Dossier Processing

1. Purpose

This document describes the processes and process controls in place under ECHA Activity 01.04 'Registration and other dossier submissions' for the REACH and CLP, Biocidal Product Regulation (BPR) and PIC Regulations.

The processes and controls are in place to ensure that:

- submitted dossiers/notifications are processed in conformity with the relevant legislative requirements;
- the legislative deadlines are respected and the Agency internal requirements for efficient dossier processing are met;
- confidential information is handled appropriately;
- the responsibilities and decision-making are unambiguously defined for all relevant activities.

2. Scope

The activity described in this Procedure covers the reception, full or partial processing and dispatch of all submitted dossiers/notifications. The scope in terms of the specific dossier/notification types is summarised in Annex 8 of this document.

3. Description

Processing tasks under REACH and CLP, BPR and PIC Regulations

The REACH, CLP and BPR processes under Activity 01.04 are essentially very similar and are outlined in sections 3.1.1 and 3.1.2, respectively. Section 3.1.3 provides a description of the PIC processes. All sub-processes under these Regulations are described in full in the relevant IQMS documentation and ECHA User Manuals.

The overall responsibility for ensuring the effective implementation of this procedure, its development, maintenance, and suitable management of changes, lies with the Process Owner.

3.1. Processing under REACH and CLP

Dossier processing is in place to ensure that the submission contains the information required by the relevant legal text and is in the necessary format for further processing by evaluating authorities (and, where relevant, for dissemination).

For registration and PPORD notification dossiers, Activity 01.04 covers the whole process, from the moment of submission to the generation of a formal decision (positive or negative) on their ability to legally manufacture/import the substance or in case of PPORD notifications to be exempted from registration obligations for a set time period. For all other dossier types (see Chapter 8. Annexes for dossier types), ECHA C1 trained staff carries out the format check, invoicing (where relevant) and financial rejections (for non-payment, where necessary). This facilitates the subsequent evaluation/assessment by other activities/processes.

The processing of submissions is, to a large extent, an automated process in REACH-IT. Manual processing is required at certain control points, which vary depending on the submission type. Regular quality checks and process controls are in place for automated steps and manual tasks respectively (section 3.2).

The central workflow application for the processing of dossiers is REACH-IT. Dossiers are submitted either through REACH-IT or through dedicated web forms on ECHA's website. Dossier content is checked using the IUCLID (International Uniform Chemical Information Database) application.

3.1.1. Format check and Business Rules verification (all dossier types)

All dossiers submitted via REACH-IT or the dedicated web-forms undergo an initial administrative check upon receipt. The format of the submitted dossier needs to be a specific type of IUCLID dossier, according to the submission type.

The submitted dossiers are scanned for known viruses. The format check ensures that the submitted file is of the appropriate format, e.g. .i5z file. It also checks that the submitted file is compliant with the XML schema used by IUCLID. Business Rules (BRs) are a set of pre-requisites that must be fulfilled before a dossier can be processed. Once the technical validation and the BR verification have passed, the submission is accepted for processing. A submission number and a submission date is then assigned to each submission that is accepted for processing. This information is communicated to the submitter via REACH-IT.

If the dossier submission fails at the format check or BR verification phase, the dossier cannot be accepted for processing and a new submission is required before any regulatory processes can be initiated. To facilitate a re-submission, the reasons for the failures are indicated in a submission report communicated to the registrant via REACH-IT.

3.1.2. Processing: Completeness check

The technical completeness check is a check on the content of the dossiers, required under REACH for registration and PPORD dossiers. These dossier types, together with any dossier for which a fee is required, also undergo a financial completeness check (See Chapter 8: Annexes).

After pre-processing, the dossier proceeds to the completeness check, which combines the technical completeness check (TCC) and the financial completeness check (FCC), as applicable.

If either TCC or FCC fails, the dossier is considered as incomplete and the outcome will be negative. When both TCC and FCC pass successfully, the outcome will be positive.

The completeness check of a registration dossier has to be performed within the legal deadline (see REACH Article 20(2)). PPORDs have an internal deadline of two weeks for processing through the completeness check.

a) Technical completeness check – TCC (Registration and PPORD only)

Each of these dossier types has its own legal requirements regarding technical completeness.

REACH-IT automatically checks that all information required by the regulation has been provided. If there is a negative result, the outcome is verified manually.

