Control of Documents and Records

1. Purpose

Most ECHA Work Programme activities and decisions lead to the reception and production of documents, which have to be managed on the basis of this procedure. This procedure sets out the principles for document and records management, ensuring in particular:

- the due creation, receipt, handling and storage of documents and records,
- the registration of documents and the identification of all records by means of appropriate markings enabling it to be filed, searched for and retrieved, and
- the preservation of ECHA's documents and records as a proof of the activities undertaken and of the fulfilment of legal obligations.

Effective and proper records management and archiving help:

- meet the ECHA Transparency obligations[1], in particularly by facilitating public access to its key documents (submitted dossiers, opinions and decisions of ECHA's governing body and scientific committees),
- fulfil the requirements under Regulation (EC) 1049/2001 on public access to documents,
- address the actions which are necessary under the COUNCIL REGULATION (EU) 2015/496 of 17 March 2015 amending Regulation (EEC, Euratom) No 354/83 as regards the deposit of the historical archives of the institutions at the European University Institute in Florence,
- support audits and legal proceedings (e.g., appeals against decisions taken by ECHA).

More topics related to information governance (see figure 1) may fall within the scope of this procedure in the future, such as:

- compliance with carbon neutrality goals which have an impact to document management,
- the historical archives declassification and transfer to Florence,
- deciding on the digital preservation strategy of ECHA information and records,
- the information management aspects of the new security regulation which will require changes to this procedure.

[1] See ECHA's Transparency Approach – update on actions for 2021-2022, MB/65/2020

Figure 1 Elements of information governance

2. Scope

This procedure applies to all (controlled)[2] documents held by ECHA and has to be implemented by all ECHA staff. It does not apply to the control of IMS documents, which is described in PRO-0001 Control of IMS Documents. This procedure is without prejudice to the legal obligations that apply to the Agency under Regulation (EC) 1049/2001 on public access to documents.

