Dossier Processing

1. Purpose

This document describes the processes and process controls applying to all dossiers submitted by industry duty holders to ECHA under the REACH, CLP, BPR and PIC Regulations, the Waste Framework Directive (WFD), as well as in the context of the "IUCLID for EFSA" activity.

These processes and controls are in place to ensure that:

- dossiers are processed in conformity with the relevant legislative requirements;
- the legislative deadlines are respected and ECHA's internal requirements for efficient dossier processing are met;
- confidential information is handled appropriately;
- the roles and responsibilities are unambiguously defined for all relevant activities.

2. Scope

This process starts when a dossier is submitted to ECHA and ends when the outcome is communicated to the submitter.

3. Description

Dossier processing is in place to ensure that the submission contains the information required by the relevant legal text and is in the appropriate format that enables further activities on the submitted data.

The REACH, CLP and BPR processes are essentially very similar and are outlined in sections 3.1 and 3.2. Section 3.3 provides a description of the PIC processes, section 3.4 a description of WFD process and section 3.5 a description of the process under the "IUCLID for EFSA" activity. Process control mechanisms are described in section 3.6. Further steps and sub-processes are described in work instructions and supportive documentation. The respective document owner is responsible for keeping these documents up to date.

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

The central workflow application for submission and processing of dossiers under REACH and CLP is REACH-IT. The only exception is for notifications under Article 45 of CLP (Poison

Centre notifications), which are processed by the ECHA Submission portal. The processing of submissions is, to a large extent, an automated process. However, manual processing is required at certain control points, which vary depending on the submission type.

An overview of different dossier types can be found in Table 1 in the Annex (section 8).

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. National Appointed Bodies (ABs) have access to the information included in the Poison Centre notifications by accessing the PCN database hosted in Interact, or by receiving the notification files through the eDelivery service.

3.1.1. Pre-validation and Business Rules (BR) check

All dossiers submitted to ECHA via REACH-IT and ECHA Submission portal undergo pre-validation and Business rules check in order to ensure that the required regulatory processes can be successfully carried out.

In pre-validation, the submitted dossiers are scanned for known viruses and undergo the format check to make sure that the submitted file is of the appropriate format, e.g. i6z file, and that it is compliant with the XML schema used by IUCLID. Subsequently, the availability and consistency of basic administrative data is assured under the Business Rules check (BR). This check is essential to make sure that the dossiers can be processed further.

The dossier can be accepted for further processing only if pre-validation and the relevant business rules are satisfied. In this case a submission number and date are automatically assigned and communicated to the submitter.

If the dossier submission fails at the pre-validation or business rule level, it 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 submitter.

3.1.2. Completeness checks

After successfully passing pre-validation and BR, registration and PPORD dossiers proceed to completeness checks, which verify whether all required information has been submitted and the payment of the fee has been received. These checks depend on the dossier type and submission reason. The completeness check has to be performed within the timeline specified in REACH Article 20(2).

3.1.2.1. Financial completeness check (FCC)

In case a fee is applicable, an invoice is opened. This is done automatically or manually depending on the dossier type, as follows:

Registration, PPORD dossiers and Requests for use an alternative name for a substance in a mixture according to CLP Art. 24: REACH-IT automatically computes a fee and generates an invoice, if applicable (see Title XI of REACH and the Fee Regulation (Commission Regulation (EC) No 340/2008 of 16 April 2008, and subsequent amendments)).

Applications for Authorisation (AfA) and proposals for harmonised classification: the invoice is created manually and sent in REACH-IT.

The financial assistants of the finance unit monitor the timely payments of outstanding invoices and reconcile them with the related payments received.

3.1.2.2. Technical Completeness Check (TCC)

Each received Registration or PPORD dossier is automatically screened in REACH-IT for technical completeness using a specially created algorithm that is specific for a dossier type depending on the legal requirements. Additionally, the automated part is completed with manual checks of certain elements of registration dossiers that cannot be checked automatically.

3.1.2.3. Overall Completeness Check (OCC)

Overall Completeness Check (OCC) combines the results of FCC and TCC, and therefore it is only relevant for registrations and PPORD notifications.

When both TCC and FCC are fulfilled, the outcome is positive.

If ECHA has not received the fee payment in full by the deadline set, the registrant is granted an extended due date for payment. If data was found incomplete in TCC, an update has to be submitted, and ECHA performs a second completeness check on the updated dossier.

3.1.3. Communicating the final outcome

Depending on the results of the previous process steps, the submission is either accepted or rejected. The final positive or negative outcome is communicated to the submitter via REACH-IT.

