Inventory

The manufacturer or importer of a substance for the purpose of PPORD, who places that substance on the market needs (irrespective of the quantity) to notify to the ECHA Classification & Labelling (C&L) Inventory the information related to the classification and labelling if the substance meets the criteria for classification as hazardous. This obligation also applies to substances used for PPORD contained in mixtures, if the mixture is classified due to

[15] Note: for volumes below 1 tonne per annum see also section 3.1.2 above (SR&D).

[16] Note: for volumes below 1 tonne per annum see also section 3.1.3 above (SR&D).

[17] Mixtures can also be voluntarily classified according to CLP before 1 June 2015, in which case the label and package must also already be in accordance with CLP.

the presence of this substance. Please note that certain information notified to the C&L Inventory will be published on ECHA website. The information that will **not** be published includes:

- the name of the notifier,
- the IUPAC name where the notifier has justified its confidentiality in IUCLID and provided a public chemical name that can be displayed[18].

If neither available test data nor any other adequate information source indicates that a substance should be classified for a physical, health or environmental hazards, a notification to the C&L Inventory is not required. For more information please consult Practical Guide 7: How to notify substances to the Classification and Labelling Inventory. It is also advised to view the "Notification to the C&L Inventory" section on the ECHA website.

### 3.2.6 Information in the supply chain

A manufacturer or importer of a substance or mixture, who has notified the use for PPORD and not registered the substance, must not make it available to the general public, i.e. it may only be made available to listed customers. However, if he supplies it to one of his listed customers in the course of the PPORD activity, he must provide that listed customer with an SDS formatted according to Annex II of the REACH Regulation, whenever a substance or mixture meets one or more of the criteria laid down in Article 31 (described above in sub-section 3.1.6 of this guidance document).

For more information on for which substances and mixtures SDSs need to be provided and by whom, please consult the *Guidance on the compilation of safety data sheets*.

If the supplier does not have to provide an SDS according to Article 31, he has to provide the listed customer with **other information** according to Article 32 of REACH. Note however that, in practice, if none of the conditions described in Article 32 (b), (c) or (d) apply (i.e. if the substance is not the subject of authorisation, it is not restricted and no information is necessary to enable appropriate risk management measures to be identified and applied) then no **other information** is needed under Article 32 for a substance or mixture for which an SDS is not required.

### 3.2.7 Downstream use of substances for PPORD

A downstream user (DU) cannot submit a PPORD notification. Since a DU is not obliged to submit a registration, a notification, which would exempt him from the registration obligation, is devoid of any effect.

The obligations under the REACH Regulation for a DU using a substance for the purpose of PPORD may differ, depending on whether the PPORD activity is covered by a PPORD notification made by the manufacturer or importer of the substance. These two situations are described below:

**a) DU is included as a listed customer in a PPORD notification submitted by his**

[18] For more information on how to derive a public name in the classification and labelling inventory for research substances please follow the technical instructions set out in Data Submission Manual 12 – How to Prepare and Submit a Classification & Labelling Notification Using IUCLID.

**supplier**

In this situation, the substance is not registered but the supplier has notified it as a PPORD substance. The DU must use the substance only for the purpose of PPORD. The DU operates under the responsibility of this supplier (the notifier) and is obliged to implement the conditions communicated by the supplier (including any conditions imposed by ECHA). If the DU wants to use the substance for other purposes, the substance has to be registered for that use by the manufacturer or importer. If the DU stops using the substance for PPORD purposes and thereby ends the cooperation with the notifier, he needs to inform his supplier, who will then be able to update his notification by removing the DU from the listed customers and possibly reducing the tonnage notified.

PPORD activity with listed customers is by definition carried out "*in cooperation*" with them". However, it may be advisable for the notifier to make contractual arrangements as a condition of supplying the substance that the notifier is informed (*inter alia*) in case of cessation of the activity. In this way, he can comply with his duty to ensure that the conditions to benefit from the PPORD exemption continue to be fulfilled (including collecting all remaining quantities).

**b) DU himself uses the registered substance for PPORD**

A DU may also carry out a PPORD activity of his own on a substance. In this case the DU himself uses the registered substance for PPORD, under his own responsibility (i.e. the PPORD use is not covered by the M/I registration). Naturally, the DU will not be listed as a listed customer for this activity. Also in this case, the DU need not (and cannot) submit a PPORD notification, since the substance has already been registered. However, **the normal obligations of a downstream user apply with certain exceptions**, as described in the *Guidance for Downstream Users* and summarised below.

