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 services 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 ECHA[1].

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 restriction intention until outcome (Restriction RoI) 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 (Restriction RoI). 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 of the intention 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.

(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 Unit D3 - Risk Management I prepares ECHA's restriction proposals with the support of other units, especially with the Unit D4 – Risk Management II.

The Units D3 and D4 support the chairs to seek volunteers among RAC and SEAC members who would act as prospective rapporteurs for a specific Annex XV restriction dossier and make 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 D3 nominates a restriction team (RT) for the case after consulting the Head of Unit for D4. The RT supports the MS, the Committees, the (co-)rapporteurs and the Chairs 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 Units D3 and D4, 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 Unit B1 - Chemistry 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 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. A MS or the Unit D3, as a Dossier Submitter, together with the Unit D4 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 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 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,

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 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 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 consultation on the SEAC draft opinion within 60 days of the date of the publication.

In the course of the process:

- RAC evaluates the Dossier Submitter's assessment of risk to human health or the environment arising from the uses of a substance, including the justification provided that implemented risk management measures (including those identified in registrations under Articles 10 to 14) are not sufficient. RAC formulates its opinion on the suggested restriction and possible options, taking into account its effectiveness, practicality and monitorability (as outlined in Annex XV). If relevant, the opinion shall include an assessment of the risks arising from possible alternatives. The views of the interested parties submitted during consultation are taken into account. RAC adopts its opinion within nine months from the start of the consultation of the Annex XV restriction report.

- SEAC evaluates the Dossier Submitter's assessment of the socio-economic impacts (the net benefits to human health and the environment of the proposed restriction may be compared to its net costs to manufacturers, importers, downstream users, distributors, consumers and society as a whole) of the proposed restriction, including the feasibility of alternatives. SEAC formulates its opinion as to whether the suggested restriction is the most appropriate Union wide measure according to article 71 of REACH, taking into account effectiveness, practicality and monitorability (as outlined in Annex XV). The comments and socio-economic analysis submitted by the interested parties during the consultation of the Annex XV restriction report and during the 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 restriction report. If the RAC opinion diverges significantly from the original proposal, the Head of Unit for D3 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 restriction 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 consultations 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 consultations on ECHA's website. In addition, the responses to the comments received during the consultations are provided by the submitting MS or the Unit D3 as a Dossier Submitter together with the Unit D4 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 Chairs of RAC and SEAC submit the compiled opinion of RAC and SEAC and necessary supporting documentation, such as the BD to the Commission.

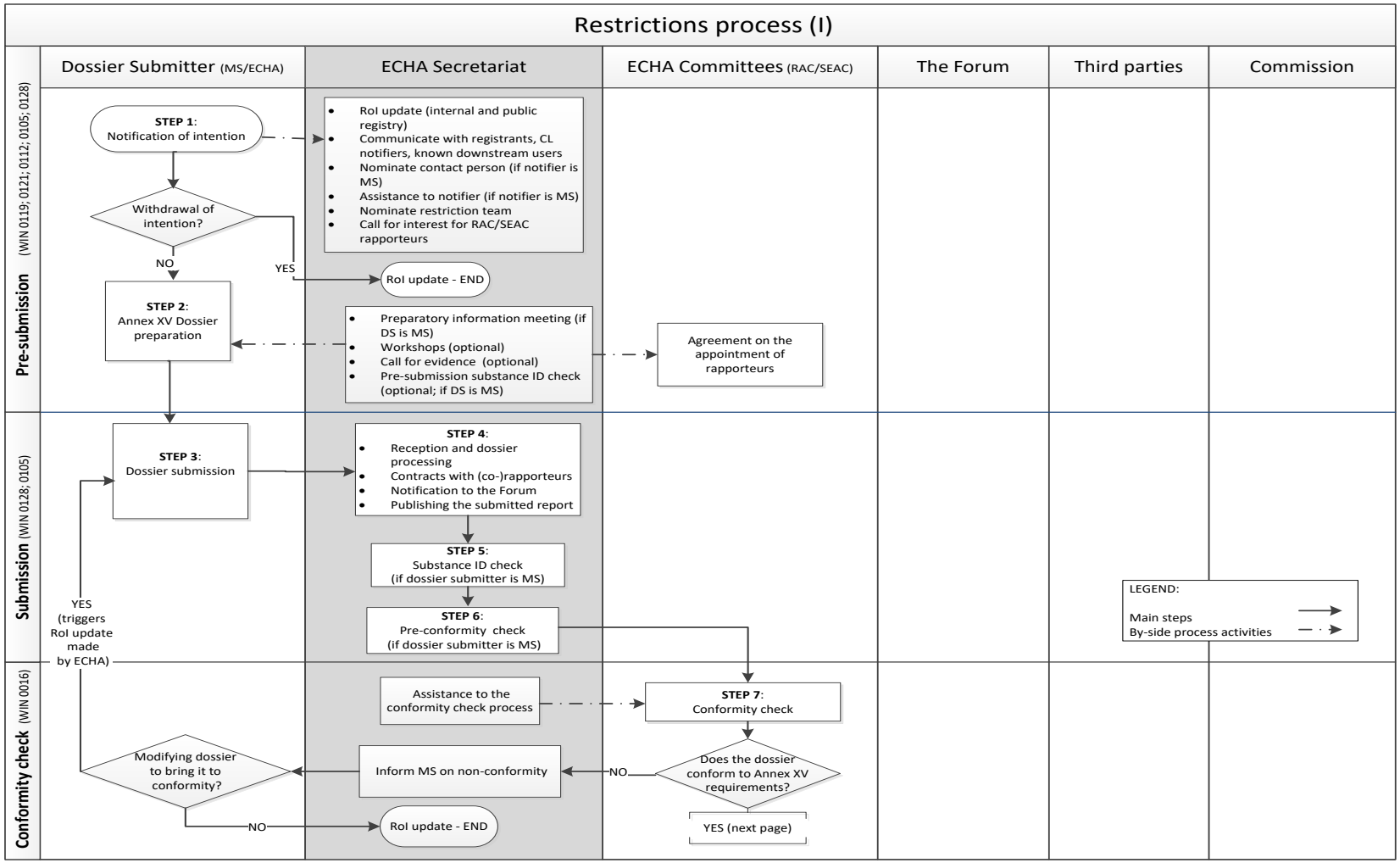
ECHA publishes the consolidated RAC and SEAC opinions, the BD and the comments made during the consultations and responses to them on its website. The RT prepares the media items and makes sure that highly restricted information is not published.