The TCC result is communicated to the submitter in REACH-IT. Submitters must complete their dossiers by submitting an update within a set deadline. A maximum of two TCC cycles are permitted per dossier (i.e. a second TCC failure results in a negative decision).

b) Financial completeness check – FCC (Registration, PPORD, CLP24, AfA and Industry CLH)

Title IX of REACH describes the general principles regarding the payment of fees and charges in relation to REACH. More specifically, the Fee Regulation (Commission Regulation (EC) No 340/2008 of 16 April 2008, amended by Commission Implementing Regulation (EU) 2015/864) stipulates the payment terms for ECHA's invoices. For all initial registrations[1], PPORD, CLP24, AfA and Industry CLH dossiers, submitters are required to pay a fee for their submissions. For registration updates (including legal entity change), the issuing of an invoice depends on the specific type of update and is described in the relevant sub-process documentation. The amount and deadlines for payment depend on the type of submission (REACH Article 74).

Once the submitter has submitted a registration, PPORD or AfA dossier and it has been accepted for processing, REACH-IT automatically computes the applicable fee, if any, for the dossier submitted. The invoice is sent to the submitter through REACH-IT. For CLP24 and Industry CLH dossiers, the invoice is created manually using the REACH-IT application. The financial assistants of the finance unit monitor the timely payments of outstanding invoices and reconcile them with the related payments received.

Invoices are also created as follow up to the SME verification process and are created manually in REACH-IT.

In addition to this mainstream invoicing work, processes are in place to issue updated invoices /credit notes via REACH-IT, for example in case the company made an error in their application. Such requests are received and managed via the Helpdesk processes and are implemented via REACH-IT.

[1] In case of standard registrations in the tonnage band of 1-10 tonnes per annum, if the full Annex VII data requirements are provided, the fee can be waived, should the registrant request it

3.1.3. Communicating the final outcome (Registration, PPORD, AfA, CLP24, Industry CLH and SEV dossiers)

Depending on the dossier type, there are three distinct possible final outcomes: (i) a formal positive decision (ii) a formal negative decision, or (iii) a communication.

a) Positive decision (Registrations and PPORDs)

If the outcome of the completeness check is considered complete for an initial submission, a reference number (a "registration number" for registrations or "PPORD notification number" for PPORDs) and a reference date are assigned for the dossier concerned. The reference number is unique for every submission type, substance and company.

The above information is communicated to the submitter in REACH-IT as a formal decision.

No new registration/notification number is assigned for updates, as these dossiers already have a reference number assigned from the initial successful submission. A formal positive decision is sent also in these cases.

b) Negative decision (Registrations, PPORDs and other submissions, where fee is to be paid)

If the outcome of the completeness check is incomplete, a negative decision or communication is issued. The submitter is informed of the reasons to the failure in the formal letter sent via REACH-IT. In case the submission was for a registration, the negative decision letter also informs the registrant of the consequences of placing the substance on the market.

Where a submission is rejected, any fees already paid are not reimbursed.

In the context of the SME verification process, non-payment of an SME 'top up' invoice (difference in what was originally paid and what should have been paid based on the actual size of the company) results in revocation of the registration and a formal negative decision letter informing the company of the consequences.

c) Other communication, following the (pre-)processing (Positive or negative (for non-financial reason) outcome for AfA, CLP24, Industry CLH and SEV submissions)

Following the applicable (pre-)processing, the outcome of the activity (accepted or rejected) is communicated to the submitter. The communication is sent through REACH-IT.

3.1.4. Informing the relevant Member State competent authority

Member State competent authorities (MSCAs) have direct access to submission information through REACH-IT. This also includes any request for further information from the registrant including deadlines set, and any information submitted by the registrant.

3.1.5. Handling of NONS Dossiers

Notifications of substances performed under Dangerous Substances Directive are considered as registrations under REACH. ECHA implemented a system for companies to request their registration numbers. Previous notifiers (registrants under REACH) have the obligation to update their notifications with certain new information, as prescribed in the REACH Regulation, when those become available. If such an update is due to an increase of the tonnage band, the standard processing procedure as described above applies. In other

cases, the update dossier is subject to fewer requirements under the technical completeness check.

3.2. Processing under the Biocides Regulation

The biocide submission sub-processes are essentially the same as those carried out under REACH and CLP, with some difference in terms of nomenclature. These processes are carried out in the R4BP 3 application (supported by the REACH-NG application in cases where invoicing is required). Depending on the dossier type, submissions which pass the format check and (where relevant, invoicing) are then forwarded to the relevant evaluating authority for further processing/decision making. This further processing can be done within ECHA (Directorate D) or by the relevant Member State.