Provided that "*the risks to human health and the environment are adequately controlled, in accordance with the requirements of legislation for the protection of workers and the environment*", the DU is exempted from preparing a CSR for the use under PPORD, even if his conditions of use are not covered in the extended SDS of his supplier or the use is advised against (see Article 37(4)(f) of the REACH Regulation). In this case, the DU has to report to ECHA the information specified in Article 38(2) of REACH Regulation (*Obligation for downstream users to report information*) within six months after receiving an SDS from the supplier that contains a registration number. Please note that the obligation to report to ECHA does not apply for the use in PPORD if this use is at a volume of less than 1 tonne per year (Article 38(5) of the REACH Regulation). The DU of a substance used for the purpose of PPORD has otherwise the same obligations under REACH as for any substance used for other purposes. The general rules on information down the supply chain therefore apply. Note that a substance with which a DU carries out process and product orientated research and development could be subject to authorisation requirements or restrictions. Detailed information on these obligations is presented in the *Guidance for Downstream Users*.

### 3.2.8 Considerations before making a PPORD notification

Prior to a the submission of a PPORD notification for a substance to ECHA, the potential PPORD notifier needs to determine whether the activity he carries out alone or in cooperation with listed customers is within the scope of the definition of product and process orientated research and development (Article 3(22)), because the notification will only exempt the notifier from the registration obligation for quantities imported or manufactured for the purpose of PPORD.

In addition, the notifier must ensure, based on the properties of the substance, that the substance will be handled in reasonably controlled conditions for the protection of workers and

the environment.

A notifier should assemble and keep available all the information he requires to carry out his duties under REACH. In particular, the following considerations should be taken into account to collect the appropriate information necessary to establish that his PPORD notification is within the scope of the definition of product and process orientated research and development and that the substance is handled in reasonably controlled conditions:

1. Is the substance manufactured or imported for the purpose of PPORD as defined above?
2. How will the notifier ensure that the substance will not be made available to the general public at any time? How will he ensure that he tracks all quantities of the substance and ensures that remaining quantities are recollected for disposal?
3. How will the notifier ensure that only his staff and the staff of listed customers can be exposed to the substance?
4. How will the notifier ensure that the substance will be handled in reasonable controlled conditions, in accordance with the requirements for the protection of workers and the environment? To do this, he should identify the applicable rules and the appropriate risk management measures described therein.

Guidance on risk management measures and use description is available in the *Guidance on information requirements and chemical safety assessment*.

It should be noted that ECHA may impose conditions as described in sub-section 7.2 of this guidance and this possibility 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 ECHA may impose.

#### 3.2.8.1 Deciding whether to submit a notification for use of a substance in PPORD activities that take place outside the EU/EEA and whether to list non-EU/EEA customers

Article 9 does not make any specific reference to substances manufactured for export for the purposes of REACH. However, the question may arise as to whether a PPORD notification should be made for activities that will only be carried out outside the EU/EEA (i.e. exported substances). A related question arises for both the cases where the notification is for activities outside the EU/EEA only and cases where some of the customers for the PPORD use are from within the EU/EEA market and others are outside it – that is whether details of customers for substances to be exported for PPORD use should be included in the list of customers with whom cooperation is carried out in any notification made.

The aim of Article 9 provisions is to give a manufacturer a basis on which to be exempted from registration obligations. Normally a registration would be needed for any substance **manufactured** at a volume of over one tonne per year that is not subject to any exemption; this obligation applies also for substances manufactured within the EU for the purposes of exports to non-EU/EEA markets. In practice, the **manufacturer** of a substance for non-EU PPORD purposes has therefore **only** two choices:

i. Make a PPORD notification in which the non-EU/EEA customer is transparently listed (either as sole listed customer or as one of a list of customers that may also include other customers inside/outside the EU/EEA) together with other necessary information to demonstrate that he is entitled to benefit from the exemption;
ii. Register any quantities of the substance manufactured above 1 tonne per annum that are **not** covered by any PPORD notification (as per (i)) above) or otherwise exempted

from Registration by different provisions of the REACH Regulation.

### 3.2.9 Compliance with conditions imposed by ECHA

ECHA may impose conditions to ensure that the conditions mentioned in Article 9(4) REACH are fulfilled. For this purpose, ECHA may also ask 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 ECHA. For more information on conditions that may be imposed by ECHA, please consult section 7 of this guidance document.

**A summary of obligations for substances used in PPORD (and comparison with those for SR&D) is provided in Appendix 1 to this guidance document.**

# 4. PPORD notification dossier

## 4.1 Information requirements

In accordance with Article 9(2), a manufacturer or importer or producer of articles who notifies ECHA of his intention to carry out PPORD by himself or in cooperation with listed customers on a substance, is exempted from the registration obligation. For that purpose, the notifier has to submit an electronic IUCLID dossier to ECHA with the following information:

*(a) the identity of the manufacturer or importer or producer of articles as specified in section 1 of Annex VI*:;

*(b) the identity of the substance, as specified in section 2 of Annex VI:;*

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 when information is reported in accordance with section 2 of Annex VI. Detailed guidance on identification and naming of substances can be found in the *Guidance for identification and naming of substances under REACH and CLP*.