In case of a successful initial submission, a reference number is assigned for the dossier concerned. The reference number is unique for every submission type, substance and company. Therefore, the reference number does not change with subsequent successful updates of the dossier.

If a submission fails, ECHA will not grant a reference number, and the submitter is informed of the reason(s) for the rejection.

For PCN notifications, the ECHA Submission portal communicates to the submitter whether the dossier has been successfully processed and dispatched to the relevant Member States. National Appointed Bodies accepting PCN notifications submitted via the ECHA Submission Portal are able to access the information through:

- PCN database hosted in Interact, for which they will need first to adhere to the set security requirements. For access to the database, Appointed Bodies must log in to the ECHA Remote access portal.
- Appointed Bodies can also request the service for eDelivery of notifications after which ECHA will register their interest and establish the communication channels with them. By setting the communication channel via eDelivery, ECHA is able to forward notifications to the Appointed Bodies. Communication with appointed bodies through eDelivery is secured via a digital certificate.

3.1.4. Handling of NONS Dossiers

Notifications of substances performed under Directive 67/548/EEC (Dangerous Substances Directive) are considered as registrations under REACH. ECHA implemented a system for companies to request their registration numbers in REACH-IT. 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 or in case of a lead dossier, 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 biocides submission sub-processes are carried out in the R4BP 3 application (supported by the REACH-Invoicing NG application in cases where invoicing is required). Depending on the application type, cases which pass pre-validation and (where relevant, invoicing) are then forwarded to the relevant evaluating authority (ECHA or the relevant Member State) for further processing/decision making.

An overview of different dossier types can be found in the Table 2 in the Annex (section 8).

For biocides applications, the unit responsible for processing submissions carries out the following tasks (manual or automated):

- Pre-validation/business rules (BR) check.
- Invoicing where relevant (see Table 2 in the Annex).
- Acceptance task to forward the application to the relevant authority and invoicing by ECHA where relevant (see Table 2 in the Annex).
- Financial rejections (negative decisions) in case of non-payment.

The outcome is communicated to the applicant in R4BP 3.

3.3. Processing under the PIC Regulation

The Prior Informed Consent (PIC) Regulation 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.

ECHA's administrative tasks under the PIC Regulation include the validation and activation of export notifications for customs clearance; registering import notifications in the system; managing explicit consents received from non-EU countries; and managing reference data in the ePIC database. These sub-processes are carried out in the ePIC application.

An overview of different notification types can be found in the Table 3 in the Annex (section 8).

3.3.1. Processing export notifications

ECHA 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

ECHA 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

ECHA 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

ECHA 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. Processing under the WFD

SCIP is the database for information on Substances of Concern In articles as such or in complex objects (Products) established under Article 9 of the Waste Framework Directive (WFD).

The information to the SCIP database is submitted through the ECHA Submission portal.

Upon submission, there is an automated data validation in place like the one described under chapter 3.1.1. The dossier can be accepted for further processing only if pre-validation and the relevant business rules are satisfied. In this case a submission number and date are automatically assigned and communicated to the submitter.

If the dossier submission fails at the pre-validation or business rule level, it 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 submitter.

ECHA will publish the information, included all successful notifications on its website.

An overview of different dossier types can be found in the Table 4 in the Annex (section 8).

3.5. Processing under the "IUCLID for EFSA" activity

ECHA and the European Food Safety Authority (EFSA) collaborate under the "IUCLID for EFSA" activity. As part of that activity, the ECHA submission portal is used by EFSA duty holders to submit regulatory dossiers (listed in section 8) in IUCLID format and then the ECHA submission portal makes available this information to EFSA.

Upon submission, there is an automated data validation in place like the one described in chapter 3.1.1. The dossier can be accepted only if pre-validation and the relevant business rules are satisfied. In this case, a submission number and date are automatically assigned and communicated to the submitter and the dossier is dispatched to EFSA where the relevant actors can access it and perform the required actions.

If the dossier submission fails at the pre-validation or business rule level, it cannot be accepted for further dispatch to EFSA, 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 submitter.

An overview of different dossier types can be found in the Table 5 in the Annex (section 8).

