

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 the consultation on ECHA's draft recommendation 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/10162/17232/gen_approach_svhc_prior_in_recommendations_en.pdf). MSC is consulted on the draft recommendation.

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ECHA launches a consultation of interested parties which lasts for 3 months on the draft recommendation. This draft includes a proposal for Annex XIV entries, including proposals for 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 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 Prioritisation Unit is responsible for the Annex XIV recommendation process. The Annex XIV Process coordinator assigns a case responsible to each substance, responsible for the substance-specific documentation. The process coordinator 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 "Prevention and Management of potential Conflicts of Interests" (PRO-0067) and WIN-0105.

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

The case responsible gathers the available information from registration dossiers, the Annex XV substance of very high concern (SVHC) dossiers, the consultations held 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 Authorisation List (Annex XIV)", the 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

Step 3: Prepare draft recommendation for Annex XIV

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The 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.

When preparing the draft Annex XIV entries, the Prioritisation Unit follows the general approach for "Preparation of draft Annex XIV entries for substances recommended to be included in Annex XIV" and the "Practical implementation document for the Annex XIV entries approach".

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

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

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; and
- the application of the agreed approaches on priority assessment and Annex XIV entries.

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

The Prioritisation Unit updates the draft recommendation for Annex XIV (see details in the records table in chapter 6), taking into account the comments received from the MSC and

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make available to the MSC draft background documents for each substance included in the draft recommendation.

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 consultation on draft recommendation for Annex XIV

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

The Prioritisation Unit makes sure that the relevant webforms for submitting comments are available and that relevant information is provided to interested parties 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 consultation. The consultation lasts for 3 months.

Go to step 8

Step 8: Handle consultation on draft recommendation for Annex XIV

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 received during the consultation 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 and the Prioritisation Unit support 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

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".

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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 attached to the MSC opinion.

Once the MSC opinion is adopted and finalised, the MSC-S makes it available to the 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 Prioritisation Unit prepares the final recommendation for Annex XIV, taking into account the comments received during the consultation from third parties and the opinion of the MSC. ECHA provides responses to all comments received from third parties.

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 latest application date and sunset 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 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);
- Comments received from interested parties during 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.

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The Prioritisation Unit submits ECHA's final recommendation for Annex XIV, after approval by the Director of Prioritisation and Integration (subject to delegation according to PRO-0059 and LIS-0030), 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 Prioritisation Unit makes sure that the final recommendation and relevant documentation is published on ECHA's website.

Go to step 13

Step 13: Support European Commission in decision-making process on inclusion of substances in Annex XIV