For biocides submissions (see Annex 8.2), ECHA C1 trained staff carries out following tasks:

- Format validation/business rules check for all submissions.
- Invoicing where relevant (see Annex 8.2).
- Financial rejections (negative decisions) in case of non-payment.
- Acceptance task to forward the application to the relevant authority.

3.3. Processing under the PIC Regulation

The Prior Informed Consent Regulation (PIC) regulates the export/import of certain hazardous chemicals from/to the European Union. It implements, within the European Union, the Rotterdam Convention on prior informed consent procedure for certain hazardous chemicals and pesticides in international trade.

This PRO covers all of ECHA's administrative tasks under the PIC Regulation, including validation and activation of export notifications for customs clearance; registering import notifications in the system; managing explicit consents received from non-EU countries; managing reference data in the ePIC database. These sub-processes are triggered after the relevant tasks are performed by external actors. ECHA staff in Unit C1, who has been trained and granted adequate processing rights (later referred to as the ECHA PIC team), performs the tasks in the ePIC application.

3.3.1. Processing export notifications

The ECHA PIC team validates export notifications submitted by exporters and pre-validated by the relevant Designated National Authorities (DNAs). Additionally, export notifications are also activated for customs clearance as well as forwarded to importing (non-EU) countries.

3.3.2. Registering import notifications

The ECHA PIC team records import notifications received from non-EU DNAs concerning the import of hazardous chemicals to the EU. ECHA also informs the relevant EU Member State DNA(s) about the import and publishes the non-confidential data on its website.

3.3.3. Managing explicit consents

The ECHA PIC team renews explicit consent requests by sending a reminder to the relevant non-EU DNA(s) if no response has been registered in ePIC. If a response is received from a non-EU DNA and registered in ePIC by an EU DNA, ECHA assesses the metadata and makes the explicit consent available in ePIC.

3.3.4. Managing reference data

The ECHA PIC team ensures that all the reference data (e.g. the chemicals or DNA contact details) in the database is up-to-date and available to all relevant actors using ePIC for the above-mentioned processes.

3.4. Process Control

The following mechanisms are in place to ensure that both the automated and manual work is carried out in accordance with agreed procedures and in compliance with the regulatory requirements.

In addition to this, this process has a Business Continuity Plan (PLA-0006) in place to ensure continuity in the event of reduced availability of IT capacity, facilities or human resources.

3.4.1. Control of manual tasks

Consistent and correct application of the manual tasks is maintained by the following organisational aspects:

- Induction and training of staff is carried out in accordance to ECHA's learning and development framework. Prior to processing the submissions, staff members receive relevant training, including on-the-job training under supervision of the processes coordinator(s). Process coordinators maintain training materials and ensure they are updated. Records of completed training are also maintained by process coordinators and other senior staff who are involved in providing the training, and they need to be updated before the relevant IT access rights can be granted.
- Application of Initiator, Verifier and/or Authoriser (I-V-A) roles by the agent processing the manual tasks – according to the complexity of the task and the observed levels of tasks being bounced back e.g. from verifiers to initiators. For PIC, I-V-A is not implemented because in most contexts ECHA is validating the work of a previous actor (EU DNA) according to relevant WINs.
- Documentation of the main process steps in the relevant WINs of sub-processes and complementary ECHA User Manuals (EUMs) are managed by the process coordinators.
- Nominations/delegations by the ECHA management (PRO-0059) are in place for controlled delegations of executive powers (in relation to invoicing, completeness check and decision sending, as needed under REACH, CLP and Biocides Regulations, not applicable under PIC Regulation). In line with the Financial Regulation, nominations/delegations for invoicing are only granted to statutory staff.
- Interest management for specified process steps, in accordance with ECHA's Declaration of Interest policy. The Conflict of Interest (CoI) check may be performed by the Head of Unit (HoU) or, most commonly, by the CoI manager, to whom the HoU has delegated this task. Team leaders and process coordinators also have access to extracts of annual declarations of the staff of Unit C1 in order to be able to do the check without full access to ECHA staff declarations. In general, the CoI check is always required in the more complex decision making processes, where a staff

member has a margin of appreciation. The CoI check is performed and recorded as specified in the relevant WINs and EUMs.
- In case an error or exception does occur in this context, this is managed under incident management implementation (section 3.2.3).