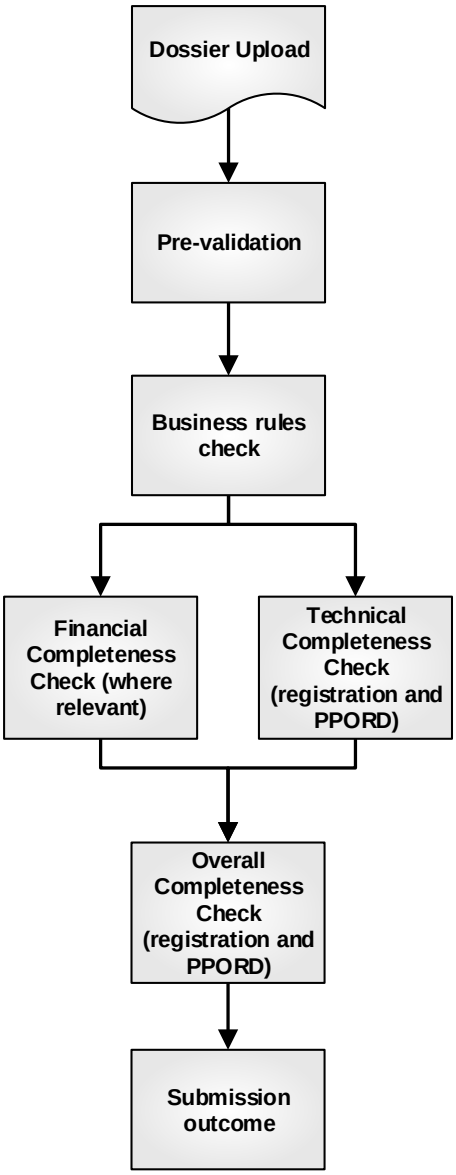
3.6. Process Control

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

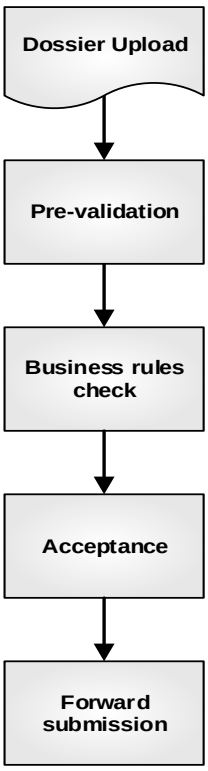
- Induction and training of staff is carried out in accordance with ECHA's learning and development framework. Prior to processing the submissions, staff members receive relevant training, including on-the-job training.
- Documentation of the main process steps in the relevant work instructions of each sub-process.
- Depending on the complexity of the task, a four or six eye principle may be in place according to relevant work instructions.
- Interest management for specified process steps, in accordance with ECHA's Declaration of Interest policy (PRO-0067). The Conflict of Interest check is performed and recorded as specified in the relevant work instructions.
- Nominations/delegations by ECHA management 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 accordance with PRO-0059 – Internal decision-making and delegation of power. In line with the Financial Regulation, nominations/delegations for invoicing are only granted to statutory staff.
- Regular Quality Checks are performed on the automated processes.
- Nonconformities are handled according to PRO-0015 – Nonconformities and External Complaints.