(c) *the classification of the substance as specified in section 4 of Annex VI, if any*;

*(d) the estimated quantity as specified in section 3.1 of Annex VI:* 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 whom PPORD cooperation is carried out, including their names and addresses.

The notifier may decide to include in his notification dossier any further information that he regards as relevant in order to demonstrate that the definition of PPORD given in the Article 3(23) and the conditions under Article 9(4) are fulfilled. That information may include a list of applicable legislation and measures (operational conditions (OC) and risk management measures (RMMs)) applied to control releases to environment and to control exposure of workers.

### 4.1.1 Preparation of the PPORD notification dossier, IT submission and invoicing

A PPORD notification dossier must be created using the IUCLID software (International Uniform Chemical Information Database) and submitted to ECHA using the submission functionality in

the REACH-IT portal. All parties can download free of charge the latest version of IUCLID from the IUCLID website (http://iuclid.eu), if used for non-commercial purposes. Before creating a substance dataset and a dossier, it is strongly recommended to read carefully the relevant Data Submission Manuals:

- Data Submission Manual 1: How to prepare and submit a PPORD notification;
- Data Submission Manual 4: How to Pass Business Rule Verification ("Enforce Rules");
- Data Submission Manual 5: How to complete a Technical Dossier for Registrations and PPORD Notifications.

For instructions on how to submit the notification dossier, please consult the REACH-IT Industry User Manuals that provide background information on REACH-IT and its link to the IUCLID website and application. Details are provided as well on how to sign-up in REACH-IT, account management and the submission procedures. Special attention should be given to Industry User Manual 6: Dossier Submission, which describes how to submit a PPORD notification dossier and how to view the submission data within REACH-IT. Upon receipt of a PPORD notification dossier, ECHA will undertake a completeness check of the submission, which includes a technical completeness check (TCC) of the PPORD notification dossier. The purpose of this technical completeness check is to ensure that all the information required by Article 9(2) of the REACH Regulation has been provided in the dossier.

ECHA will issue a submission number and an invoice for the notification. The submission number will subsequently be replaced by the notification number[19]. The notifier must pay the relevant fee according to the Fee Regulation (EC) No 340/2008[20] after the invoice has been received. The invoice will contain the reference number to be quoted for the payment. ECHA will provide the PPORD notification number after verifying the completeness of the information and the payment of the relevant PPORD fee. The preparation and submission of a PPORD notification dossier using IUCLID is described briefly below.

#### 4.1.1.1 Signing-up in REACH-IT

Signing-up in REACH-IT is the starting point for any data submission to ECHA. Please refer to the Industry User Manual 1: Getting started with REACH-IT, for a general overview of the system. Each company and party must create an account in REACH-IT, online, providing the required identification details (i.e. legal entity name, contact details and billing information).

For more information, please consult Industry User Manual 2: Sign-up and account management and Industry User Manual 3: Login and Message Box.

For step-by-step instructions on how to submit the PPORD notification dossier via REACH-IT, please consult Industry User Manual 6: Dossier Submission, which describes how to submit a PPORD notification dossier and how to view the submission data within REACH-IT.

[19] Please note: the notification number has the same format as a registration number (as both are assigned by REACH-IT as reference numbers), but starts with the digit 04 (instead of 01); it is not a registration number. Its assignment demonstrates that a notification has been made and checked for completeness.

[20] As amended by Commission Implementing Regulation (EU) No 254/2013 of 20 March 2013

#### 4.1.1.2 Using IUCLID

After creation of a legal entity (*i.e.* Legal Entity Object (LEO)) in IUCLID or in REACH-IT, the notifier has to create the substance dataset in IUCLID, where the information on the substance can be entered. Please note that in the case of a PPORD notification, it is necessary to create the legal entities of the notifier and its customers (recipients). More information about legal entities can be found in the Industry User Manual Industry User Manual 2: Sign-up and account management and in the Data Submission Manual 1: How to prepare and submit a PPORD notification.
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 are summarised in Table 1 below.

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

| Links between Article 9(2), Annex VI and IUCLID sections | | |
|---|---|---|
| **Article 9(2)** | **Annex VI** | **IUCLID** |
| (a) identity of the manufacturer or importer or producer of articles | Section 1: General registrant information | Legal identity section and Substance dataset:<br>1.1 Identification |
| (b) identity of the substance | Section 2: Identification of the substance | Substance dataset:<br>1.1 General information<br>1.2 Composition<br>1.4 Analytical information |
| (c) classification and labelling | Section 4: Classification and labelling | Substance dataset:<br>2 Classification & Labelling and PBT assessment |
| (d) estimated quantity | Section 3.1 | Substance dataset:<br>1.9 Product and process orientated research and development |
| (e) listed customers | | Substance dataset:<br>1.8 Recipients |

**1) Identity of the manufacturer or importer or producer of articles**

Information regarding the identity of the notifier as specified in Article 9(2)(a) and Annex VI (section 1) must be reported under the IUCLID Legal identity section. All fields and all information specified in section 1 of Annex VI have to be entered in IUCLID 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 representative (TPR) appointed under Article 4 of the REACH Regulation referred to in these sections only apply to registration.

