Identification of Substances of Very High Concern

1. Purpose

This procedure describes the identification of substances of very high concern (SVHCs) as set out in Article 59 of the REACH Regulation. It includes

- the preparation of Annex XV dossiers for SVHC identification by ECHA at the request of the European Commission
- the handling of the Annex XV SVHC dossiers submitted to ECHA by a Member State Competent Authority (MSCA) or prepared by ECHA.

This procedure is designed to ensure that:

- Internal requirements for an efficient SVHC identification process are met
- Legislative deadlines are respected
- The SVHC proposals referred to the Member State Committee (MSC) contain enough information to allow the assessment by this committee
- The communication and co-operation between MSCAs, MSC and the European Commission is defined.

2. Scope

The SVHC identification process takes place in the context of Authorisation (Title VII of REACH). This process has two possible starting points:

- An MSCA submits an Annex XV dossier proposing identification of a substance as an SVHC or
- The European Commission requests that ECHA prepares such an Annex XV SVHC dossier.

The procedure ends either with the identification of the substance as an SVHC and the publication of the updated Candidate List or, with an MSC agreement or a European Commission decision that the substance has or has not been identified as an SVHC.

3. Description

3.1. General

A Member State or ECHA, at the request of the Commission, can propose a substance to be identified as a substance of very high concern (SVHC). Where the substance is identified as an SVHC it is included in the Candidate List, for eventual inclusion in the Authorisation List (Annex XIV of the REACH Regulation). The SVHC identification process includes a period of public consultation which lasts for forty five days.

After publication of the proposal, anyone can comment on it or provide further information to be used in the subsequent steps of the authorisation process, for example, related to the uses of the proposed substance or regarding alternatives for the substance. If no comments are received, or the comments provided do not trigger the involvement of the Member State Committee (MSC), the substance is included in the Candidate List. When the comments received require the involvement of the MSC, the proposals and the comments will be forwarded to the Committee to agree on the identification of the substance as an SVHC. If the committee does not reach a unanimous agreement, the matter will be referred to the European Commission.

3.2. Detailed description

Stage 1: Annex XV dossier preparation

In cases where the European Commission requests ECHA to prepare an Annex XV SVHC dossier, this stage is to ensure that the dossier is prepared in accordance with Annex XV. The dossier should contain all the relevant information needed

- to allow the MSC to come to an agreement on the identification of the substance as an SVHC, in cases where the dossier is referred to this committee (Part I of the Annex XV report),
- to provide further information relevant for the follow-up processes (Part II of the Annex XV report).

LIS-0006 applies for this stage.

Step 1 – Prepare Annex XV dossier

The Head of Unit (HoU) selects the case responsible, ensuring that no conflict of interest exists and documenting his/her action in accordance with the Policy for Managing potential Conflicts of Interests (MB/45/2011), PRO-0067 and WIN-0105. The case responsible plans and organises the preparation of the Annex XV SVHC dossier. He or she will establish a Dossier Expert Group (DEG) comprising experts with the required expertise (e.g. Substance Identity (SID) expert). This DEG will be involved in the preparation of the Annex XV SVHC dossier. Each person in this DEG is responsible for the relevant parts of the dossier within their expertise. Where needed, the case responsible is also managing the outsourcing of the development of certain parts of the dossier.

Step 2 – Revision of the Annex XV dossier

The SVHC Process Coordinator (SVHC-PC) and Head of Unit are responsible for the review of the Annex XV SVHC dossier. The Legal Affairs Unit provides legal support in the preparation of the dossier, while the SID expert ensures the correct substance identity. Where further work is needed, the case responsible and the expert group revise the dossier as necessary.

Step 3 – Submit dossier

The SVHC Assistant (SVHC-AST) submits the final Annex XV SVHC report.

