

## Prioritisation and Annex XIV recommendation

### 1. Purpose

This procedure first describes how ECHA assesses the priority of substances on the Candidate List for eventual inclusion in Annex XIV. The procedure further describes how ECHA prepares the draft recommendation for prioritised substances, how public consultation and the opinion making of the Member State Committee (MSC) are handled and how ECHA's Annex XIV recommendation is finalised.

This is to make sure that:

- The agreed approaches are followed when prioritising substances from the Candidate List and when preparing the draft Annex XIV entries.
- Comments from third parties and the opinion of the MSC are handled properly and taken into account as relevant.
- ECHA prepares its recommendation for Annex XIV in a timely and high quality manner.
- Any possible conflict of interest is handled according to the corresponding documentation.

### 2. Scope

Complying with the legal requirements in REACH, this procedure is followed at least once every second year. It starts with the prioritisation of substances included in the Candidate List of substances for eventual inclusion in Annex XIV. The procedure ends with the support to the European Commission in decision making and the update of the list of substances included in Annex XIV on ECHA's website.

### 3. Description

#### 3.1. General

ECHA regularly assesses the substances from the Candidate List to determine which ones should be included in the Authorisation List (Annex XIV of the REACH Regulation) as a priority.

The prioritisation is based on information on the intrinsic properties, the uses and the volumes of the substances on the EU market that fall within the scope of the authorisation requirement. The approach to carry out the prioritisation is consulted with the MSC ([http://echa.europa.eu/documents/10162/13640/gen\\_approach\\_svhc\\_prior\\_in\\_recommendations\\_en.pdf](http://echa.europa.eu/documents/10162/13640/gen_approach_svhc_prior_in_recommendations_en.pdf)). MSC is consulted on the draft recommendation.

**Prioritisation and Annex XIV recommendation**

ECHA launches a public consultation which lasts for 90 days on the draft recommendation. This draft includes a proposal for Annex XIV entries, including the latest application dates and sunset dates.

The MSC prepares its opinion on the draft recommendation taking into account the received comments. The opinion of the committee and the comments received during the public consultation are considered when ECHA finalises its recommendation, which is submitted to the European Commission, for a decision on the substances to be included in the Authorisation List.

### 3.2. Detailed description

The Classification and Prioritisation Unit is responsible for the Annex XIV recommendation process. The Head of Unit/Process coordinator (AXIV-PC) assigns a case responsible (AXIV-CRs) to each substance, responsible for the substance-specific documentation. The AXIV-PC prepares the common documentation and coordinates the process.

When assigning the tasks within this procedure, the Head of Unit is responsible for managing possible conflicts of interest properly in accordance with the Policy for Managing potential Conflicts of Interests (MB/07/2014), PRO-0067 and WIN-0105.

#### **Step 1: Assess the priority of the substances on the Candidate List**

The AXIV CRs gather the available information from registration dossiers, the Annex XV substance of very high concern (SVHC) dossiers, the public consultation during the SVHC identification process, other REACH/CLP data and other sources where relevant.

Based on the available information and following the "General Approach for Prioritisation of Substances of Very High Concern (SVHCs) for Inclusion in the List of Substances Subject to Authorisation", the Classification and Prioritisation Unit prioritises substances from the Candidate List for eventual inclusion in Annex XIV.

The outcome of the priority assessment is documented in the "Priority assessment results of the Candidate List substances assessed".

#### **Go to step 2**

#### **Step 2: Consult Member State Committee (MSC) on the priority assessment**

The MSC Secretariat (MSC-S) provides the draft "Priority assessment results of the Candidate List substances assessed" to the MSC, requesting comments as relevant. The MSC is requested to provide:

- comments on the information used for priority assessment;
- comments on the application of the agreed approach; and
- views on aspects to be considered by ECHA when prioritising substances to be recommended and for preparing the draft recommendation.

#### **Go to step 3**

**Prioritisation and Annex XIV recommendation****Step 3: Prepare draft recommendation for Annex XIV**

The Classification and Prioritisation Unit selects a set of substances from the Candidate List to be included in the draft recommendation for Annex XIV.

The selection is based on the priority of the substance (as documented in the priority assessment) and takes into account the comments received from the MSC.

The number of substances selected takes into account ECHA's and the anticipated workload of the Risk Assessment Committee (RAC) and the Committee for Socio-Economic Analysis (SEAC) relating to future applications for authorisation.

With the proposed set of substances, the Classification and Prioritisation Unit prepares the draft recommendation for Annex XIV, consisting of:

- priority assessment of substances on the Candidate List;
- draft Annex XIV entries for the proposed substances; and
- draft background documents for each substance proposed for Annex XIV.