### 2) Identity of the substance

The notifier needs to submit in section 1 (in particular sections 1.1, 1.2, 1.4) of the IUCLID Substance dataset sufficient information to enable the substance to be identified as referred to in Article 9(2)(b) and section 2 of Annex VI to the REACH Regulation. In particular, in section 1.2 of the IUCLID dataset, 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 account.

Substance identification should be based on at least the substance identification parameters listed in REACH Annex VI, section 2:

- the IUPAC and/or other name and other identifiers, *e.g.* CAS number, EC number (section 2.1);
- the molecular and structural information (section 2.2);
- the chemical composition (section 2.3).

A substance is completely identified by its chemical composition, *i.e.* the chemical identity and the 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, *e.g.* its composition, degree of purity, nature of impurities and information on the analytical methods used. The notifier is advised to consult the *Guidance for identification and naming of substances under REACH and CLP* to clearly identify and name his substance in the notification dossier.

### 3) Classification and labelling

The notifier has to specify in section 2 of the IUCLID Substance dataset the classification and labelling of his substance for physical, health and environmental hazards, if available. The available information on classification and labelling should be reported in section 2.1 - (GHS) of IUCLID, in accordance with the Global Harmonised System (GHS). Please note that since the entry into force of the CLP Regulation for substances (on 1 December 2010), the provision of classification and labelling information in section 2.2 (DSD-DPD) according to Directive 67/548/EEC (DSD) has been optional.

Further information on the documentation of the classification and labelling within IUCLID is provided in the *Guidance on registration* and in Data Submission Manual 1: How to prepare and submit a PPORD notification. It is also recommended to consult Data Submission Manual 5: How to complete a technical dossier for registrations and PPORD notifications. In case the substance composition varies, it should be carefully evaluated whether this could have some impact on the classification and labelling of the substance.

### 4) Estimated quantity

The notifier must report the estimated quantity of the substance in the calendar year (of the notification) as specified in section 3.1 of Annex VI to the REACH Regulation. This estimate should be entered in section 1.9 of the IUCLID Substance dataset.

### 5) Listed customers

Unless the notifier undertakes the PPORD activity exclusively by himself, the notifier must identify in the IUCLID dossier any customer, with whom cooperation in the context of the PPORD notification is (to be) established. The information should be reported in section 1.8 of the IUCLID Substance dataset and must include as a minimum the name and address of the customer(s). More information can be found in Data Submission Manual 1: How to prepare and submit a PPORD notification and Data Submission Manual 5: How to complete a technical dossier for registrations and PPORD notifications.

#### 6) Additional information

The notifier has also the possibility to include in his notification dossier any further information he regards as relevant for the PPORD notification dossier. That information may include a list of applicable legislation and measures (OC and RMMs) applied to control releases to the environment and to control exposure of workers. Any such documentation is to be attached in the "Document" field or provided in the "Remarks" field in section 1.9 of the IUCLID Dossier. The SDS(s) submitted to the recipient(s) can be included in section 13 of the IUCLID dossier.

### 4.1.2 Completeness check

ECHA will undertake a completeness check of the notification within 2 weeks of the submission date (see Article 9(3) and (5) of the REACH Regulation). 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, ECHA will inform the registrant before expiry of the two-week period, as to what further information is required in order for the notification to be complete, and set a reasonable deadline to supply it (Article 20(2) and Article 9(3)). If the fee has not been paid, ECHA will set an extended due date for the fee payment. The notifier must complete his notification accordingly.

If the notification is not completed or the payment is not received by the deadline, ECHA will reject the notification.

A very useful IUCLID application called "Validation Assistant plug-in" offers a notifier the possibility to check the completeness of his PPORD notification before he submits it to ECHA via REACH-IT. It is recommended to run the plug-in first on the substance dataset and then on the final dossier. Using the plug-in in both steps is vital to avoid any unnecessary failures and potential rejection if the submission is for a requested update. The latest version of the plug-in can be downloaded via the notifier's IUCLID website account at: http://iuclid.echa.europa.eu. For further details, please refer to Data Submission Manual 5: How to complete a Technical Dossier for Registrations and PPORD Notifications.

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

### 4.1.3 Fees

The fees for the notification of a substance in accordance with Article 9(2) of the REACH Regulation are specified in Annex V of the Fee Regulation (EC) No 340/2008, as amended by Commission Implementing Regulation (EU) No 254/2013 of 20 March 2013.