3.4.2. Verification of automated processes

The processing of submitted dossiers is to a large extent automated in REACH-IT. Both R4BP 3 and ePIC have currently a lesser degree of automation. Following practices are applied to ensure that the automated tasks are performed correctly:

- Prior to the launch of a new version of an IT system, extensive testing is carried out on existing, adapted and new functionalities in accordance with our IT Product and Project management Procedures.
- Requesting process-related configuration changes (e.g. changes in the I-V-A configuration) is managed by a controlled process and an approval is required from the Process Owner.
- In relation to the automated processes, Quality Checks (QCs) have been implemented for business rules, invoicing, completeness check and decision sending in REACH-IT. There is no automated regulatory output in R4BP 3 or ePIC at the current time. The QC consists of:
    - random samples of the output verified by trained ECHA staff to ensure that it is in line with the expected outcome
    - automated reports (generated using Business Objects) which allow the Process Coordinators to check that the number and timing of outputs are in balance with the incoming dossiers
    - automated database log checks administered and in some cases, manual database log checks carried out by Directorate I, where automation has not been implemented. These trigger an alert in case for example a task becomes suspended at a process step.
- In case an error or an exception does occur in this context, this is managed under our incident management implementation (section 3.2.3).

Quality Check can be adapted based on the current needs of the process. Especially after new releases of IT systems, emphasis is placed on new or adapted functionalities or in response to issues arising. The QC performed by trained ECHA staff is outlined in the relevant EUMs. The outcome is reported in the Unit C1 weekly submission coordination meeting.

3.4.3. Incidents and nonconformities

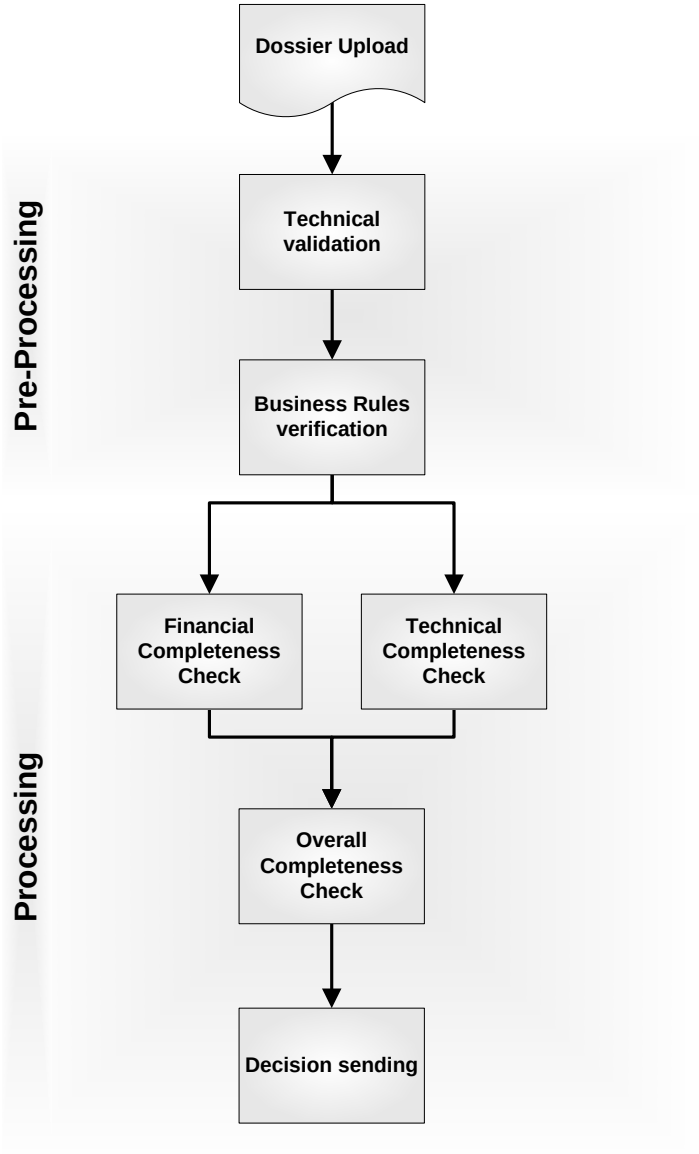
Incidents/exceptions may arise in context of:

- Manual process controls outlined in section 3.2.1
- Automated process controls outlined in section 3.2.2
- A report from a submitting company or other external party of suspected incorrect behaviour.
- A request for non-standard processing of a particular case if, for example, a company requests an adaptation to a process in a context which has not been previously encountered and standardised.

