

Handling restriction proposals under REACH

1. Purpose

This procedure describes the restrictions process as established by the REACH Regulation Title VIII, Chapter 2 ('Restrictions process'). The purpose of the process is to ensure that the Committee for Risk Assessment (RAC) and Committee for Socio-economic Analysis (SEAC) provide high quality and timely opinions on proposals to restrict the manufacturing, placing on the market or use of substances posing a risk to human health or the environment.

This procedure is designed to make sure that:

- the restriction proposals conform with the criteria defined in Annex XV and are handled according to the process specified in Article 69 of the REACH Regulation;
- the opinions of RAC and SEAC meet the requirements set out in Articles 70 and 71 of the REACH Regulation respectively so that the Commission can meet its legal obligations as specified in Article 73 of the REACH Regulation;
- legislative deadlines are respected;
- internal requirements for the efficient processing of restriction proposals are met;
- efficient communication among the Member States (MSs), third parties, RAC and SEAC, the Forum, the ECHA Secretariat and the European Commission is well defined.

2. Scope

This procedure covers the restrictions process, considering four possible starting points for the submission of the restriction proposals.

The procedure ends when an amendment of Annex XVII is published in the Official Journal and when ECHA publishes the amendment on its website. Should the Commission not adopt a restriction, ECHA provides the link from its website to the Official Journal that makes the Commission's communication public.

3. Description

Restrictions under the REACH Regulation are used when there is an unacceptable risk to human health or the environment arising from the manufacture, use or placing on the market of substances that need to be addressed on a Union-wide basis and when risk management measures under other REACH processes or other European legislation are considered insufficient.

Under the REACH Regulation, Annex XVII lists all restrictions on the manufacture, placing on the market and use of a substance on its own, in mixtures and in articles. Annex XVII needs to be amended when a new restriction is adopted or existing restrictions are modified. A decision on the amendment of Annex XVII is done by the Commission according to the procedure referred to in Article 133(4) of the REACH Regulation.

3.1. Pre-submission

3.1.1. Initiation of the restrictions process

The preparation of a proposal for a restriction is the responsibility of an MS, or of ECHA¹.

The process starts when:

- an MS sends a notification of intention to prepare a dossier for a restriction proposal according to Article 69(4) of the REACH Regulation;
- inclusion of the MS's intention in the Registry of Intention after the Commission decision to authorise the provisional measure, that an MS has taken a leading role to the preparation of the restriction dossier for a restriction proposal according to Article 129(3) of the REACH Regulation (Safeguard clause);
- the Commission requests ECHA to prepare a dossier for a restriction proposal, according to Article 69(1) of the REACH Regulation; or
- ECHA decides to prepare a dossier on its own initiative, according to Article 69(2) of the REACH Regulation, for substances listed on Annex XIV and where it considers the use in articles not to be adequately controlled.

ECHA publishes the notification of intentions on its website (Registry of Intentions). The process coordinator notifies the registrants of the substance(s) concerned according to Article 69(4) of the REACH Regulation. In addition, notifiers for the Classification and Labelling Inventory and any known downstream users for the substance proposed to be restricted are informed about the intention by the process coordinator.

The MSs or ECHA need to prepare and submit the Annex XV restriction dossier within 12 months of the notification in the Registry of Intentions for submission under Articles 69(1), 69(2) and 69(4) of the REACH Regulation. Collaboration among the MSs and/or with ECHA in the preparation of the dossier is supported.

If the safeguard clause is used, the assigned MS shall prepare and submit the Annex XV restriction dossier within three months of the date of the Commission decision, according to Article 129(3) of the REACH Regulation.

3.1.2. Dossier preparation and pre-restriction information meetings (PRIM) on restriction proposals

The process coordinator or restriction team (RT) (if already nominated) provides support to the MS by:

- (i) organising a PRIM;
- (ii) providing a platform for the communication with other MSs;
- (iii) providing scientific support if requested; and if needed

¹ The European Commission makes proposals for substances on its own, in a mixture or in an article which meet the criteria for classification in the hazard classes carcinogenicity, germ cell mutagenicity or reproductive toxicity, category 1A or 1B and could be used by consumers (article 69(2) of REACH). ECHA and its scientific committees are not involved in this process and this is not further described in this procedure.