Where the notification is submitted by a micro, small or medium-sized enterprise (SME)[21], ECHA will levy a reduced fee as set out in Table 1 of Annex V of the Fee Regulation.

[21] SME is defined in Commission Recommendation 2003/361/EC.

#### 4.1.4 When can the manufacture/import of the substance be started?

The notifier may start the manufacture or import of substance or mixture or production of the article for the purpose of PPORD two weeks after the notification date communicated with the reference number by ECHA after receipt of the notification dossier, in the absence of any indication to the contrary (see Article 9(5)).

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

# 5. PPORD notification update for new information

## 5.1 Change of information or new information available

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.

This can be relevant, e.g., where one of the following changes:

- Estimated quantities
- Classification and labelling of the substance
- List of customers involved
- Relevant new information on substance identification and composition (as long as the identity of the substance itself is not changed, in which case a new notification would be needed)

For more detailed information please consult section 8.3 (Creating a new dossier to update a PPORD notification) of the Data Submission Manual 1: How to prepare and submit a PPORD notification.

## 5.2 Cessation of the PPORD

The notifier can inform ECHA about the cessation of the PPORD using a specific REACH-IT functionality. After the cessation of the PPORD, the notifier must register the substance, if he intends to keep manufacturing or importing it.

For detailed step-by-step instructions on how to inform ECHA of cessation and restart of manufacture, please see chapter 3.4 of Industry User Manual 6: Dossier Submission.

When the PPORD ceases (or the exemption expires), the notifier must re-collect remaining quantities for disposal, unless he registers the substance.

## 5.3 Types of PPORD notification updates

REACH-IT makes a distinction between the “initial” submissions and “update” submissions. The “initial” submission is the first submission of a notification dossier for a substance. The “update” submissions are all subsequent submissions for that same substance and the same

dossier with updated information. Therefore, an update submission always takes place after the initial submission is completed. The reasons for the submission of an update dossier are classified as either “spontaneous” or “further to a request”. Spontaneous updates can be made in the following situations:

- Change of estimated quantities;
- Change in classification;
- Change in composition;
- Additional analytical information;
- Change of customers(s);
- Extension (prolongation) of the exemption period for PPORD (see sub-section 6.1 of this guidance document).

“Further to a request” updates are updates made to provide information explicitly requested by ECHA. Such an information request may arise, for example, after a decision by ECHA to request additional information in accordance with Article 9(4). In this case, the communication or decision number has to be quoted to allow association of the update submission with the communication or decision issued by ECHA.

For more technical instructions on how to update the PPORD notification dossier via REACH-IT, please consult Industry User Manual 6: Dossier Submission, which describes how to submit or update a PPORD notification dossier and how to view the submission data within REACH-IT.

### 5.4 Using IUCLID for PPORD notification update

The notifier may update his PPORD notification by submitting an updated IUCLID dossier, wherein reference to the latest previous PPORD submission number is made.

The IUCLID dossier should be created according to instructions provided in sub-sections 4.1.1 and 4.1.1.2, of this guidance document.

Before submitting the dossier to ECHA, it is strongly recommended to check the completeness of the submission by using the Validation Assistant plug-in (former TCC plug-in). It is recommended to run the plug-in first on the substance dataset and then on the final dossier. Using the plug-in in both steps is vital for the notifier to avoid any unnecessary failures and potential rejection if the submission is for a requested update.

In addition, by using the fee calculation plug-in the fee associated to the PPORD notification extension can be estimated. Both plug-ins can be downloaded from the IUCLID website.

For more information on updating a PPORD notification in IUCLID please consult Data Submission Manual 1: How to prepare and submit a PPORD notification.

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

According to Article 9(7) of REACH Regulation, the PPORD notifier has the possibility to request

an extension of the five-year exemption period by a further maximum of five years, or by a further maximum of ten 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[22].

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 programme (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?
- What result is expected to be achieved during the duration of the extension requested?

The notifier should be able to provide:

- scope and objectives of the foreseen R&D project;
- main relevant tasks necessary to achieve the final aim;
- main means and/or methods (*i.e.* field trials, laboratory activities, plant batches, customer testing, etc.) to perform the main relevant tasks;
- schedule and foreseen timing for completing each of the identified project tasks and the overall R&D.

The notifier should be able to support the need for an extension by providing the connection between the initial exemption and the R&D performed during the first 5 years and the new R&D program and its objectives. The process for requesting an extension of the exemption from registration is described in more detail in sub-section 6.1 below.

After examination of the request, ECHA drafts a decision, and submits it for comments to the Competent Authority of each Member State (MSCA) in which the manufacture, import or product and process orientated research takes place. ECHA will take into account the comments received from the MSCA(s) in its final decision on the request (see Article 9(8)).