4. Flowchart

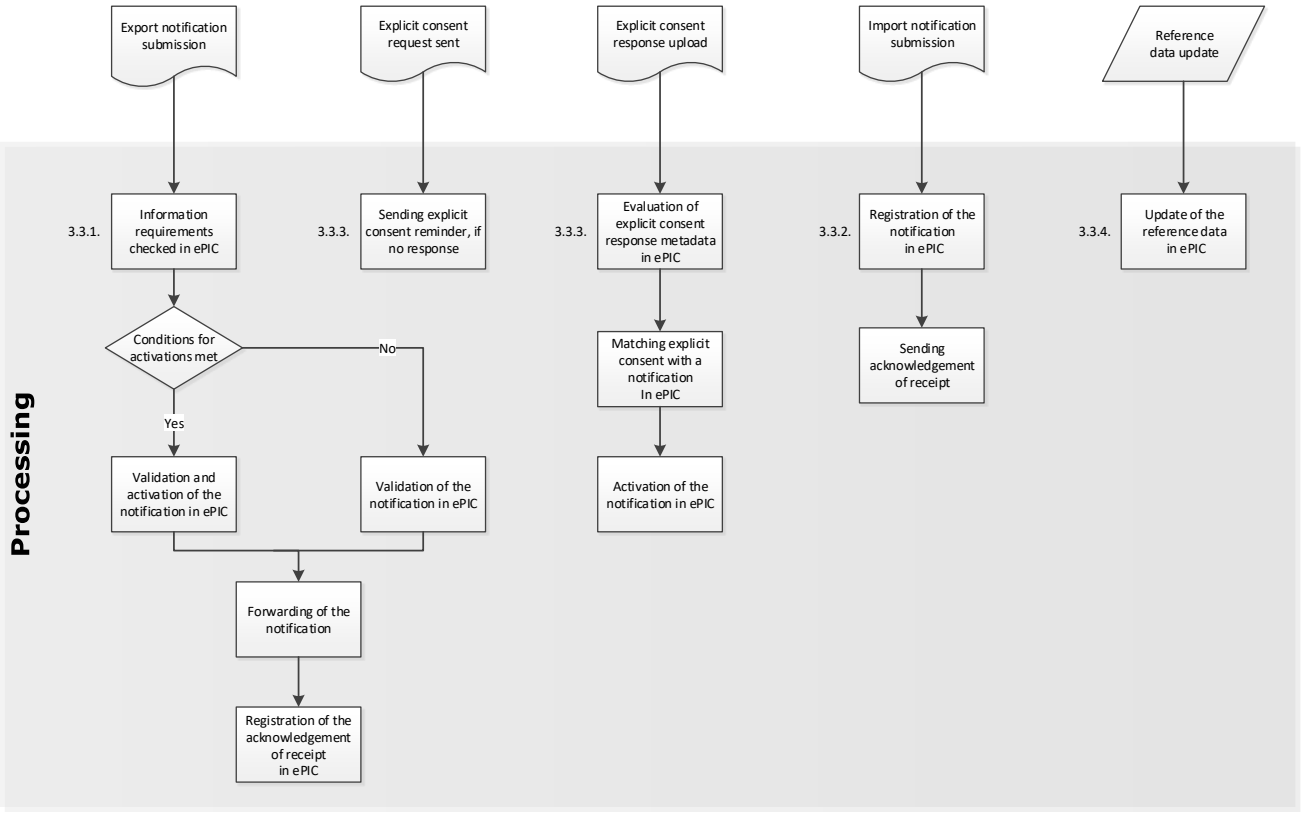
4.1. Processing under REACH and CLP



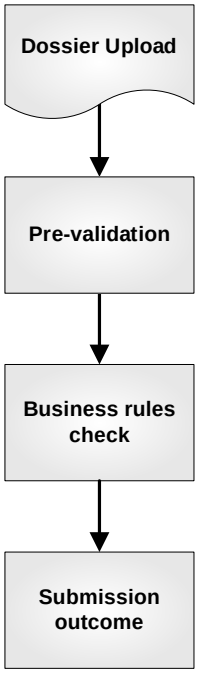
4.2. Processing under BIOCIDES



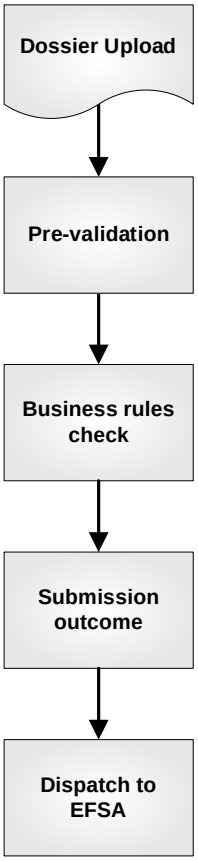
4.3. Processing under PIC



4.4. Processing under WFD



4.5. Processing under "IUCLID for EFSA" activity



5. Definitions

Term or abbreviation	Definition
AfA	Application for Authorisation
BPR	Biocides Regulation (EU) No 528/2012
BR	Business Rules – administrative checks carried out on submissions to ensure the dossier/notification can be processed by ECHA
CLP	Classification, Labelling and Packaging Regulation (EC) No 1272/2008
CLP Art. 24	Alternative Chemical Name request under the CLP regulation
DNA	Designated National Authority
eDelivery	CEF (Connecting Europe Facility) building block to allow public administrations to exchange electronic data and documents with other public administrations, businesses and citizens, in an interoperable, secure, reliable and trusted way
EFSA	European Food Safety Authority
ePIC	IT application developed for processing submissions under the PIC regulation
FCC	Financial Completeness Check – process step to verify if the applicable fees have been paid in time
Interact	ECHA interact is the central portal that supports Member States, Committees and working groups of ECHA in their tasks related to the REACH process
Invoicing NG	IT tool developed to carry out invoicing tasks under BPR
IUCLID	International Uniform Chemical Information Database - a software application to capture, store, maintain and exchange data on intrinsic and hazard properties of chemical substances
MSCA	Member State Competent Authority
NONS	Notifications of substances performed under Directive 67/548/EEC (Dangerous Substances Directive)
OCC	Overall Completeness Check, which combines the result of FCC and TCC
PCN	Poison Centres Notification
PIC	Prior Informed Consent Regulation (EU) No 649/2012
PPORD	Product and Process Orientated Research and Development
PPP	Plant Protection Products