3. Description

3.1. ECHA's documented information structure

[2] See Figure 2 for controlled and uncontrolled documents

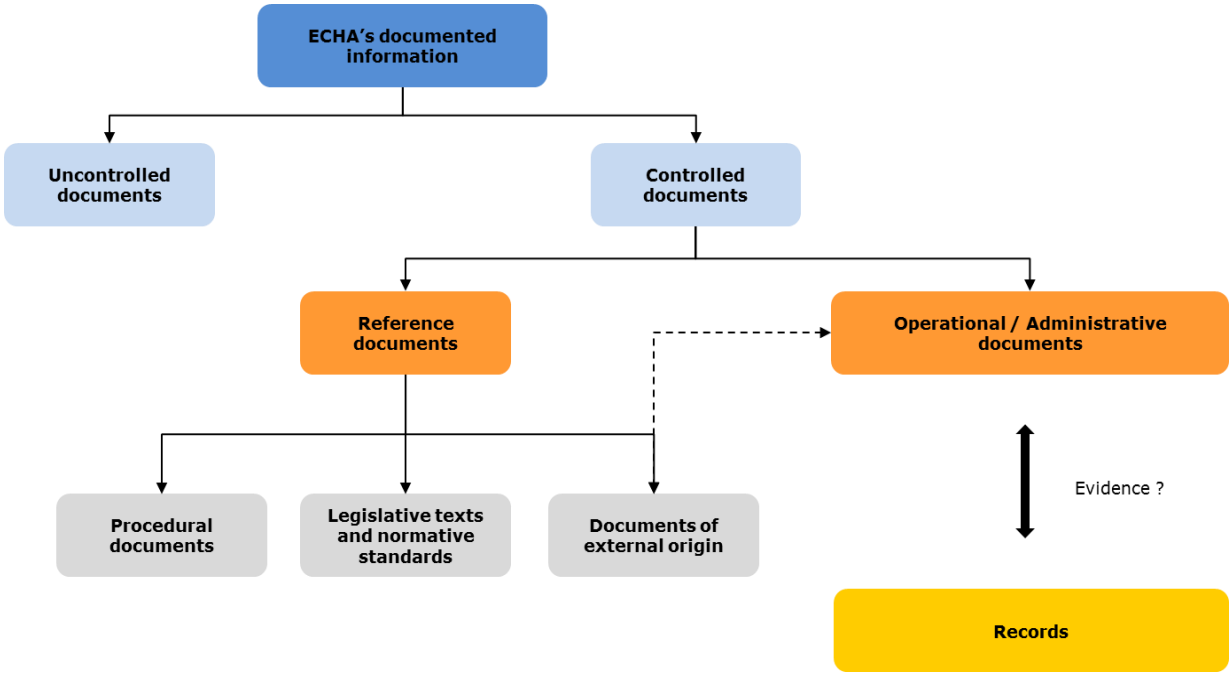

Figure 2 ECHA's documented information structure

Uncontrolled documents are linked with informal (ad hoc) procedures or communications and do not require any controls as described in this procedure (e.g. no specific registration, filing and storage requirements). They should be disposed as soon as they are no longer needed.

Examples: non-approved draft versions of documents, internal communications exchanged between ECHA staff, informal communications exchanged between ECHA staff and external partners, etc.

Reference documents are those **documents** that support and set the framework for the operational work of the Agency.

Examples: PROs, WINs, ED decisions (IMS **procedural** documents), REACH, Staff Regulations, ISO standards, building standards (legislative texts and normative standards), IT manuals, journals, books, reports of the Court of Auditors (documents of external origin), etc.

Operational/administrative documents are those documents which derive from the administrative and operational processes of the Agency, including the output produced and the relevant documents supporting/pertaining to such decision making. The process owners shall identify from among the operational/administrative documents the records that give evidence of the actions carried out.

Examples: see examples of uncontrolled documents

Evidence documents (records) are those operational/administrative documents created, received and maintained as evidence of the actions carried out in the framework of ECHA's

official tasks. A record should correctly reflect what was communicated or decided or what action was taken. It should be able to support the needs of the business to which it relates to and used for accountability purposes (e.g. audits) or legal proceedings (e.g. appeals issued on ECHA's opinions or decisions).

In ECHA's context this means that documents that match the following conditions shall be qualified as records:

- They are considered final/approved versions,
- They document decisions taken by the Agency or provide evidence of the performance of ECHA's duties, required for audit or for the fulfilment of legal obligations,
- They are in whatever medium (audio-visual, paper, electronic, digital etc).

Examples: incoming industry or Member State dossier, outcome of conflict of interest check, accordance check decision, public consultation procedure documents (final RCOM tables), approved (versions of) draft decisions, proposals for amendment, final decisions/opinions, meeting minutes, annual declaration of interest, mission claims, job applications, environmental reports etc.

3.2 Responsibilities

The process owner is responsible

- For defining the different roles in the approval lifecycle of a document,
- For deciding the security classification of documents,
- For filing and storing their documents according to the requirements described in section 3.3.4 and Annex 1 to this procedure ,
- For ensuring that the last updated version of their documents stored in any IT system is always available and retrievable,
- For defining the records relevant to their processes and the corresponding retention periods.

The responsibilities related to specific aspects of record management are indicated in the respective IMS documents.

The Information Management Assistant is responsible for drafting and communicating the corporate policies on document management and support Units in their implementation. The Information Management Assistant also ensures that document management IT systems comply with the respective policies and acts as the Records Manager in those systems when required.

The Archivist is responsible for providing the necessary guidance related to the management of physical records and ensures that the physical archives maintenance complies with the internal rules.

3.3 Control of documents

3.3.1 Registration and metadata

Documents to be registered are all (incoming / outgoing) communications that require an action or follow-up, regardless of their medium (electronic, physical) and format (e-mails, letters, web-forms). As an absolute minimum, all incoming / outgoing communications that are qualified as records in the *LIS-0026 ECHA Retention Schedule* are to be registered. Documents are registered through the Mail Registry or any other IT system in place that guarantees an equivalent result (see Annex 1). Duplication of registration should be avoided.