**Go to step 4****Step 4: Consult MSC on draft recommendation for Annex XIV**

The MSC-S provides the draft recommendation with all the relevant documentation to the MSC, requesting comments:

- on the prioritised substances;
- the draft Annex XIV entries;
- the application of the agreed approaches on priority assessment and Annex XIV entries; and
- the information provided in the substance-specific background documents.

**Go to steps 5 and 6****Step 5: Appoint MSC rapporteur and establish working group**

The MSC-S makes sure that a rapporteur for preparing the MSC opinion on ECHA's draft recommendation is identified and appointed according to the "Working Procedure of the Member State Committee". A second member may be appointed as co-rapporteur.

Additionally, the MSC-S may invite volunteers for a working group to support the MSC rapporteur when preparing the opinion on ECHA's draft recommendation. MSC-S prepares draft mandate of the working group for a decision by MSC to establish such a group.

The MSC-S supports the rapporteur when setting-up the working group.

**Go to step 8**

## Prioritisation and Annex XIV recommendation

**Step 6: Update draft recommendation for Annex XIV**

The Classification and Prioritisation Unit updates the draft recommendation for Annex XIV (see details in step 3 and in the records table in chapter 7), taking into account the comments received from the MSC.

For substances included in the draft recommendation, **go to step 7**.

For substances not included in the draft recommendation, **go to step 1** (the process restarts again in the next recommendation round).

**Step 7: Start public consultation on draft recommendation for Annex XIV**

The Classification and Prioritisation Unit prepares all relevant documentation for the public consultation, taking into account Articles 118 and 119 of REACH, and makes sure that it is published on the ECHA website.

The Classification and Prioritisation Unit makes sure that the relevant webforms for submitting comments are available and that relevant information is provided to the public on ECHA's website in a timely manner.

It defines the start date and the deadline for commenting and ensures the correct functioning of the public consultation. The public consultation lasts for 90 days.

**Go to step 8****Step 8: Handle public consultation on draft recommendation for Annex XIV**

During the public consultation, once relevant comments have been received, the Classification and Prioritisation Unit compiles the comments made on a substance in a document (ComRef document), which the MSC-S makes available to the MSC.

In accordance with the respective working procedures, the MSC-S makes sure that the MSC rapporteur and the working group, if established, receive all comments from third parties as soon as possible after the end of the commenting period. This is to help the MSC rapporteur and the working group prepare the MSC opinion on the draft Annex XIV recommendation.

After the end of the commenting period a compilation of comments received (ComRef document) is published on ECHA's website.

**Go to step 9****Step 9: Manage MSC opinion forming on draft recommendation**

The MSC-S supports the MSC rapporteur and the working group when forming the opinion on the draft recommendation, following the "Working Procedure of the Member State Committee" as appropriate.

The MSC-S makes the draft opinion available to the MSC members and facilitates its discussion.

**Go to step 10**

## Prioritisation and Annex XIV recommendation

**Step 10: Finalise the MSC opinion on draft recommendation**

The MSC-S makes sure that the MSC opinion on the draft recommendation for Annex XIV is agreed on by the MSC, in accordance with the "Working Procedure of the Member State Committee".

The MSC-S supports the rapporteur in the opinion preparation and ensures that it is provided to the MSC members for discussion and adoption.

If the opinion is adopted by the majority of the members, MSC-S ensures that the minority positions are properly documented and to be attached to the MSC opinion.

Once the MSC opinion is adopted and finalised, the MSC-S makes it available to the Classification and Prioritisation Unit.

The opinion expresses the view of the MSC on the draft recommendation, taking into account the comments received. It also includes the minority positions, if any.

**Go to step 11****Step 11: Prepare and submit the final recommendation for Annex XIV to COM**

The Classification and Prioritisation Unit prepares the final recommendation for Annex XIV, taking into account the comments received during the public consultation from third parties and the opinion of the MSC. ECHA provides responses to all comments received.

The final recommendation consists of:

- Annex XIV recommendation document, which includes the recommended entries with:
  - o substance identity;
  - o intrinsic properties of the substance referred to in Article 57;
  - o sunset date;
  - o application date;
  - o review periods for certain uses (if appropriate);
  - o uses or categories of uses exempted from the authorisation requirement (if any) and conditions for such exemptions (if any);
  - o exemptions for PPORD (if any); and
  - o the maximum quantity exempted for such exemptions.
- Background documents for the recommended substances.
- Updated priority assessment results of the substances included in the draft recommendation. This final recommendation is accompanied by:
- The opinion of the Member State Committee on the draft recommendation of priority substances for Annex XIV entries (including minority positions, if relevant);

**Prioritisation and Annex XIV recommendation**

- Comments received from interested parties during public consultation (ComRef document) and final replies prepared (RCOM); and
- Other documents relevant for decision making by the European Commission, such as the approaches used for priority assessment and Annex XIV entries.