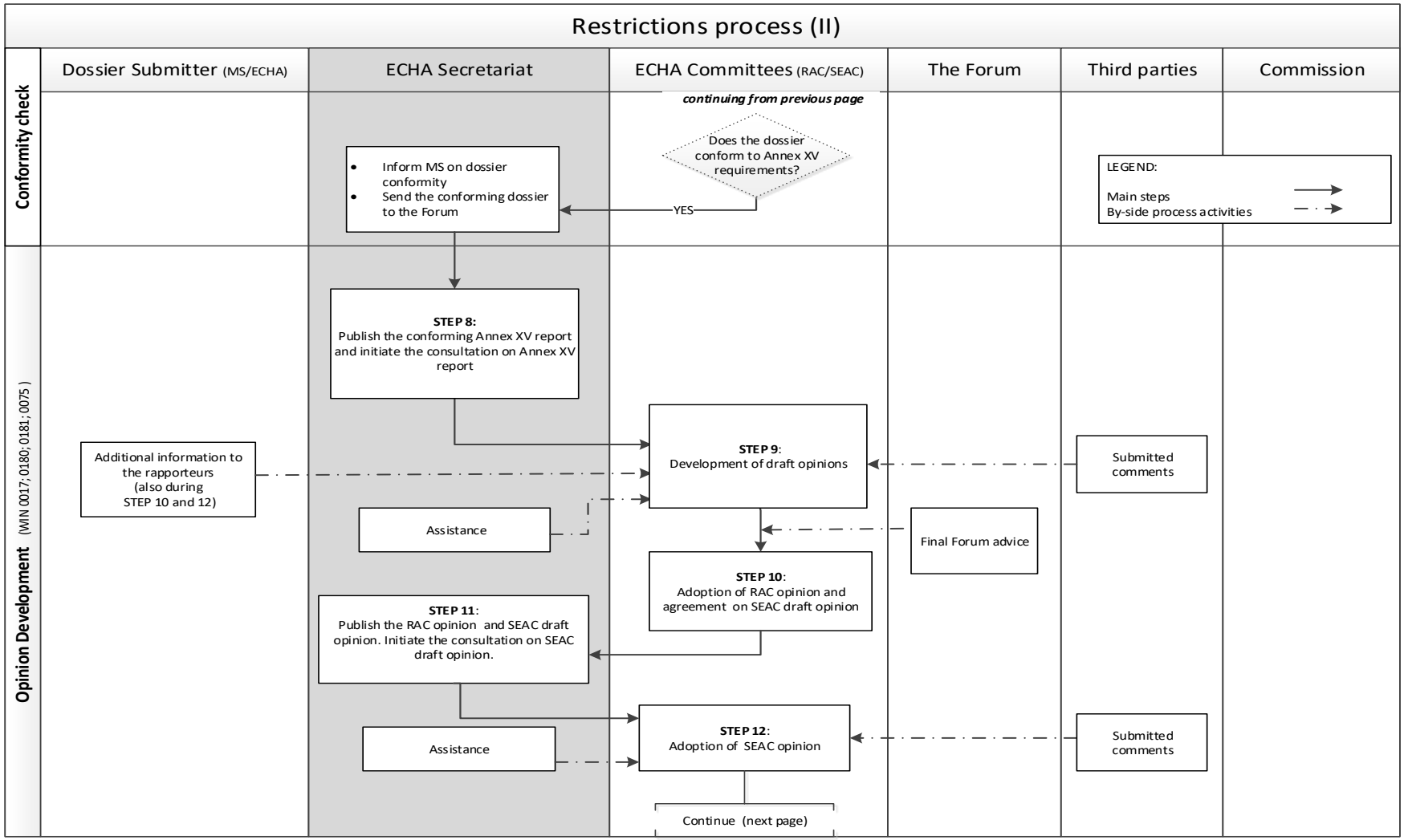
3.5. Decision

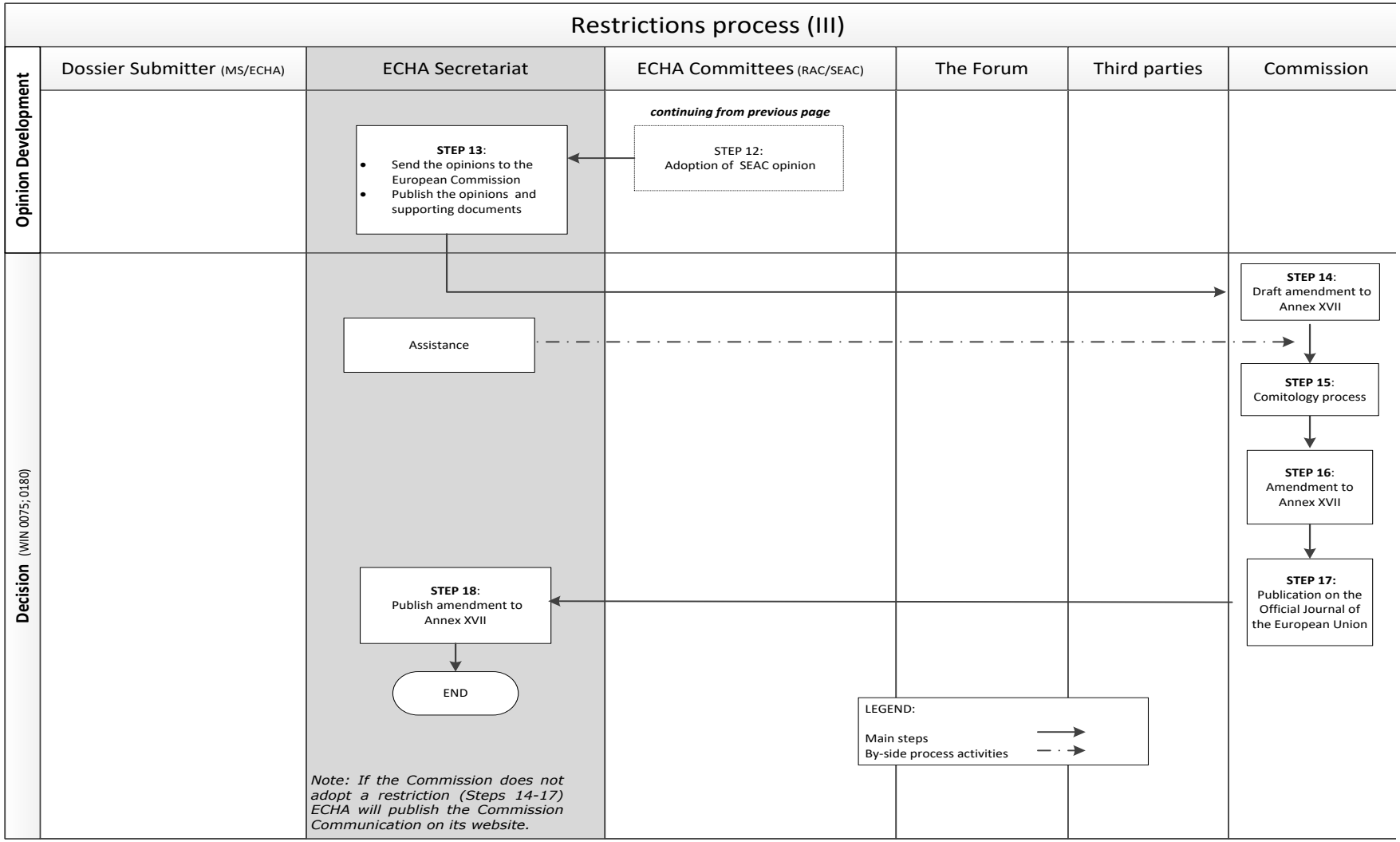
The European Commission prepares a draft amendment to Annex XVII within three months after receiving the opinions. If the draft amendment diverges from the original proposal or if it does not take the opinions into account, the Commission shall annex a detailed explanation of the reasons for the differences. 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