Term or abbreviation	Definition
Pre-validation	Pre-validation consists of virus, format and XML checks
R4BP 3	IT application developed for processing submissions to ECHA under BPR
REACH	Registration, Evaluation, Authorisation and Restriction of Chemicals Regulation (EC) No 1907/2006
REACH-IT	IT application developed for processing submissions to ECHA under REACH and CLP
SCIP	Substances of Concern In articles as such or in complex objects (Products)
SVHC	Substances of Very High Concern
TCC	Technical Completeness Check – verification process to ensure that the submitted dossier/notification fulfils all the data requirements stipulated by the relevant regulation
WFD	Waste Framework Directive

6. Records

Record name	Security level	Comments
Conflict of Interest check results	Internal	
Decisions, formal communications	Internal	
Explicit consents	Internal	
Export and import notifications	Internal	
Invoices, credit notes	Internal	
IUCLID dossiers	Internal	
Quality check results	Internal	
Submissions, applications	Internal	
Supporting process documentation	Internal	
Training records, delegations	Internal	

7. References

Associated document code	Document name
(EC) No 1272/2008	CLP Regulation
(EC) No 1907/2006	REACH Regulation and subsequent implementing and delegated regulations
(EC) No 340/2008 & (EU No 254/2013 & (EU) 2015/864	REACH Fee Regulation and subsequent amendments and corrigenda
(EU) No 440/2010	CLP Fee Regulation
(EU) No 528/2012	Biocides Regulation and subsequent amendments
(EU) No 564/2013	Biocides Fee Regulation
(EU) No 649/2012	Prior Informed Consent Regulation
Directive 67/548/EEC	Dangerous Substances Directive
ED/68/2019	ECHA's Learning and Development Framework
Directive 2008/98/EC	EU Waste Framework Directive
Regulation (EC) No 1107/2009	Plant Protection Products Regulation

8. Annexes

8.1. Dossier types processed under REACH and CLP

Table 1. Overview of the dossier types submitted and the respective checks performed

Dossier type	Submitter	Process owner (ECHA unit)	Format and Business Rules check (BR)	Technical Completeness Check (TCC)	Financial Completeness Check (FCC)
Registration dossier (REACH Art. 7, 10, 17, 18, 20)	Industry	A3, A4	X	X	X
PPORD (REACH Art. 9)	Industry	B1	X	X	X

Application for Authorisation (REACH Art. 62 and 63)	Industry	D4	X	n/a	X
Proposal for harmonised classification and labelling (CLP Art. 37)	Industry	C1	X	n/a	X
Request for use of an alternative chemical name for a substance in a mixtures (CLP Art. 24)	Industry	C1	X	n/a	X
Inquiry (REACH Art. 26)	Industry	B1	X	n/a	n/a
Classification, Labelling and Packaging Notification (CLP Art. 40)	Industry	C1	X	n/a	n/a
Downstream user report (REACH Art. 38)	Industry	B4	X	n/a	n/a
Downstream user notification of authorised uses (REACH Art. 66)	Industry	D4	X	n/a	n/a
Substance in article notification (REACH Art. 7(2))	Industry	B4	X	n/a	n/a
Proposal for harmonised classification and labelling (CLP Art. 37)	MSCAs ECHA	C1	X	n/a	n/a

Poison centre notification (CLP Art. 45 and Annex VIII)	Industry	A3	X	n/a	n/a

8.2. Industry initiated submission types processed under BPR

Table 2. Overview of the dossier types submitted and the respective checks performed

Application type	Case abbreviation	Name	Invoiced by ECHA
Active substance related applications	AS-APP	Approval of an active substance	X
		Amendment to the conditions of an approved active substance	X
	AS-RNL	Renewal of the approval of an active substance	X
	AN-APP	Inclusion of an AS in Annex I	X
	AS-ACC	Inclusion on the list of active substance suppliers (Article 95)	X
	AA-CCL	Inclusion on the list of active substance suppliers (Article 95) cancellation on request	n/a
	AA-ADC	Inclusion on the list of active substance suppliers (Article 95) administrative change on request	n/a
	AA-UPD	Scientific data update of inclusion in Article 95 (active substance suppliers) list	n/a
	AA-TRS	Transfer of Article 95 asset (access to active substance dossier)	n/a
	RP-NOT	Review Programme notification	X