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- (iv) including links on ECHA's website to an MS's possible call for evidence and raising publicity of the call for evidence using ECHA's information channels.

The Risk Management Implementation Unit prepares ECHA's restriction proposals with the support of other units if needed.

The Committees Secretariat seeks volunteers among RAC and SEAC members who would act as prospective rapporteurs for a specific Annex XV restriction dossier and makes a proposal of the rapporteurs to the Committees for agreement. ECHA's policy on managing potential conflicts of interest set out in WIN-0105 Prevention of Conflicts of Interest is applied.

The Head of Unit for Risk Management Implementation nominates a restriction team (RT) for the case after consulting the Head of Unit for the Committees Secretariat. The RT supports the MS, the Committees, the (co-)rapporteurs and the Chairmen of the Committees throughout the process. In the nomination ECHA's policy on managing potential conflicts of interest set out in WIN-0105 is applied. The RT consists of staff of the Risk Management Implementation Unit and the Committees Secretariat Unit, as well as other units, when appropriate and provides scientific, technical, legal and administrative support. The support includes the sound and timely management and the correct procedural records of the work of the ECHA Secretariat and the Committees (WIN-0112).

3.2. Submission

MSs or ECHA submit the Annex XV dossier for restriction. The Substance Identification & Data Sharing Unit checks the substance identification of the proposal and the outcome is communicated to the dossier submitter with the conformity check report. For the dossiers submitted by MSs, the RT prepares the preliminary conformity check outcome, which is communicated to the (co-)rapporteurs. For ECHA dossiers, no preliminary conformity check outcomes are prepared. ECHA publishes the submitted Annex XV reports, normally within 2 weeks of submission, on its website in order to alert interested parties of the upcoming public consultation. The RT makes sure that highly restricted information is not published.

3.3. Conformity check

After the restriction proposal is submitted, the Committees check whether the submitted restriction dossier conforms to the requirements of Annex XV of the REACH Regulation. An MS or Risk Management Implementation Unit, as a Dossier Submitter, may bring the non-conforming dossier into conformity after receiving the reasons of the non-conformity and resubmit the dossier within 60 days. The dossier is again checked for its conformity by the Committees and if it is not in conformity, the process is terminated.

3.4. Opinion development

ECHA initiates the public consultation with the conforming Annex XV restriction reports. The RT prepares the media items and makes sure that highly restricted information will not be published. Interested parties may submit comments and supporting documentation during the public consultation on the Annex XV report within six months of the date of the publication. For the substance(s) for which a restriction is proposed, the RT informs:

- i) the registrants,
- ii) notifiers to the Classification and Labelling (C&L) Inventory,

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- iii) registrants of alternatives,
- iv) notifiers to the C&L Inventory of alternatives, and
- v) relevant stakeholders.

The restriction process coordinator informs Member State competent authorities (MSCAs) about the start of the public consultation.

The process of the Committees opinion development encompasses a strict time regime to ensure the fulfilment of the legal deadlines. The Forum shall provide advice to RAC and SEAC on the enforceability of the proposed restriction, according to Article 77(4)(h). After the adoption of the RAC opinion and agreement on the SEAC draft opinion, ECHA publishes the RAC opinion and SEAC draft opinion on its website, and initiates a public consultation on the SEAC draft opinion.

The RT prepares the media items and makes sure that highly restricted information is not published. Interested parties may submit comments and supporting documentation during the public consultation on the SEAC draft opinion within 60 days of the date of the publication.