Restrictions process (I)
Dossier Submitter (MS/ECHA)
ECHA Secretariat
ECHA Committees (RAC/SEAC)
The Forum
Third parties
Commission
Pre-submission (WIN 0119; 0121; 0112; 0105; 0128)
Submission (WIN 0128; 0105)
Conformity check (WIN 0016)
STEP 1: Notification of intention
RoI update (internal and public registry)
Communicate with registrants, CL notifiers, known downstream users
Nominate contact person (if notifier is MS)
Assistance to notifier (if notifier is MS)
Nominate restriction team
Call for interest for RAC/SEAC rapporteurs
Withdrawal of intention?
NO
YES
RoI update - END
STEP 2: Annex XV Dossier preparation
Preparatory information meeting (if DS is MS)
Workshops (optional)
Call for evidence (optional)
Pre-submission substance ID check (optional; if DS is MS)
Agreement on the appointment of rapporteurs
STEP 3: Dossier submission
STEP 4:
Reception and dossier processing
Contracts with (co-)rapporteurs
Notification to the Forum
Publishing the submitted report
STEP 5: Substance ID check (if dossier submitter is MS)
STEP 6: Pre-conformity check (if dossier submitter is MS)
YES (triggers RoI update made by ECHA)
LEGEND:
Main steps
By-side process activities
Assistance to the conformity check process
STEP 7: Conformity check
Does the dossier conform to Annex XV requirements?
NO
Inform MS on non-conformity
Modifying dossier to bring it to conformity?
NO
RoI update - END
YES (next page)


Restrictions process (II)
Conformity check
Opinion Development (WIN 0017; 0180; 0181; 0075)
Dossier Submitter (MS/ECHA)
ECHA Secretariat
ECHA Committees (RAC/SEAC)
The Forum
Third parties
Commission
continuing from previous page
Does the dossier conform to Annex XV requirements?
YES
Inform MS on dossier conformity
Send the conforming dossier to the Forum
LEGEND:
Main steps
By-side process activities
STEP 8: Publish the conforming Annex XV report and initiate the consultation on Annex XV report
Additional information to the rapporteurs (also during STEP 10 and 12)
STEP 9: Development of draft opinions
Submitted comments
Assistance
Final Forum advice
STEP 10: Adoption of RAC opinion and agreement on SEAC draft opinion
STEP 11: Publish the RAC opinion and SEAC draft opinion. Initiate the consultation on SEAC draft opinion.
Assistance
STEP 12: Adoption of SEAC opinion
Submitted comments
Continue (next page)


Restrictions process (III)
Opinion Development
Decision (WIN 0075; 0180)
Dossier Submitter (MS/ECHA)
ECHA Secretariat
ECHA Committees (RAC/SEAC)
The Forum
Third parties
Commission
continuing from previous page
STEP 12: Adoption of SEAC opinion
STEP 13:
Send the opinions to the European Commission
Publish the opinions and supporting documents
STEP 14: Draft amendment to Annex XVII
Assistance
STEP 15: Comitology process
STEP 16: Amendment to Annex XVII
STEP 17: Publication on the Official Journal of the European Union
STEP 18: Publish amendment to Annex XVII
END
LEGEND:
Main steps
By-side process activities
Note: If the Commission does not adopt a restriction (Steps 14-17) ECHA will publish the Commission Communication on its website.

5. Definitions

Term or abbreviation	Definition
BD	Background document (Annex XV restriction report that is revised to be in line with the opinions of RAC and SEAC)
Chair	Chair of RAC and Chair 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
Restriction RoI	Registry of restriction intentions until outcome
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 consultation
Unit D3 – Risk Management I	ECHA's Unit with overall responsibility for the preparation of restriction proposals and managing the restriction process under REACH.
Unit D4 – Risk Management II	ECHA's Unit with overall responsibility for managing the application for authorisation process under REACH. It provides expertise on socio-economic issues for the restriction process.

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)
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)
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