	AS-EVA	Active substance evaluation under Regulation (EU) No 1062/2014 (Participant)	X
	TE-APP	Assessment of technical equivalence	X
	AN-CHG	Amendment of active substance in Annex I	X
		Amendment of restrictions of an active substance in Annex I	n/a
	AS-UPD	Scientific data update of active substance	n/a
	AN-UPD	Scientific data update of active substance in Annex I	n/a
	DI-SUB	Declaration of interest to notify	n/a
	IN-REA	Inquiry to share data for an active substance	n/a
National authorisations	NA-MRS	Mutual recognition in sequence	X
	NA-MRP	Mutual recognition in parallel	X
	CC-APP	Request for classification of a change to a product authorisation	X
	NA-APP	National authorisation (including provisional) with the option of mutual recognition	n/a
	NA-RNL	Renewal of national authorisation (including subject to mutual recognition)	n/a
	NA-BBS	National authorisation of the same biocidal product (authorised)	n/a
	NA-BBP	National authorisation of the same biocidal product (pending)	n/a

	NA-ADC	National authorisation request for change (admin)	n/a
	NA-MIC	National authorisation request for change (minor)	n/a
	NA-MAC	National authorisation request for change (major)	n/a
	NA-MRG	Merge of product authorisations in one product family	n/a
	NA-TRS	Transfer of a national authorisation	n/a
	NA-CCL	National authorisation cancellation on request	n/a
	IN-REB	Inquiry to share data for a biocidal product	n/a
	ET-NOT	Notification of an experiment or test	n/a
	NA-NPF	National authorisation notification of a product in a product family	n/a
	NE-NOT	Notification of an unexpected or adverse effect – national authorisation	n/a
	PP-APP	Parallel trade permit	n/a
Union authorisations	UA-APP	Union authorisation (including provisional)	X
	UA-BBP	Union authorisation of the same biocidal product (pending)	X
	UA-MAC	Union authorisation major change on request	X
	UA-ADC	Union authorisation administrative change on request	X

	UA-TRS	Transfer of a Union authorisation	X
	UA-MIC	Union authorisation minor change on request	X
	UA-BBS	Union authorisation of the same biocidal product (authorised)	X
	UP-APP	Application for pre-submission	n/a
	IN-REB	Inquiry to share data (biocidal product)	n/a
	UA-NPF	Notification of product in product family for Union authorisation	n/a
	UE-NOT	Notification of unexpected or adverse effect for Union authorisation	n/a
Simplified authorisations	CC-APP	Request for a classification of a change to a product authorisation	X
	SA-APP	National authorisation - simplified procedure	n/a
	SA-BBS	Simplified authorisation of the same biocidal product (authorised)	n/a
	SA-BBP	Simplified authorisation of the same biocidal product (pending)	n/a
	SA-ADC	Simplified authorisation administrative change on request	n/a
	SA-MIC	Simplified authorisation minor change on request	n/a
	SA-MAC	Simplified authorisation major change on request	n/a
	SA-TRS	Transfer of a simplified authorisation	n/a

	SA-NPF	Notification of product in product family for simplified authorisation	n/a
	SE-NOT	Notification of unexpected or adverse effect for simplified authorisation	n/a
	SN-NOT	Notification for placing on the market	n/a
	SN-ADC	Administrative change of notification for placing on the market	n/a
	SN-CCL	Cancellation of notification for placing on the market	n/a
	IN-REB	Inquiry to share data (biocidal product)	n/a
Other	SM-APP	SME verification	n/a

8.3. Dossier types processed under PIC

Table 3. Overview of the dossier types submitted and the respective checks performed

Submitter	Submission type	Fee
Industry	Export notification	n/a
Non-EU DNA	Import notification	
EU DNA	Explicit consent response	

8.4. Dossier types processed under WFD

Table 4. Overview of the dossier types submitted and the respective checks performed

Submitter	Submission type	Fee
Industry	Notification	n/a
Industry	SSN (Simplified SCIP Notification)	

8.5. Dossier types processed under "IUCLID for EFSA" activity

Table 5. Overview of the dossier types submitted and the respective checks performed

Submitter	Submission type	Fee
Industry	EU PPP Basic substance application	n/a
Industry	EU PPP Active substance application (product)	
Industry	EU PPP Micro-organisms application (product)	
Industry	EU PPP MRL application	