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

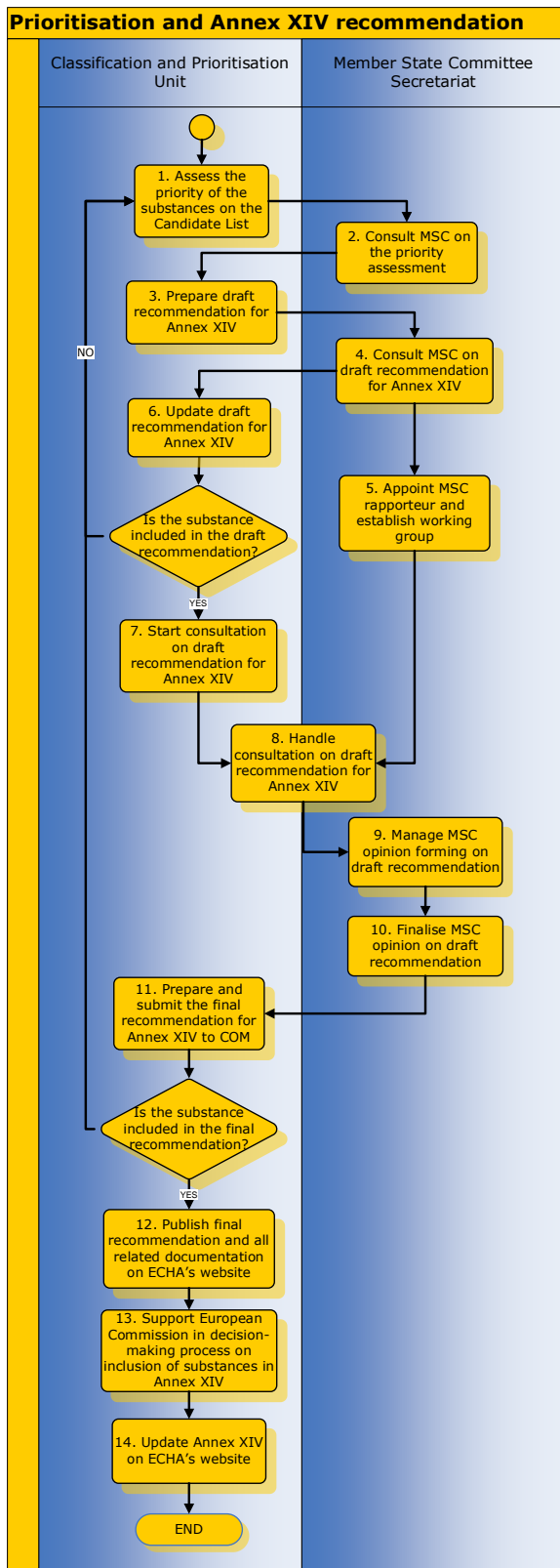
Go to step 14

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 prioritisation Unit ensures the update of the Authorisation List on ECHA's Website and makes sure that all related relevant information is made available.

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4. Flowchart



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5. Definitions

Term or abbreviation	Definition
COM	European Commission
ComRef document	The table of comments for each substance containing the comments and references to the relevant replies
ECHA	European Chemicals Agency
MSC	Member State Committee
MSC-S	Member State Committee Secretariat
PPORD	Product and process oriented research and development
PRO	Procedure
RAC	Committee for Risk Assessment
RCOM	Response to comments document
SEAC	Committee for Socio-Economic Analysis
SVHC	Substance of very high concern
WIN	Work 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 Prioritisation Unit and consulted with the MSC. The approach is applied by the 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 Prioritisation Unit and consulted with the MSC. The approach is applied by the Prioritisation Unit when defining the draft Annex XIV entries.

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Record name	Security level	Comments
Setting Latest Application Dates – Practical implementation document for the Annex XIV entries approach	Public	Published on ECHA’s website: The implementation document is drafted by the Prioritisation Unit and consulted with the MSC. The approach is applied by the Prioritisation Unit 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 (step 1).
Draft recommendation for Annex XIV	Internal	The draft Annex XIV recommendation consists of: - Priority assessment of substances on the Candidate List (steps 3 and 6); - Draft Annex XIV entries (steps 3 and 6); and - Draft background documents (for each substance proposed for Annex XIV), (step 6).
MSC rapporteur’s letter of appointment	Internal	Letter of appointment of MSC rapporteur (and where relevant, of MSC co-rapporteur, step 5).
Mandate of MSC working group	Internal	Mandate of the MSC working group (if established, step 5).
Comments on draft recommendation by interested parties (individual comments submitted via webform during the consultation)	Restricted	Comments received via webform during consultation (step 8) 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 attachments and

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Record name	Security level	Comments
		organisation name where claimed confidential, step 8).
MSC opinion on draft recommendation for Annex XIV	Public	MSC opinion (includes minority positions, as relevant, step 10).
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 Prioritisation Unit to public and confidential comments, showing how the comments have been considered when finalising the Annex XIV recommendation (step 11). For transparency and readability reasons this is provided in two separate documents:</p> <ul style="list-style-type: none"> -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. - RCOM document: Separate reply documents with all referenced replies for a substance or group of substances.
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 (step 11):</p> <ul style="list-style-type: none"> - Annex XIV recommendation document, specifying the Annex XIV entries; - Background documents (for all substances included in the draft recommendation); - Priority assessment of all Candidate List substances (at start of consultation) and updated priority assessment for substances recommended for Annex XIV; - MSC opinion; - Approaches used.
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 (step 11).
Decision on inclusion of substances in Annex XIV	Public	COM document, published in the Official Journal (step 14).
List of substances included in Annex XIV	Public	Published on ECHA's website following publication of decision in the Official Journal (step 14).

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7. References

Associated document code	Document name
EC No 1907/2006	REACH Regulation 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

8. Annexes

N/A