PPORD assessment process

1. Purpose

The purpose of this procedure is to describe the assessment of dossiers for product and process orientated research and development (PPORD) submitted to ECHA and the steps taken to ensure the adequacy of the exemption from the general obligation to register in accordance with Article 9 of the REACH Regulation.

This procedure is designed to enable the Agency to decide whether:

1. there is a need to impose conditions based on a sound and consistent expert judgement in accordance with Article 9(4) of the REACH Regulation and
2. an extension of the exemption period is justified by the research and development programme in accordance with Article 9(7) of the REACH Regulation.

2. Scope

This procedure starts when the submission of the PPORD dossier is considered as complete after passing the mandatory submission checks that are conducted by the Dossier Submission and PIC Unit (PRO 0002) and relevant identifiers of the dossier submission are used to be stored in the PPORD database of the Substance Identity and Data Sharing Unit (in line with POL 0007). It ends when either the PPORD dossier is closed without further action or a Decision requesting further information, imposing conditions, or granting an extension from the general obligation to register, is sent to the PPORD notifier through REACH-IT.

3. Description

PPORD dossiers refer either to an initial submission, a spontaneous update or a requested update and are handled by two processing procedures:

1. PPORD Decision-making process according to Article 9(4)(imposing conditions):

   A manufacturer or importer or producer of articles who uses a substance in quantities greater than one tonne per year in product and process orientated research and development (PPORD) submits a PPORD notification in the form of a IUCLID dossier through REACH-IT to ECHA. This dossier needs to contain information in accordance with Article 9(2) of the REACH Regulation and may concern the notifier's own PPORD or a PPORD conducted in cooperation with the listed customers. If new information becomes available, the notifier needs to update the PPORD dossier and send a spontaneous update through REACH-IT. If ECHA finds the information provided in the PPORD dossier to be insufficient to be able to decide whether there is a need to impose conditions, further information can be requested and the notifier has to submit a requested update.

2. PPORD Decision making process according to Article 9(7) (extensions):

If the first five years of the exemption period are not sufficient to finalise the PPORD activity, the notifier can request an extension in accordance with Article 9(7) of the REACH Regulation. To justify an extension of the original PPORD notification, the notifier needs to include a Research and Development programme in the updated PPORD dossier and indicate in the IUCLID dossier that it concerns a prolongation of the PPORD.

Only those PPORD dossiers for which the submissions are considered as complete because they have fulfilled the technical requirements for processing (Business Rules) are accepted for the PPORD process.

The handling of PPORD dossiers is divided into four stages:

Phase 1 – Screening and allocation of PPORD dossiers (see 3.1)

All PPORD submissions that have been accepted for processing are screened to identify dossiers “of concern” or “extension requests”. These latter dossiers are always allocated for expert assessment. Dossiers not identified for expert assessment are allocated for automatic closure.

Phase 2 – Expert Assessment (see 3.2)

PPORD dossiers identified in Phase 1 as “of concern” or “extension requests” undergo an expert assessment. Depending on the type of dossier, the Substance Dossier Manager (SDM) decides whether:

(a) the information provided by the notifier is considered adequate to conclude that the requirements of Articles 9.2 and 9.4 are reasonably fulfilled and the dossier can be closed, or

(b) a request of further information to decide to impose conditions needs to be sent, or

(c) there is a need to impose conditions with the aim to ensure that the PPORD substance or the mixture or article in which the substance is incorporated:

- is handled in reasonable conditions, in accordance with the requirements of legislation for the protection of workers and the environment;
- is only used by the notifier and/or listed customer(s) with which the PPORD cooperation is carried out; and
- is not made available to the general public on its own, in a mixture or in an article.

(d) an extension can be granted as the request is justified by the Research and Development programme (Article 9.7).

Phase 3 – Review of the Draft Decision (see 3.3)

A Draft Decision requesting further information (RFI) or imposing conditions (IC) or granting or not granting an extension (Ex) is reviewed by another expert in the Substance Identity and Data Sharing Unit to ensure that the respective requirements are fulfilled.

Phase 4 – Communication with notifier and, where necessary, Member State Competent Authorities (MSCAs) (see 3.4)

In case of a Decision (RFI, IC and/or Ex) the results of the assessment are communicated to the notifier. If the information provided in a PPORD dossier (excluding extension requests) is found to be sufficient, the conclusions of the assessment are not communicated to the notifier. MSCAs are consulted on any Draft Decision on imposing conditions in accordance with Article 9.4 of the REACH Regulation and extension requests in accordance with Article 9(7) of the REACH Regulation. Comments provided by the MSCA(s) within 30 days during the consultation period are considered to prepare the Final Decision. Following approval by the Authorising Officer, the Final Decision is sent to the notifier.