In the course of the process:

- RAC formulates its opinion based on the evaluation of the assessment of risk to human health or the environment arising from the uses of a substance, including the appropriateness and effectiveness of the risk management measures as described in the restriction dossier and, if relevant, an assessment of the risks arising from possible alternatives. The views of the interested parties submitted during public consultation are taken into account. RAC adopts its opinion within nine months from the start of the public consultation of the Annex XV restriction report.
- SEAC formulates its opinion based on the evaluation of the assessment of the socio-economic factors and the availability, suitability and technical feasibility of alternatives associated with the uses of the substance as described in the restriction dossier. The comments and socio-economic analysis submitted by the interested parties during the public consultation of the Annex XV report and during the public consultation of the SEAC draft opinion are taken into account. The SEAC opinion is adopted within 12 months from the publication of the Annex XV report. If the RAC opinion diverges significantly from the original proposal, the Director of Risk Management may decide to postpone the adoption of the SEAC opinion by three months.

The RT assists RAC and SEAC throughout the opinion-making process. During the process, the Annex XV report is transformed into the background document (BD), which supports the opinions of the Committees. The BD addresses the recommendations of the Committees during the conformity check and addresses how the comments submitted in the public consultation have been taken into account. The BD is prepared by a group consisting of the RT, the (co-)rapporteurs and the Dossier Submitter. The RT regularly publishes the non-confidential comments received through public consultations on ECHA's website. In addition, the responses to the comments received during the public consultations are provided by the submitting MS or Risk Management Implementation Unit as a Dossier Submitter and the (co-)rapporteurs in response to comments tables (responses to the comments on the Annex XV report and responses to the comments on SEAC draft opinion).

The Chairmen of RAC and SEAC submit the compiled opinion of RAC and SEAC and necessary supporting documentation, such as the BD to the Commission.

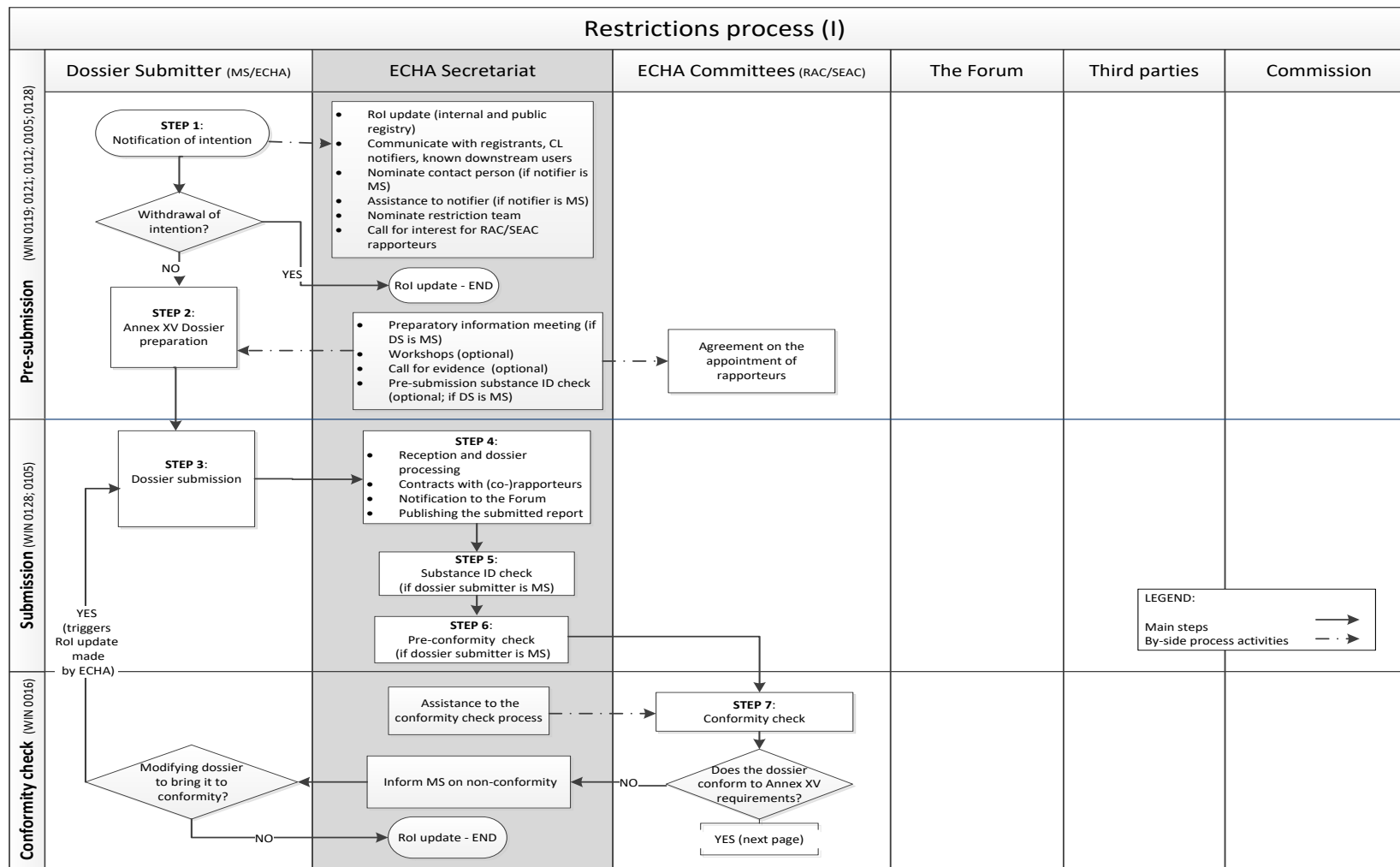
ECHA publishes the consolidated RAC and SEAC opinions, the BD and the comments made during the public consultations and responses to them on its website. The RT prepares the media items and makes sure that highly restricted information is not published.