The duration of the extension proposed by ECHA to MSCAs in the draft decision will be limited to a period that is justified by the R&D program submitted by the notifier and it may be shorter than five years. Once the notifier has a defined research and activity program and they know whether the PPORD activity will continue beyond the expiry date, they may eventually request a further extension of the exemption period to cover the full maximum term foreseen by the REACH Regulation. Since the extension period starts after the last day of the initial five-year exemption period, the notifier is recommended to submit his request for an extension of the exemption at least four months in advance to allow ECHA to examine the request and draft a decision, consult the relevant MS(s) and, potentially, revise the decision before issuing a decision on the request to the notifier.

[22] Note that any PPORD activity (other than in development of medicinal products for human or veterinary uses) which involves listed customers is automatically placing on the market and therefore cannot benefit from a 10 year exemption.

## 6.1 Request for an extension

The exemption period ends after 5 years. However, notifiers can request an extension of the exemption period, if they have not finalised the PPORD within these five years. To do so, they can submit an extension request to ECHA via REACH-IT.

The extension request currently takes the form of a notification update and it is indicated in the IUCLID dossier header as a spontaneous update of the current notification.
When creating the dossier (step 6 of the IUCLID dossier creation wizard) the box "The submission is an update" must be ticked and then the last submission number related to the PPORD notification for which an extension is requested must be inserted ("Last submission number" field). In addition, the box "Spontaneous update" must be ticked and a new repeatable block of information has to be created (green cross button to be ticked). In that block, it is mandatory to select “extension of exemption period for PPORD” as the justification for the update. In case this information is not properly selected, the update will not be processed as a request for extension.

A research and development programme that justifies the extension must be attached to this request in section 1.9 of IUCLID ("Product and process orientated research and development"). A template for providing information about the research and development program and reasons for request for extension is provided on the ECHA website (http://echa.europa.eu/support/dossier-submission-tools/reach-it/ppord) under the section “Related documents”.

Upon submission of the extension request, the notifier will receive an invoice for a charge for the extension. After the charge is paid, ECHA will make a decision (in consultation with the relevant Member States) on whether the extension of the exemption is justified for the period requested. ECHA recommends submission of the extension request at least four months before the expiry date of the original exemption. This timeline enables ECHA to process the request on time, and ensures no interruption of the PPORD exemption. Payment of the fee should be made as soon as possible, but in any case within 30 days, as ECHA must await the payment of the fee before it can assess the extension request.

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

As detailed in Article 9(4) of the REACH Regulation, ECHA may decide to impose conditions on the PPORD activity at any time during the exemption period, with the aim of ensuring that the following requirements are fulfilled:

- The substance will be handled only by staff 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) of the REACH Regulation;
- 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 mixture or in an article;
- Remaining quantities of the substance will be re-collected for disposal after the exemption period.

ECHA may therefore ask the notifier to provide additional necessary information (7.1) that

allows a conclusion that either the conditions are fulfilled or that there is a need for conditions to be imposed (examples of the latter in 7.2 below).

## 7.1 Request by ECHA for additional necessary information from a PPORD notifier

The information provided in the PPORD notification is relevant for ECHA in order to verify if legal requirements under Article 9(4) are fulfilled or to decide if conditions need to be imposed with the aim of ensuring that these requirements are fulfilled. To fulfill Article 9(4) requirements in each phase of the life cycle of the substance, the notifier should be able to demonstrate that:

- he has identified the applicable legal requirements under the legislation for the protection of workers and the environment and he can ensure that those requirements are fulfilled;
- he keeps track of the quantities of substance used in the PPORD by himself and by listed customers. This include the amounts of the substance used as such, in mixtures or incorporated into articles, the amounts lost in the processes and the residual amounts which are recollected for disposal;
- he is able to provide documentation (*e.g.* shipment documents, disposal documents, information on process losses, etc.) proving that these quantities are tracked.

If the information provided in the PPORD notification does not allow ECHA to conclude that Article 9(4) requirements are fulfilled, ECHA may request additional information that is necessary to determine whether conditions should be imposed.

Additional information requested by ECHA may include:

- a list of applicable legislation and measures taken by the notifier and, where relevant, his listed customers to comply with this legislation, for example a description of the operational conditions (OC) and risk management measures (RMMs) applied to control releases to the environment and exposure of workers;
- information on the quantities used to carry out the PPORD in order to ascertain that the substance is not made available to the general public at any point in time in any form;
- written assurances that the substance is not provided to the general public;
- written assurances about the appropriate re-collection for disposal at the end of the exemption period;
- the identity of the substance as well as its composition has a direct impact on the potentially known physical, chemical, toxicological and eco-toxicological properties. Such properties may results in the classification of the substance. Without correct identification of the substance and information on its composition, it may be impossible to determine its hazardous properties and subsequently apply correct classification and labelling and therefore to ensure the application of reasonably controlled conditions. Thus, ECHA may need additional information for an unambiguous identification of the PPORD substance, information about the intrinsic properties of the substance and information on the correct classification and labelling;
- other necessary information as identified by ECHA on a case-by-case basis.