3.1. Screening and allocation of PPORD dossiers (steps 1-7 on the flowchart)

All PPORD dossiers, which have passed the mandatory submission checks (conducted as described in PRO-0002 “Dossier Processing”) are accepted for processing.

The PPORD Process Coordinator (PC) screens all newly submitted PPORD dossiers to identify dossiers “of concern” and “extension requests” and allocates these always for expert assessment while the dossiers not selected for expert assessment will be closed and is therefore considered completed.

The PPORD PC assigns the PPORD dossiers taking into account any potential Conflict of Interest (CoI) (according to WIN-0105) before making the final assignment. For all PPORD dossiers chosen for expert assessment, a record is made in ECHA’s Business Application that stores data, indicating whether a potential CoI was found or not.

The PPORD PC also checks if any new submission relates to a spontaneous update or a requested update. In such a case, whenever possible, the spontaneous and/or requested update dossier is allocated to the same SDM in the PPORD database (and if possible to the same verifier) who dealt with the initial submission.

3.2. Expert Assessment (step 8 on the flowchart)

A Substance Dossier Manager (Initiating Agent) (SDM (IA)) will be responsible for the PPORD dossier.

3.2.1 Assessment of initial submission (steps 9-13 on the flowchart)

The SDM (IA) assesses the substance identity (SID), checks the provided classification and labelling (C&L), the number of recipients, estimated quantities produced/imported and used in the PPORD activity, and verifies that all requirements of Articles 9(2) and 9.4 are met. The IA prepares an assessment report with the findings and conclusions. All steps are carried out following the internal working instruction (WIN-0178).

If the provided information is satisfactory, the IA suggests to close the dossier. If the Verifying Agent (VA) agrees with the IA, the case can be closed and no further action is needed.

If the provided information in the PPORD dossier is not sufficient, and as such it is not possible to verify whether the PPORD substance:

- is used in reasonable conditions,
- is only used by the notifier and/or listed customer(s) with which the PPORD cooperation is carried out, and
- is not made available to the general public on its own, in a mixture or in an article,

the IA flags this in the report and drafts a decision requesting further information (RFI) in order to clarify whether there is a need to impose conditions. Both the assessment report and draft decision are verified by the VA.

3.2.2 Requested update (steps 14-18 on the flowchart)

If there is a requested update submitted following the Decision (RFI), the IA retrieves the report and Decisions (RFI) and assesses whether the additional information requested has been provided in the dossier update.

If the IA concludes during the expert assessment that the provided additional information is sufficient the dossier is closed. However, if the provided additional information is not satisfactory and/or reveals that there is a need to impose conditions, the IA prepares the assessment report and drafts a Decision to impose conditions (IC). Both are verified by the VA.

3.2.3 Extension request (steps 19-25 on the flowchart)

If a research and development (R&D) programme is provided by the notifier, in particular in an extension request of the PPORD activity, the IA verifies its content following internal working instruction (WIN-0179). The IA concludes whether it covers a PPORD activity and whether the requested extension can be granted or not, and prepares the report with the justification to grant or not to grant the extension and corresponding decision. Both are verified by the VA. If the provided R&D programme is not sufficient to grant the extension, the IA prepares an informal communication to request additional R&D information. When reviewed by the VA and agreed, the communication is sent to the notifier. Once the notifier has provided the additional R&D information and it has been found to be satisfactory, the IA prepares the Draft Decision to grant the extension. If, however, the updated R&D information is not found satisfactory or no additional R&D information is provided, the IA prepares the Draft Decision to not to grant the extension.

In all the above scenarios where the VA does not agree with the IA, the VA provides comments and the IA revises the report and/or Draft Decision. The VA verifies the amended report and/or revised Draft Decision and if the VA still considers a need to make changes, the cycle starts again until there is agreement.

3.3. Review of Draft Decisions (steps 26-28 on the flowchart)

A Draft Decision requesting further information (RFI) or imposing conditions (IC) or granting or not granting an extension (Ex) is reviewed by another expert in the Substance Identity and Data Sharing Unit to ensure that the respective requirements are fulfilled and that the information requested (in case of RFI and IC) is proportional and the extension period (in case of Ex) is justified by the R&D programme.