The Classification and Prioritisation unit submits ECHA's final recommendation for Annex XIV, after approval by the Deputy Executive Director (subject to delegation by the Executive Director), together with the MSC opinion on the draft recommendation, a letter informing about the submitted recommendation and other documentation to the European Commission (COM) for decision making.

For substances included in the final recommendation, **go to step 12**.

For substances not included in the final recommendation, **go to step 1** (the process restarts again in the next recommendation round).

**Step 12: Publish final recommendation and all related documentation on ECHA's website**

The Classification and Prioritisation Unit makes sure that the final recommendation and relevant documentation is published on ECHA's website.

**Go to step 13****Step 13: Support COM in decision-making process on inclusion of substances in Annex XIV**

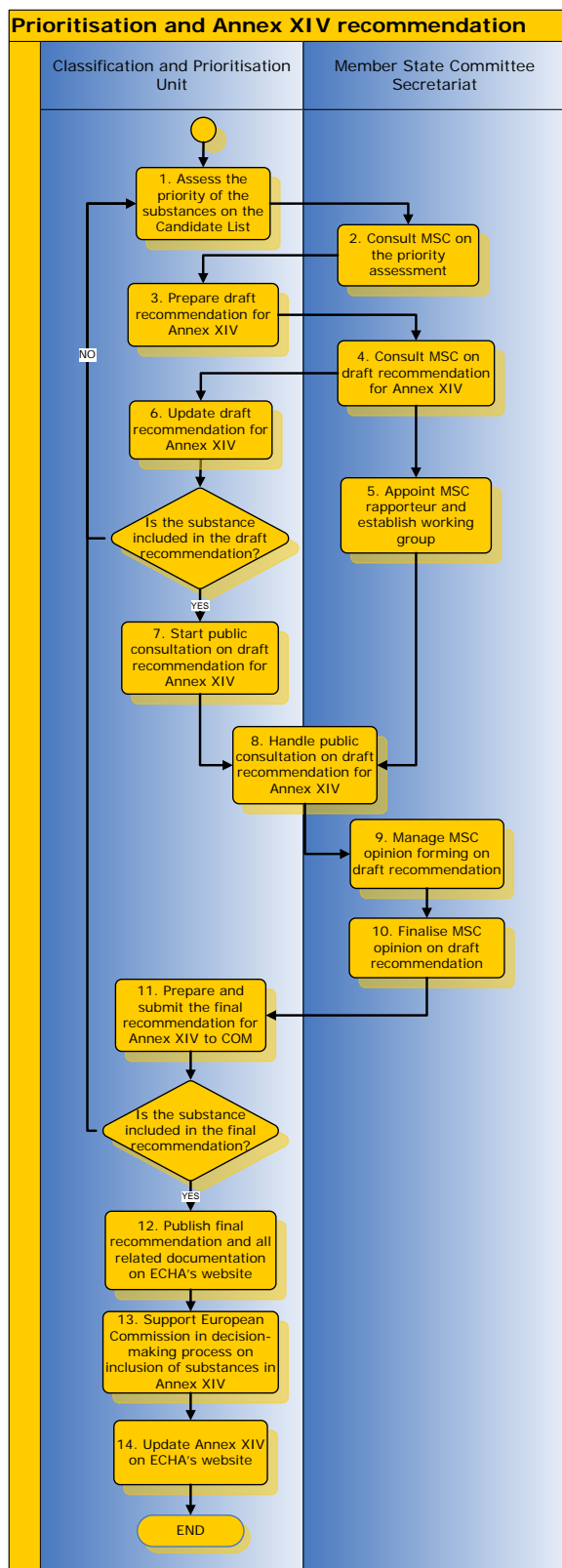
Where necessary and requested, the Classification and Prioritisation Unit supports the European Commission (COM) during the decision-making process on inclusion of substances in Annex XIV.

**Go to step 14****Step 14: Update Annex XIV on ECHA's website**

Once the COM has taken the decision on including substances in Annex XIV according to Article 133(4) of REACH, the Classification and Prioritisation Unit prepares all relevant information needed for updating ECHA's website and makes sure that the Annex XIV information is updated.