Documents and records stored in a document management system have a set of minimum metadata associated to them in order to describe their context, content and structure and their management through time. The basic metadata and their default values are defined in the relevant IT Architecture document. Annex I (see pages 9-10 below) list all IT Systems which manage documents against certain criteria which are directly linked with the metadata captured in those systems.

3.3.2 Approval procedure

The approval of each record needs to be documented and stored together with the record (e.g. circulation sheet or approval log). A physical signature to authenticate ECHA documents is only needed when explicitly required by law (e.g. contracts and other documents specified in the Financial Regulation) and can thus be left out when the approval process can be demonstrated by other means (e.g. an electronic workflow with an approval log).

3.3.3 Distribution and Classification

All documents in ECHA shall be marked with the different security levels as defined in *Annex 1 of PRO-0085 Access to ECHA Information* (Public – Internal – Restricted – Highly Restricted). All documents which have no security marking have to be considered Internal.

3.3.4 Filing plan and storage

The ECHA filing plan is a hierarchical structure (from general to specific) and it consists of a sequence of headings (activity – process – sub-process) based on the *LIS-0009 ECHA Activity and Process Structure*.

Electronic mailboxes are reserved for storing personal or informal communications used within a specific Unit without relevance for ECHA's official tasks or legal obligations. Shared drives are used only for the storage of the following exceptions:

1. Large/heavy files which exceed the capacity limitation of SharePoint, 100MB/file (e.g. IUCLID files, audio visual files, publications, manuals with graphics/images, business object reports).
2. Large backup files (
3. Files which are not supported in SharePoint (e.g. shared Excels, cross-linked Excels, Access files).
4. Files saved during software testing.
5. Short lived preliminary documents which will in the future be automatically destroyed after 6 months (to be saved in W:\@public).

External Collaboration Platforms (i.e. Secure-CIRCABC) are reserved for exchanging information with external organisations and users in order to perform regulatory tasks

allotted to ECHA. Documents shared, using the external collaboration platforms, shall be initially stored in ECHA's recognised document management systems.

The storing method selected for each ECHA process shall fulfil the security requirements described in *Annex 1 of PRO-0085 Access to ECHA Information.* As a principle, the storage of documents in multiple locations should be avoided.

The storage of paper originals shall only be necessary if a physical signature is required by law or internal administrative rules (e.g., for control or audit purposes, see also under 3.3.2 approval procedure). In all other cases, a scan or electronic version of the record shall be sufficient. The scanning process should ensure that the following standards are met:

a) The scanned copy is in PDF format with a minimum resolution of 300dpi,
b) All pages of the document have been digitised,
c
d) The scans are legible and at least as readable as the originals,
e) The colour (s) is accurate (scanning equipment uses 24bit colour depth).

After scanning, the paper original may be destroyed after a period of 6 months.

3.3.5 Preservation of documents

Process Owners have to decide how long they need to retain their documents according to their business needs.

The Information Management Assistant shall manage the *LIS-0026 ECHA Retention Schedule* in which the Process Owners shall identify the (types of) records relevant for their processes and define their retention time The ECHA Retention Schedule will further determine the elimination, second appraisal or permanent preservation of the documents listed, after the expiration of their respective retention time.

All permanent records shall be transferred, to the extent possible, to ECHA's permanent archive, managed electronically in Dynamic Case Records Management (DCRM). DCRM is the system selected to support the provisions of the Archiving Council Regulation 2015/496 as regards the deposit of the historical archives of the institutions at the European University Institute in Florence. Permanent records in paper format can be transferred to the permanent physical archives, although ECHA shall strive to digitalise such permanent records where possible.

In line with the Archiving Council Archiving Regulation 2015/496 and its implementing rules, all permanent records shall be declassified and made publicly available after 30 years, unless they deserve further protection due to commercial interests or personal data protection[3]. Other records (i.e. administrative records) in electronic or physical format shall be destroyed after the expiration of their retention period indicated in the *LIS-0026 ECHA Retention Schedule*.