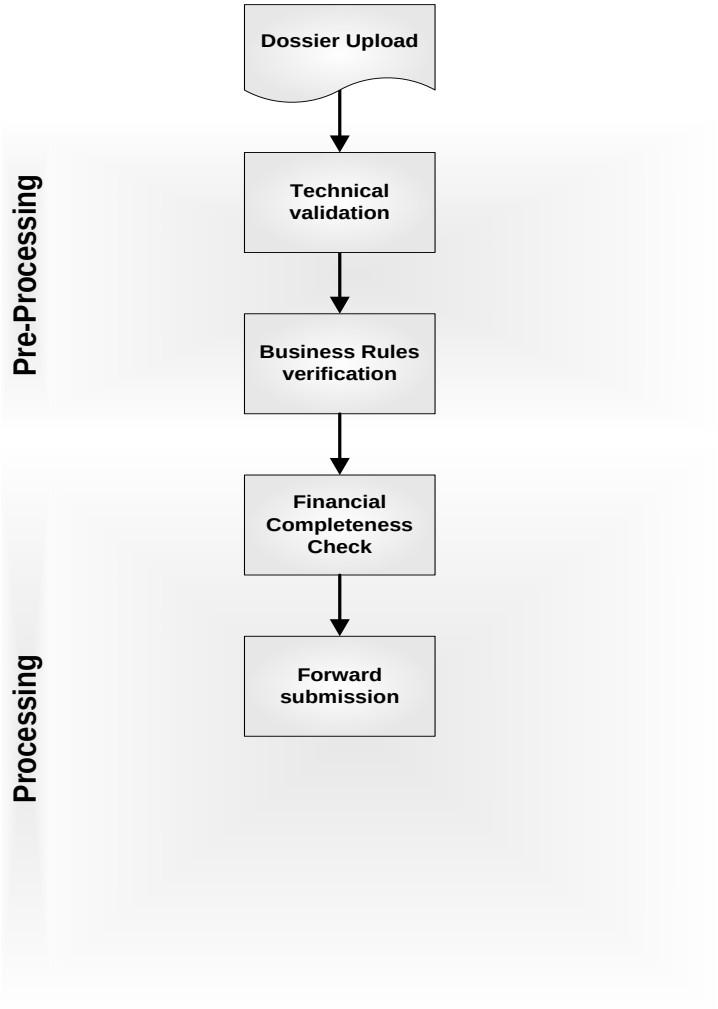
Nonconformities are handled according to PRO-0015 – Nonconformities, Corrective and Preventive Action and Handbook HAN-0018 – Quality Management in Remedy.