Prioritisation and Annex XIV recommendation

## 4. Flowchart



### Prioritisation and Annex XIV recommendation

## 5. Definitions

Term or abbreviation	Definition
AXIV-PC	Process coordinator in the Annex XIV recommendation process, responsible for general documentation and managing the process
AXIV-CR	Case responsible in the Annex XIV recommendation process, responsible for the substance-specific documentation
COM	European Commission
ECHA	European Chemicals Agency
HoU	Head of Unit responsible for the Annex XIV recommendation process
MSC	Member State Committee
MSC-S	Member State Committee Secretariat
PRO	Procedure
RCOM	Response to comments document
SVHC	Substance of very high concern
WIN	Working instruction

## 6. Records

Record name	Security level	Comments
Candidate List of substances for eventual inclusion in Annex XIV	Public	Published on ECHA's website. The recommendation only considers substances not already recommended previously.
General approach for prioritisation of SVHCs for inclusion in Annex XIV	Public	Published on ECHA's website: The approach is drafted by the Classification and Prioritisation Unit and consulted with the MSC. The approach is applied by the Classification and Prioritisation Unit when assessing the priority of Candidate List substances
General approach on preparation of draft Annex XIV entries	Public	Published on ECHA's website The approach is drafted by the Classification and Prioritisation Unit and consulted with the MSC The approach is applied by the Classification and Prioritisation Unit



## Prioritisation and Annex XIV recommendation

Record name	Security level	Comments
		when defining the draft Annex XIV entries
Priority assessment of substances on the Candidate List	Internal	Contains priority assessment outcome of all assessed substances, according to the agreed approach (record no. 2)
Draft recommendation for Annex XIV (contains priority assessment, the draft Annex XIV entries and the draft background document for each substance)	Internal	The draft Annex XIV recommendation consists of: - Priority setting document; - Draft Annex XIV entries; and - Draft background documents (for each substance proposed for Annex XIV)
MSC written comments on draft recommendation for Annex XIV (if any)	Internal	Any written comments (if any) from MSC on the draft recommendation presented separately or collated in one document.
MSC rapporteur's letter of appointment	Internal	Letter of appointment of MSC rapporteur (and where relevant, of MSC co-rapporteur)
Mandate of MSC working group	Internal	Mandate of the MSC working group (if established)
Comments on draft recommendation by interested parties (individual comments submitted via webform during the public consultation)	Restricted	Comments received via webform during public consultation consisting of: - Personal information on submitter (always confidential); - Information on organisation (organisation name can be claimed confidential by submitter); - Comments submitted (not confidential); and - Attachments (non-confidential and/or confidential)
Document containing compiled comments (ComRef document contains comments received by third parties for each substance or group of substances proposed for Annex XIV)	Restricted	Contains generic information on the submitter of the comment, the comments and attachments.  Confidential and non-confidential versions (latter without confidential

## Prioritisation and Annex XIV recommendation

Record name	Security level	Comments
		attachments and organisation name where claimed confidential)
MSC opinion on draft final recommendation for Annex XIV	Public	MSC opinion (includes minority positions, as relevant)
Compiled comments (ComRef document) and responses to these comments (RCOM document) for each substance or group of substances proposed for Annex XIV	Restricted	<p>Comments and their replies prepared by the Classification and Prioritisation Unit to public and confidential comments, showing how the comments have been considered when finalising the Annex XIV recommendation. For transparency and readability reasons this is provided in two separate documents:</p> <ul style="list-style-type: none"> <li>-Com Ref document: the table of comments for each substance containing the comments (the attachments of the comments are attached to this document) and references to the relevant replies.</li> <li>- RCOM document: Separate reply documents with all referenced replies for a substance or group of substances.</li> </ul>
Final recommendation for Annex XIV (including final prioritisation assessment the recommended Annex XIV entries and the final background document for each substance) as well as supporting documents	Restricted	<p>Documents:</p> <ul style="list-style-type: none"> <li>- Annex XIV recommendation document, specifying the Annex XIV entries;</li> <li>- Background documents (for all substances included in the draft recommendation)</li> <li>- Priority assessment of all Candidate List substances (at start of PC) and updated priority assessment for substances recommended for Annex XIV</li> <li>- MSC opinion</li> <li>- Approaches used</li> </ul>
Letter for submission of the final recommendation to the Commission	Internal	Letter to the Commission on the submission of the final recommendation and its annexes
Decision on inclusion of substances in Annex XIV	Public	COM document, published in the Official Journal

## Prioritisation and Annex XIV recommendation

Record name	Security level	Comments
List of substances included in Annex XIV	Public	Published on ECHA's website following publication of decision in the Official Journal

## 7. References

Associated document code	Document name
EC No 1907/2006	REACH Regulation (EC) No 1907/2006 concerning the registration, evaluation, authorisation and restriction of chemicals
Working procedures of the Member States Committee	Working procedures for the MSC in providing the opinion on the draft Recommendation of priority substances to be included in Annex XIV – workflow, tasks, possible procedures and communication
MB/07/2014	Review of the policy for managing potential conflicts of interest

## 8. Annexes

N/A