For this, the respective Draft Decision is stored in Dynamic Case (DC), a Business application that stores PPORD process data, so that the expert can review it and include comments if necessary. The comments are taken into consideration when finalising the Decision.

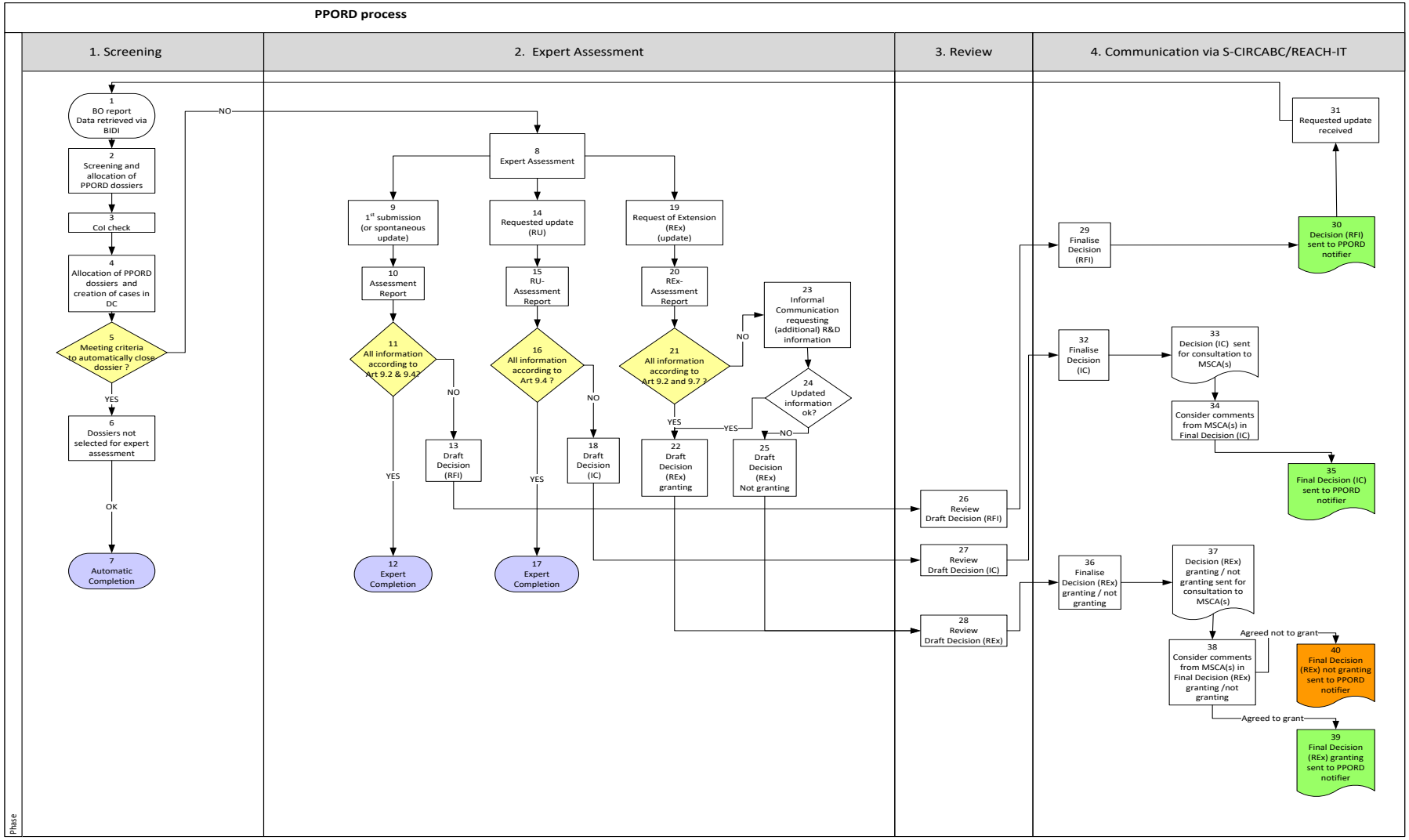
3.4. Communications with notifier and, where necessary, MSCAs (steps 29-40 on the flowchart)

If the information provided in a PPORD dossier (excluding extension requests) is found to be adequate to fulfil the requirements of Articles 9.2 and 9.4 by the IA and VA the conclusions of the assessment are not communicated to the notifier.