3.5. Decision

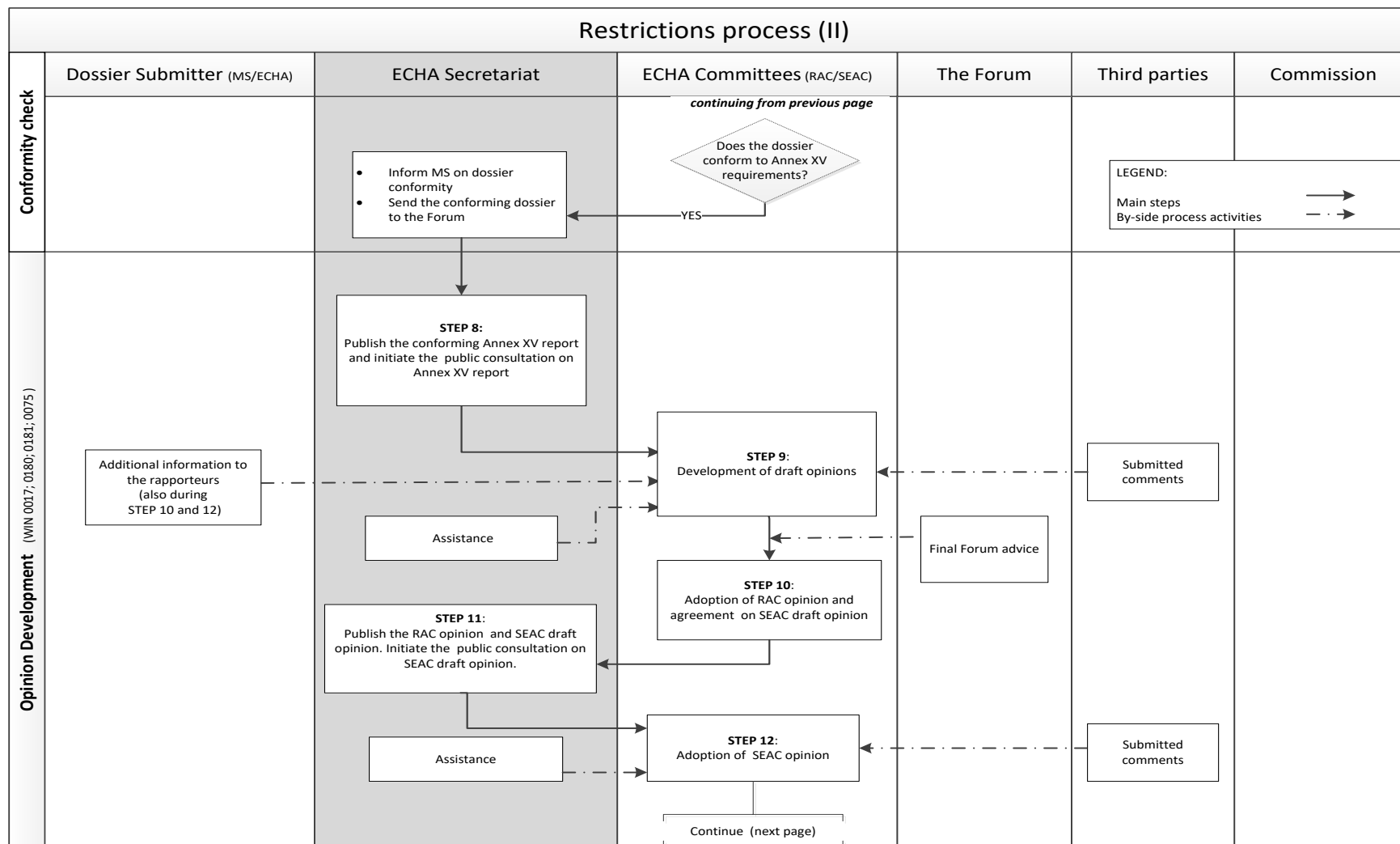
The European Commission prepares a draft amendment to Annex XVII within three months after receiving the opinions. If the draft amendment diverges from the original proposal or if it does not take the opinions into account, the Commission shall annex a detailed explanation of the reasons for the differences. The draft amendment is submitted to the MSs and finally the Commission takes the decision according to Article 133(4). On request, the RT provides assistance to the Commission during the decision-making phase.