4. Flowchart

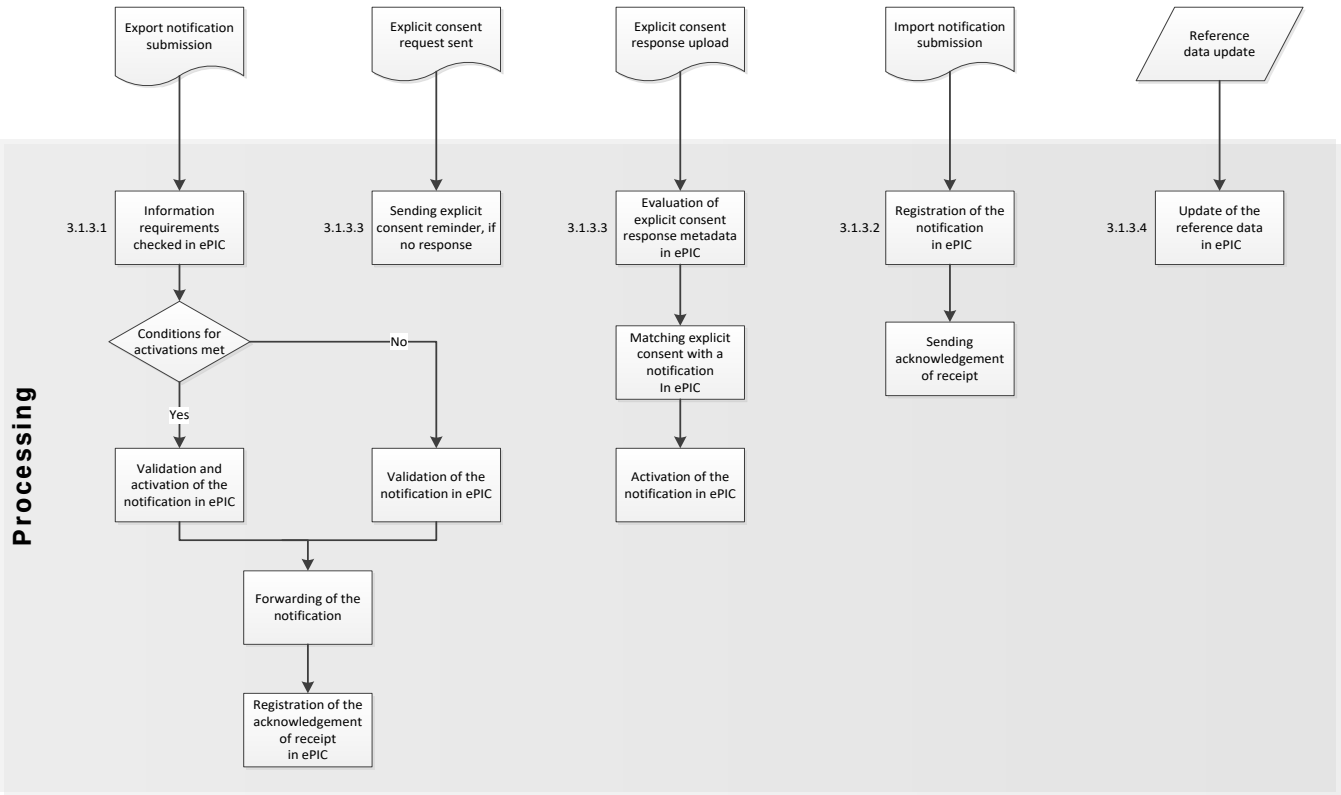
4.1. Processing under REACH and CLP for registrations and PPORD notifications (other dossier types are processed as outlined in Section 3.1.1.1 – 3.1.1.2)



4.2. Processing under BIOCIDES



4.3. Processing under PIC



5. Definitions

Term or abbreviation	Definition
BR	Business Rule(s) – administrative checks carried out on submissions to ensure the dossier/notification/etc. can be processed by ECHA
CoI	Conflict of Interest
DNA	Designated National Authority
ePIC	IT application developed for processing submissions under the PIC regulation
EU	European Union
FCC	Financial Completeness Check – process step to verify if the applicable fees have been paid in time
HoU	Head of Unit
IQMS	Integrated Quality Management System
IUCLID	International Uniform Chemical Information Database - is a software application to capture, store, maintain and exchange data on intrinsic

Term or abbreviation	Definition
	and hazard properties of chemical substances. Used for submitting data to ECHA under most REACH and BPR submission contexts.
MSCA	Member State competent authority
NC-CAPA	Nonconformities, Corrective and Preventive Action
REACH-IT	IT application developed for processing most of the dossiers submitted to ECHA under REACH and CLP
R4BP 3	IT application developed for processing most of the dossiers submitted to ECHA under BPR
REACH-NG	IT tool developed to carry out invoicing tasks under BPR
SME	Small and Medium Enterprise
TCC	Technical Completeness Check – verification process to ensure that the submitted dossier/notification/etc. fulfils all the data requirements stipulated by the relevant regulation

6. Records

The Registration records are referred in the work instructions (WINs) of relevant sub-processes

Record name	Security level	Comments
N/A		

7. References

Associated document code	Document name
(EC) No1907/2006	REACH Regulation and subsequent implementing and delegated regulations
(EC) No1272/2008	CLP Regulation
(EC) No 340/2008 & (EU) 2015/864	REACH Fee Regulation and subsequent amendments and corrigenda
Regulation (EU) No 528/2012	Biocides Regulation and subsequent amendments
Regulation (EU) No 564/2013	Biocides Fee Regulation
EU No 649/2012	Prior Informed Consent Regulation

Associated document code	Document name
Directive 67/548/EEC	Dangerous Substances Directive
ED_99_2014	ECHA's Learning and Development Framework