[3] See latest ED declassification decision ED/16/2019

4. Flowchart

N/A

5. Definitions

Term or abbreviation	Definition
Document	Any (structured) content whatever its medium (written on paper or stored in electronic form) concerning a matter relating to the policies, activities and decisions falling within the institutions sphere of responsibility. In ECHA's context this shall include all documents created or received, regardless of the format (paper or electronic). Metadata form an integral part of the document.
DCRM	Dynamic Case Records Management
Case documentation	Group of documents organised in such a way as to form a coherent and relevant unit in terms of the actions carried out in the handling/implementation of a case (e.g. substance evaluation case, dossier registration case, selection procedure case, appeal case, etc.).
Filing plan	A filing plan is a coherent logical structure that allows staff to organize correctly those documents they deem as important. It also makes them discoverable and available when they are stored in a Document Management System.
Metadata	Data describing context, content and structure of documents and records and their management through time.
Preservation	Processes and operations involved in ensuring the technical and intellectual survival of authentic records through time (ISO 15489-1:2001).
Process Owner	Person or role responsible for the effective and efficient functioning of the process. He/she has the necessary authority to take action or make decisions with an impact on the process performance (PRO-0008).
Registration	Act of giving a record a unique identifier on its entry into a system (ISO 15489-1:2001).
Retention period	Lifetime defined for different type of files, taking into account its administrative usefulness for units/directorates, statutory and legal obligations and its potential historical value.
S-CIRCABC	External Collaboration Platform
IMS document	Procedures (PROs), Work Instructions (WINs), etc. as described in PRO-0001.

6. Records

N/A

7. References

Associated document code	Document name
Regulation No 31 (EEC), 11 (EAEC)	Staff Regulations of Officials and Conditions of Employment of Other Servants of the European Community
Management Board Decision 30/2019	Financial Regulation of the European Chemicals Agency
(EU) 2015/496	Council Regulation amending Regulation (EEC, Euratom) No 354/83 as regards the deposit of the historical archives of the institutions at the European University Institute in Florence
(EC) No 1049/2001	Regulation of the European Parliament and of the Council of 30 May 2001 regarding public access to European Parliament, Council and Commission documents
(EU) 2018/1725	Regulation of the European Parliament and of the Council of 23 October 2018 on the protection of natural persons with regard to the processing of personal data by the Union institutions, bodies, offices and agencies and on the free movement of such data
ED-0037	Use of S-CIRCABC for Handling ECHA Information
C (2020)4482	Commission Decision of 6.7.2020 on records management and archives
SEC (2020)800	Implementing Rules for Decision C (2020) 4482 on records management and archives
ISO 15489-1	Information and documentation – Records Management – Part1: Concepts and principles

8. Annexes

Annex 1: Information management capabilities of ECHA's document management systems

Annex 1: Information management capabilities of ECHA's document management systems

Legend: x = no √ = yes

Document management systems	Filing in accordance with LIS-0009	Accepted storage location	Mail registration functionality	Approval workflow (replacing physical signature)
REACH-IT	x	√	√ (outgoing)	√
R4BP	x	√	√	√
ePIC	x	√	√ (outgoing)	N/A
HRMS	x	√	√ (incoming)	√
MiMA	x	√	N/A	√
Remedy	x	√	√	√
ABAC	x	√	√ (incoming)	√
Dynamic Case	√	√	√	√
Records Management (RM)	√	√	N/A	N/A
SharePoint (general)	√	√	x	x
Office 365 SharePoint	x	√	x	Only for documents in FIMSII
SP Mail Registry	x	√	√	x
SP ATD	x	√	√	x
SP EasySign	x	√	x	√
SP DoI Management Tool	x	√	N/A	√
Shared drives	x	x	x	x

Document management systems	Filing in accordance with LIS-0009	Accepted storage location	Mail registration functionality	Approval workflow (replacing physical signature)
S-CIRCABC	x	x	x	x
Interact	x	x	x	x
FMBs	x	x	x	x
IMS (Integrated Management System)	√	√	x	√
ELM (Events Logistic Management)	x	√	√ (outgoing invitations)	x