The request will include a deadline for submission of the information. If the requested information is not submitted within the deadline ECHA will invite the relevant National Enforcement Authorities (NEA(s)) to take appropriate action. When all the necessary additional information has been supplied ECHA (in consultation with the Member States) will make a decision on what conditions (if any) should be imposed.

## 7.2 Examples of possible conditions that may be imposed

The following (non-exhaustive) list includes examples of conditions that ECHA may impose on notifiers of substance used in PPORD with the aim to ensure that requirements of Article 9(4) are fulfilled:

i. to submit periodic overviews of the quantities manufactured, imported, used, lost, disposed of, etc.. ECHA will specify for each individual case whether the updates need only be sent to ECHA, only to the MSCA or to both;

ii. to provide written assurance that the substance is only handled by staff of listed customers, that the substance is not made available to the general public and that any remaining quantity will be recollected for disposal after the exemption period;

iii. to prove that the above-mentioned quantities are traceable[23];

Specifically, ECHA may impose on the notifier the obligation to provide information and documentation showing that traceability is ensured for these recorded quantities from the various sources and paths taken for the full duration of the PPORD activity;

iv. to provide written assurance that the substance will be used in accordance with the requirements of legislation for protection of human health and the environment; the assurance can include a list of applicable legislation and measures;

v. to provide appropriate documentation to describe OC and RMM [24, 25] applied to control exposure of workers or releases to the environment (*i.e.* to comply with the applicable legislation for the protection of workers and the environment);

[23] The notifier must be able to provide documented proof of these quantities (e.g. through shipment documents, disposal documents, information on process losses, on the substance fate, etc.).

[24] The information should describe the technical means used during the whole lifecycle of the substance, including potential accidents, to reasonably minimise emissions in the environment and any potential exposure: the procedural measures and control technologies, the cleaning and maintenance procedures, the training programme and authorising system for the personnel. The description should include the evaluation of the expected efficacy of those means in ensuring reasonably controlled conditions taking into account the substance characteristics, the process description, the consumption rate(s), the release rate(s), sewage treatment plant used, air emission abatement system selected, etc.

[25] The information should describe the technical means used during the whole lifecycle of the substance, including potential accidents, to reasonably minimise emissions in the workplaces and any potential exposure of workers: the procedural measures and control technologies, the cleaning and maintenance procedures, the training programme and authorising system for the personnel. The description should include the evaluation of the expected efficacy of those means in ensuring reasonably controlled conditions taking into account the substance characteristics, the process description, the consumption rate(s), the release rate(s), local exhaust ventilation used, the general and personal protective equipment (PPE) selected, etc.

vi. to provide a confirmation from all customers involved in the PPORD activity that their use takes place in compliance with the requirements of the legislation for the protection of workers and the environment;

vii. to implement other conditions, as appropriate and on a case-by-case basis, if risks from using the substance are identified (limits in quantities, time, activities, etc.) relevant for each life stage of the substance.

# 8. Confidentiality

As underlined in Article 9(9), ECHA and the MSCAs concerned must always keep confidential any information submitted by the manufacturer or importer of a substance for the purpose of PPORD.

# Appendix 1: Summary of the obligations for substances used in SR&D and PPORD

| Type of obligation | Substance used in SR&D | Substance used in PPORD |
|---|---|---|
| **Registration** | • not required for a substance used according to the definition of SR&D given in Article 3(23).<br>• See sub-section 3.1.1 | • temporarily not required for a substance notified according to Article 9(2).<br>• See sub-section 3.2.1 |
| **Authorisation** | • not required if the use of substance falls within the definition of SR&D given in Article 3(23).<br>• See sub-section 3.1.2 | • required for a substance listed in Annex XIV and used in PPORD, unless exempted, cf. the column *"Exempted (categories of) uses"* in Annex XIV.<br>• See sub-section 3.2.2 |
| **Restriction** | • does not apply if the manufacture, use or placing on the market of the substance falls within the definition of SR&D given in Article 3(23).<br>• See sub-section 3.1.3 | • applies to the use of substance in PPORD, unless it is explicitly exempted in Annex XVII.<br>• See sub-section 3.2.3 |
| **Classification, labelling and packaging according to CLP** | • Rrequired, even if a substance or mixture falls within the definition of SR&D given in Article 3(23), unlessit is not placed on the market.<br>• See sub-section 3.1.4 | • required for substances used in PPORD or mixtures containing them, irrespective of whether these substances or mixtures are made available to the listed customers or not.<br>• See sub-section 3.2.4 |
| **Notification to the C&L Inventory** | • required if the substance (or a mixture containing it) is classified as hazardous and it is placed on the market;<br>• See sub-section 3.1.5 | • required if the substance (or a mixture containing it) is classified as hazardous and it is placed on the market;<br>• See sub-section 3.2.5 |