If there is a Decision (RFI), the results will be communicated to the notifier through REACH-IT outlining discrepancies, missing information and requesting information to be provided in the requested update (respective MSCA(s) obtain a copy). Once the requested update is received, the process starts from step 1 (see flowchart).

The MSCAs are consulted on any Draft Decision on imposing conditions in accordance with Article 9.4 of the REACH Regulation and extension requests in accordance with Article 9(7) of the REACH Regulation. Comments provided by the MSCA(s) within 30 days during the consultation period are considered and if applicable included in the Final Decision. Each Final Decision is approved and signed by the Authorising Officer before it is sent to the notifier. The National Enforcement Authorities (NEAs) are informed through the ECHA Portal Dashboard-NEA when a Final Decision (IC) is sent to the notifier.

4. Flowchart


PPORD process
1. Screening
2. Expert Assessment
3. Review
4. Communication via S-CIRCABC/REACH-IT
Phase
1 BO report Data retrieved via BIDI
2 Screening and allocation of PPORD dossiers
3 CoI check
4 Allocation of PPORD dossiers and creation of cases in DC
5 Meeting criteria to automatically close dossier ?
NO
YES
6 Dossiers not selected for expert assessment
OK
7 Automatic Completion
8 Expert Assessment
9 1st submission (or spontaneous update)
10 Assessment Report
11 All information according to Art 9.2 & 9.4?
NO
YES
12 Expert Completion
13 Draft Decision (RFI)
14 Requested update (RU)
15 RU-Assessment Report
16 All information according to Art 9.4 ?
NO
YES
17 Expert Completion
18 Draft Decision (IC)
19 Request of Extension (REx) (update)
20 REx-Assessment Report
21 All information according to Art 9.2 and 9.7 ?
NO
YES
22 Draft Decision (REx) granting
23 Informal Communication requesting (additional) R&D information
24 Updated information ok?
YES
NO
25 Draft Decision (REx) Not granting
26 Review Draft Decision (RFI)
27 Review Draft Decision (IC)
28 Review Draft Decision (REx)
29 Finalise Decision (RFI)
30 Decision (RFI) sent to PPORD notifier
31 Requested update received
32 Finalise Decision (IC)
33 Decision (IC) sent for consultation to MSCA(s)
34 Consider comments from MSCA(s) in Final Decision (IC)
35 Final Decision (IC) sent to PPORD notifier
36 Finalise Decision (REx) granting / not granting
37 Decision (REx) granting / not granting sent for consultation to MSCA(s)
Agreed not to grant
38 Consider comments from MSCA(s) in Final Decision (REx) granting /not granting
40 Final Decision (REx) not granting sent to PPORD notifier
Agreed to grant
39 Final Decision (REx) granting sent to PPORD notifier

5. Definitions

Term or abbreviation	Definition
BIDI	Business Intelligence and Data Integration ECHA's business intelligence and reporting IT tool
Business Rules	The business rules are automatic checks done in REACH-IT to establish that the submitted dossiers meet a set of minimum requirements. They ensure that the dossiers can be handled properly and that the required regulatory processes can be successfully carried out.
BO	Business Object
CIRCABC	Communication and Information Resource Centre for Administrations, Businesses and Citizens
C&L	Classification and Labelling
CoI	Conflict of Interest
ECHA	European Chemicals Agency
IUCLID	International Uniform Chemical Information Database Software application used to capture and store, submit, and exchange data on chemical substances
DC	Dynamic Case
Ex	Extension
HoU	Head of Unit
IC	Imposing Conditions
IA	Initiating Agent
MSCA	Member State Competent Authority
NEA	National Enforcement Authority
PC	Process Coordinator
PPORD	Product and Process Orientated Research and Development
REACH-IT	Online platform to submit and process dossiers under REACH, CLP, Biocides and PIC Regulations. It also allows ECHA and the Member States Competent Authorities to review dossiers.
REx	Request of Extension

Term or abbreviation	Definition
RFI	Request of Further Information
RU	Requested Update
SID	Substance Identity
SDM	Substance Dossier Manager
VA	Verifying Agent

6. Records

Record name	Security level	Comments
CoI check	Restricted	
Communication to notifier	Internal	
Communication to MSCA(s)	Internal	
Communication to NEA	Internal	

7. References

Associated document code	Document name
Regulation (EC) No 1907/2006	REACH Regulation
Regulation (EC) No 1272/2008	CLP Regulation

8. Annexes

N/A