8. Annexes

8.1. Dossier types processed under REACH and CLP

Submitter	Submission type	Fee	C1 task	Process owner
Industry	Registration dossier (REACH Art. 7, 10, 17, 18, 20)	Yes	Full processing	C1
Industry	Product and Process Oriented Research and Development (PPORD) notification dossier (REACH Art. 9)		Full processing	C2
Industry	Application for Authorisation (AfA) REACH Art. 62 and 63		Pre-processing	D3
Industry	Request of use of an alternative chemical name for substances in mixtures (CLP Art. 24)		Pre-processing	D2
Industry	Proposal for harmonised classification and labelling (CLP Art 37)		Pre-processing[2]	D2
Industry	Inquiry (REACH Art. 26)	No	Pre-processing (automated)	C2
Industry	Pre-registration (REACH Art. 28)		Full processing (automated)	C1
Industry	Classification, Labelling and Packaging Notification (CLP Art. 40)		Full processing (automated)	D2
Industry	Downstream user report (REACH Art. 37)		Full processing (automated)	D2
Industry	Substance in article notification (REACH Art. 7(2))		Full processing (automated)	D2

[2] Pre-processing of Industry CLH dossiers are done in cooperation between D2 and C1.
[3] Pre-processing of Member State CLH dossiers are done in cooperation between D2 and C1.

MSCAs ECHA	Substance evaluation dossier (REACH Title VI + Guidance on Evaluation, chapter 3.5.1)		Pre-processing	E2
MSCAs ECHA	Proposal for harmonised classification and labelling (CLP Art. 37)		Pre-processing[3]	D2

8.2. Dossier types processed under Biocides

Submitter	Submission type	Fee
Industry	Approval of an active substance in an additional product type (Articles 7,8,9 and 10 of Regulation (EU) No 528/2012)	Yes
Industry	Assessment of technical equivalence (Article 54 of Regulation (EU) No 528/2012)	Yes
Industry	Chemical similarity check (Article 80(1) of Regulation (EU) No 528/2012, Article 15 of Commission Implementing Regulation (EU) 564/2013 and ECHA Management Board Decision 31/2013)	Yes
Industry	Classification of a change to a product authorisation (Article 51 of Regulation (EU) No 528/2012 and Article 3 of Commission Implementing Regulation (EU) 414/2013)	Yes
Industry	Inclusion on the list of active substances and suppliers (Art 95 of Regulation (EU) No 528/2012 and Regulation (EU) 334/2014)	Yes
Industry	Mutual recognition in parallel (Articles 34 and 37 of Regulation (EU) No 528/2012)	Yes
Industry	Mutual recognition in sequence (Articles 33 and 37 of Regulation (EU) No 528/2012)	Yes
Industry	Renewal of active substance (Articles 13 and 14 of Regulation (EU) No 528/2012)	Yes
Industry	Notification of unexpected or adverse effect for union authorisation (Article 47 of Regulation (EU) No 528/2012)	No
Industry	Union authorisation (Articles 43 and 44 of Regulation (EU) No 528/2012)	Yes

[3] Pre-processing of Member State CLH dossiers are done in cooperation between D2 and C1.

Industry	Amendment to the conditions of an approved active substance (Article 15 of Regulation (EU) No 528/2012)	Yes
Industry	Inclusion in Annex I of the BPR (Article 28 of Regulation (EU) No 528/2012 and Articles 3,4 and 5 of the Commission Implementing Regulation (EU) 88/2014)	Yes
Industry	Amendment of an active substance in Annex I of the BPR (Article 28 of Regulation (EU) No 528/2012 and Articles 3,4 and 5 of the Commission Implementing Regulation (EU) 88/2014)	Yes
Industry	Inquire to share data (for a biocidal product) (Articles 61 and 62 of Regulation (EU) No 528/2012)	No
Industry	Inquire to share data (for an active substance) (Articles 61 and 62 of Regulation (EU) No 528/2012)	No
Industry	National authorisation - simplified procedure (Articles 25 and 26 of Regulation (EU) No 528/2012)	No
Industry	National authorisation (Articles 29 and 30 of Regulation (EU) No 528/2012)	No
Industry	National authorisation administrative change on request (Articles 49 and 50 of Regulation (EU) No 528/2012 and Articles 6 and 9 of the Commission Implementing Regulation (EU) 354/2013)	No
Industry	National authorisation major change on request (Articles 49 and 50 of Regulation (EU) No 528/2012 and Articles 8 and 9 of the Commission Implementing Regulation (EU) 354/2013)	No
Industry	National authorisation minor change on request (Articles 49 and 50 of Regulation (EU) No 528/2012 and Articles 7 and 9 of the Commission Implementing Regulation (EU) 354/2013)	No
Industry	National authorisation of the same biocidal product (authorised) (Article 17(7) of Regulation (EU) No 528/2012 and Articles 3 and 5 of the Commission Implementing Regulation 414/2013)	No
Industry	National authorisation of the same biocidal product (pending) (Article 17(7) of Regulation (EU) No 528/2012 and Articles 3 and 5 of the Commission Implementing Regulation 414/2013)	No
Industry	Notification for placing on the market (Article 27 of Regulation (EU) No 528/2012)	No
Industry	Notification of experiment or test (Article 56(2) of Regulation (EU) No 528/2012)	No
Industry	Notification of product in product family for national authorisation (Article 17(6) of Regulation (EU) No 528/2012)	No