The Commission Regulation to restrict a substance is published in the Official Journal as an amendment of Annex XVII of REACH. ECHA publishes the amendment on its website. Should the Commission not adopt a restriction, ECHA provides the link from its website to the Official Journal that makes the Commission's communication public.

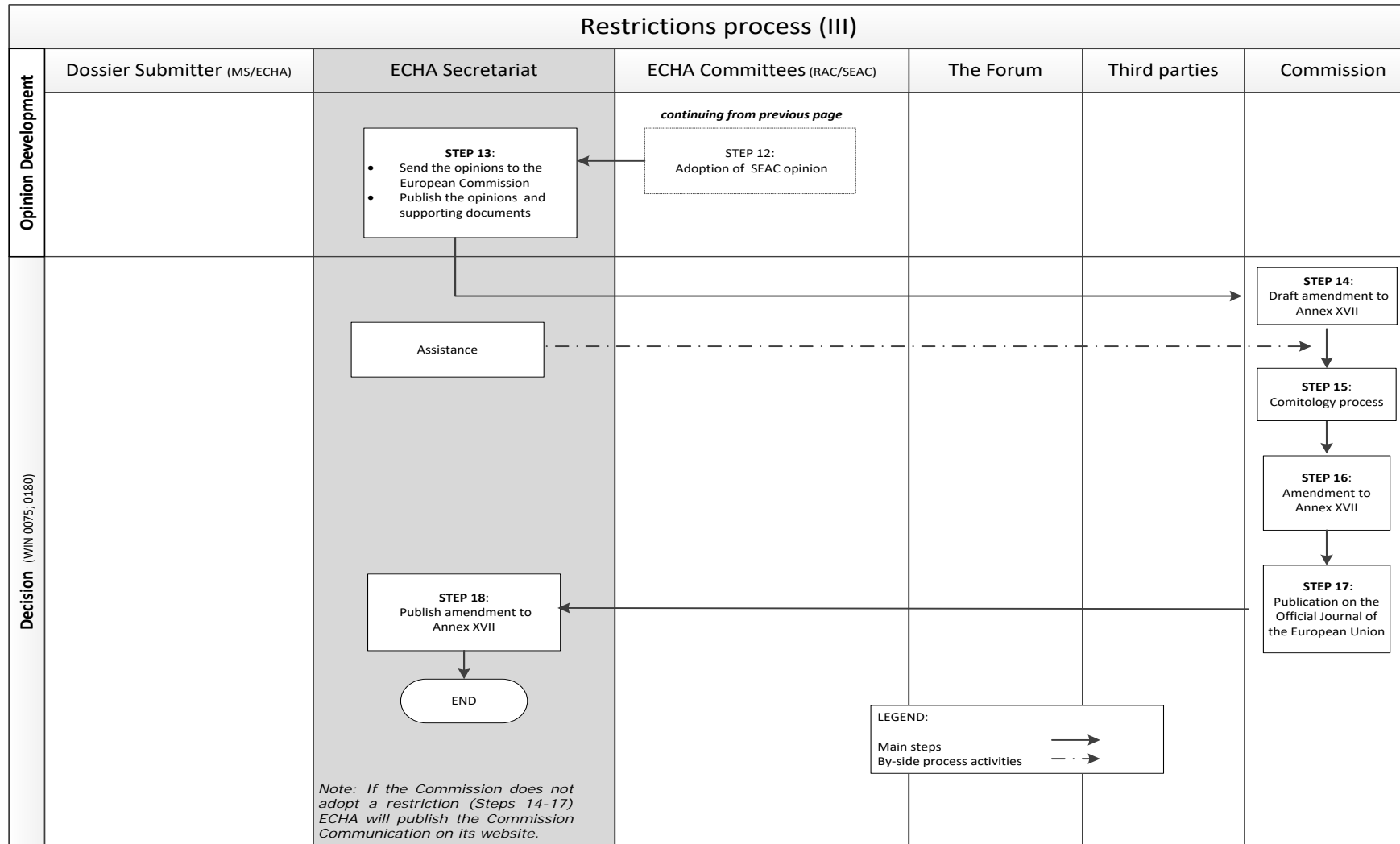
4. Flowchart



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5. Definitions

Term or abbreviation	Definition
BD	Background document (Annex XV report that is revised to be in line with the opinions of RAC and SEAC)
Chairmen	Chairman of RAC and Chairman of SEAC
C&L	Classification and labelling
Forum	Forum for Exchange of Information on Enforcement
MS	Member State
MSCA	Member State competent authority for REACH Regulation
PRIM	Pre-restriction information meeting on restriction proposal
RAC	Committee for Risk Assessment
RT	Restriction team
SEAC	Committee for Socio-economic Analysis
Third parties	In the restrictions process, registrants of the substance in concern and interested parties providing comments during public consultation

6. Records

The records mentioned in this PRO are listed in the relevant process related Work instructions.

7. References

Associated document code	Document name
EC No 1907/2006	The REACH Regulation concerning the registration, evaluation, authorisation and restriction on chemicals
N/A	Guidance on the preparation of an Annex XV dossier for restriction (available on ECHA website)
N/A	Guidance on Socio-economic Analysis – Restrictions (available on ECHA website)

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Associated document code	Document name
N/A	Addendum to the guidance on Annex XV restrictions and to the guidance on socio-economic analysis (SEA) – restrictions. Explanatory note – Format of Annex XV restriction report. (available on ECHA website)
N/A	Addendum to the guidance on socio-economic analysis (SEA) – Restrictions. Calculation of compliance costs. (available on ECHA website)
ED/21/2015	Delegation of the power to authorise decisions and communications to the Director of Risk Management
N/A	Working procedure for RAC and SEAC on conformity check on Annex XV restriction dossiers (available on ECHA website)
N/A	Working procedure for RAC and SEAC on developing opinions on Annex XV restriction dossiers (available on ECHA website)
N/A	Working procedure for developing Forum advice on enforceability of the Annex XV proposals for restrictions (available on ECHA website)

8. Annexes

N/A