| Type of obligation | Substance used in SR&D | Substance used in PPORD |
|---|---|---|
| **Information in the supply chain** | Substance is hazardous:<br>• SDS required if the substance (or a mixture containing it) is hazardous according to Article 31(1);<br>Substance is not hazardous:<br>• SDS not required;<br>• SDS-type information may be provided voluntarily;<br>• Information according to Article 32 is required. However, in practice, if none of the conditions described in Article 32 (b), (c) or (d) apply then no other information is needed under Article 32 for a substance or mixture for which an SDS is not required.<br>See sub-section 3.1.6 for both the above | Substance is hazardous:<br>• SDS must be provided (to the listed customers) if the substance (or a mixture containing it) is hazardous according to Article 31(1);<br>Substance is not hazardous:<br>• SDS not required;<br>• SDS-type information may be voluntarily provided to the listed customers only;<br>• Providing information according to Article 32 (to the listed customers) is required. However, in practice, if none of the conditions described in Article 32 (b), (c) or (d) apply then no other information is needed under Article 32 for a substance or mixture for which an SDS is not required.<br>See sub-section 3.2.6 for both the above |

| Type of obligation | Substance used in SR&D | Substance used in PPORD |
|---|---|---|
| **Downstream user (DU) obligations** | • Normal obligations of a DU apply as for any substance generally<br><br>(No specific sub-section in this document; for general DU obligations see the ECHA *Guidance for Downstream Users* at: http://echa.europa.eu/guidance-documents/guidance-on-reach ) | DU is included as a listed customer in a PPORD notification submitted by the supplier:<br>• DU must use the substance only for the purpose of PPORD;<br>• DU must implement the conditions communicated by his supplier (including any conditions imposed by ECHA);<br>DU uses the registered substance for his own PPORD under his own responsibility:<br>• normal obligations of a DU apply as for any standard substance;<br>• CSR for the PPORD is not required according to Article 37(4)(f);<br>• DU must report to ECHA the information specified in Article 38(2) for substances used in PPORD in quantity at above 1 tonne/year.<br>See sub-section 3.2.7 for both the above |
| **Compliance with conditions imposed by ECHA** | • not applicable; | • required for any conditions imposed by ECHA in accordance with Article 9(4).<br>• See sub-section 3.2.9 **and Section 7 in its entirety.** |

# Appendix 2: Text of Article 9 of REACH

***"Exemption from the general obligation to register for product and process orientated research and development (PPORD)***

*1. Articles 5, 6, 7, 17, 18 and 21 shall not apply for a period of five years to a substance manufactured in the Community or imported for the purposes of product and process orientated research and development by a manufacturer or importer or producer of articles, by himself or in cooperation with listed customers and in a quantity which is limited to the purpose of product and process orientated research and development.*

*2. For the purpose of paragraph 1, the manufacturer or importer or producer of articles shall notify the Agency of the following information:*

*(a) the identity of the manufacturer or importer or producer of articles as specified in section 1 of Annex VI;*

*(b) the identity of the substance, as specified in section 2 of Annex VI;*

*(c) the classification of the substance as specified in section 4 of Annex VI, if any;*

*(d) the estimated quantity as specified in section 3.1 of Annex VI;*

*(e) the list of customers referred to in paragraph 1, including their names and addresses.*

*The notification shall be accompanied by the fee required in accordance with Title IX.*

*The period set out in paragraph 1 shall begin at receipt of the notification at the Agency.*

*3. The Agency shall check the completeness of the information supplied by the notifier and Article 20(2) shall apply adapted as necessary. The Agency shall assign a number to the notification and a notification date, which shall be the date of receipt of the notification at the Agency, and shall forthwith communicate that number and date to the manufacturer, or importer, or producer of articles concerned. The Agency shall also communicate this information to the competent authority of the Member State(s) concerned.*

*4. The Agency may decide to impose conditions with the aim of ensuring that the substance or the mixture or article in which the substance is incorporated will be handled only by staff of listed customers as referred to in paragraph 2(e) in reasonably controlled conditions, in accordance with the requirements of legislation for the protection of workers and the environment, and will not be made available to the general public at any time either on its own or in a mixture or article and that remaining quantities will be re- collected for disposal after the exemption period.*

*In such cases, the Agency may ask the notifier to provide additional necessary information.*

*5. In the absence of any indication to the contrary, the manufacturer or importer of the substance or the producer or importer of articles may manufacture or import the substance or produce or import the articles not earlier than two weeks after the notification."*

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