Industry	Parallel trade (Article 53 of Regulation (EU) No 528/2012)	No
Industry	Renewal of national authorisation (Article 31 of Regulation (EU) No 528/2012)	No
Industry	Active substance evaluation under Directive 98/8/EC (Participant) (Article 90 of Regulation (EU) No 528/2012)	Yes
Industry	Simplified authorisation of the same biocidal product (authorised) (Article 17(7) of Regulation (EU) No 528/2012 and Articles 3 and 5 of the Commission Implementing Regulation 414/2013)	No
Industry	Simplified authorisation of the same biocidal product (pending) (Article 17(7) of Regulation (EU) No 528/2012 and Articles 3 and 5 of the Commission Implementing Regulation 414/2013)	No
Industry	Simplified authorisation major change on request (Articles 49 and 50 of Regulation (EU) No 528/2012 and Articles 8 and 9 of the Commission Implementing Regulation (EU) 354/2013)	No
Industry	Simplified authorisation minor change on request (Articles 49 and 50 of Regulation (EU) No 528/2012 and Articles 8 and 9 of the Commission	No
Industry	Simplified authorisation administrative change on request (Articles 49 and 50 of Regulation (EU) No 528/2012 and Articles 8 and 9 of the Commission	No
Industry	Renewal of simplified authorisation (Article 31 of Regulation (EU) No 528/2012)	No
Industry	Notification of product in a product family for simplified authorisation (Article 17(6) of Regulation (EU) No 528/2012)	No
Industry	Notification of unexpected or adverse effect for simplified authorisation Renewal of simplified authorisation (Article 47 of Regulation (EU) No 528/2012)	No
Industry	Pre-submission for union authorisation (Annex III (2) of Regulation (EU) No 528/2012)	No
Industry	Union authorisation of the same biocidal product (pending) (Article 17(7) of Regulation (EU) No 528/2012 and Articles 3 and 5 of the Commission Implementing Regulation 414/2013)	No
Industry	National authorisation cancellation on request (Article 49 of Regulation (EU) No 528/2012)	No
Industry	Union authorisation major change on request (Article 50 of Regulation (EU) No 528/2012)	Yes

Industry	Notification of product in product family for Union authorisation (Article 17(6) of Regulation (EU) No 528/2012)	Yes
Industry	Union authorisation minor change on request (Article 50 of Regulation (EU) No 528/2012)	Yes
Industry	Union authorisation of the same biocidal product (authorised) (Article 17(7) of Regulation (EU) No 528/2012 and Article 2, 4 and 6 of Regulation (EU) No 1802/2016)	Yes
Industry	Union authorisation administrative change on request (Article 50 of Regulation (EU) No 528/2012 and Article 10 and 13 of Regulation (EU) No 354/2013)	Yes
Industry	Transfer of a national authorisation (Annex I, Title I, Section I of the Commission Implementing Regulation (EU) No 354/2013)	No
Industry	Merge of product authorisations in one product family (Annex I, Title I, Section I of the Commission Implementing Regulation (EU) No 354/2013)	No
Industry	Transfer of a simplified authorisation (Annex I, Title I, Section I of the Commission Implementing Regulation (EU) No 354/2013)	No
Industry	Transfer of a Union authorisation (Annex I of Regulation (EU) No 354/2013)	Yes
Industry	SME verification (Article 6 of Commission Implementing Regulation (EU) No 564/2013)	No
Industry	Declaration of interest to notify (Article 16 of Regulation (EU) No 1062/2014)	No
Industry	Review Programme notification (Article 17 of Regulation (EU) No 1062/2014)	Yes
Industry	Change of participants (Article 10 of Regulation (EU) No 1062/2014)	No
Industry	Active substance evaluation under Regulation (EU) No 1062/2014 (Participant)	Yes

8.3. Dossier types processed under PIC

Submitter	Submission type	Fee
Industry	Export notification	No
Non EU DNA	Import notification	

EU DNA	Explicit consent response	