Stage 2: Ensure accordance of dossiers prepared by MSCAs

This stage is only performed when the Annex XV SVHC dossier is submitted by an MSCA. The information provided by the MSCA in the dossier is assessed against the requirements outlined in Annex XV of REACH. This is to ensure that the proposal contains all the relevant information enabling the MSCAs, ECHA and interested parties to comment on the proposal and for the MSC to come to an agreement, in cases where the dossier is referred to this committee (Part I of the Annex XV report). It is also to ensure that Part II of the report allows third parties to provide information relevant for the follow-up processes, while not containing confidential information. Confidential information can be submitted provided it is accompanied by a justification as to why the information should not be published. This stage gives the submitting MSCAs the opportunity to improve their dossier, where deemed necessary. WIN-0070 and LIS-0007 apply here.

Step 4 – Receive draft dossier and upload report

The SVHC-AST receives the draft Annex XV SVHC dossier submitted by the MSCA, checks the technical correctness of the submitted report and relevant attachments for further processing.

Step 5 – Substance identification check

The draft Annex XV SVHC dossier is checked against the information requirements related to the identification of the substance outlined in Annex XV of REACH as relevant for the identification of the substance as SVHC. The Substance Identity and Data Sharing Unit (SID-Unit) is responsible for the SID check.

Step 6 – Accordance check

The Head of Unit/SVHC-PC assigns case responsible to handle the dossier, taking into account possible conflict of interest in accordance with the Policy for Managing potential Conflicts of Interests (MB/45/2011), PRO-0067 and WIN-0105. The assigned case responsible performs the Accordance Check, ensuring that all the information required in Annex XV of REACH is present and that the submitted Annex XV SVHC dossier contains the relevant information to enable the MSC to take a decision. The accordance check is reviewed by the SVHC-PC and where relevant Legal Affairs Unit may be requested to provide legal support. The case responsible communicates the outcome of the accordance check to the Dossier Submitter (DS).

Based on the outcome of the accordance check the DS decides whether to submit the dossier again within the set deadline or to proceed with the current dossier. In case of a resubmission, a new Annex XV SVHC dossier is submitted and steps 4 to 6 are repeated as necessary.

Stage 3: Public consultation

Once ECHA receives the final Annex XV SVHC dossier, the SVHC Process Coordinator acknowledges the receipt of the dossier. ECHA makes this dossier available within 30 days of receipt to the other MSCAs for commenting. A public consultation is also initiated by ECHA. At this stage, it is ensured that the DSs are aware of received comments, so that they are able to take all comments into account appropriately. WIN-0071 applies to steps 7 to 9, WIN-0031 applies to steps 10 and 11, while WIN-0072 applies to steps 12 and 13.

Step 7 – Acknowledge dossier receipt

When the final Annex XV SVHC dossier has been submitted to ECHA, the SVHC Process Coordinator authorises its acknowledgement of receipt which is sent to the DS.

Step 8 – Make dossier available to other MSCAs for commenting

The SVHC-AST makes the Annex XV SVHC dossier available to all MSCAs for commenting within 30 days of receipt as outlined in Art. 59(3).

Step 9 – Start public consultation

The SVHC-PC prepares and the web-team launches the public consultation on ECHA's website. The substances proposed to be identified as SVHCs are published together with the corresponding Annex XV SVHC report. The public consultation is open for a period of 45 days, during which interested parties are invited to comment on the identification of the substance as an SVHC and the justification given in Part I of the Annex XV SVHC report. Interested parties are also invited to provide information on the proposed substance i.e. information on volume, uses, exposure and alternatives to the proposed substance, further to the available information provided in Part II of the Annex XV report. In cases where the substance is identified as an SVHC, such information is relevant for the follow-up processes, particularly for priority setting and recommendation of the substance for inclusion in Annex XIV.

Step 10 – Inform MSC about the start of commenting

The MSC-Secretariat (MSC-S) informs the MSC about the start of the public consultation. This is to make the MSC aware of the proposals for identification of substances as SVHCs, which may be referred to this committee.

Step 11: Publish comments on ECHA website (SVHC team, D2)

Inform MSC of the comments received

After the close of the public consultation the comments will be published on the ECHA website. The MSC-S will inform MSC that comments have been received in the public

consultation. This is to make the MSC aware of the substance(s), which will need to be referred to the MSC, and allow sufficient time for the MSC to prepare for the SVHC identification process.

Step 12 – Ensure preparation of support document and responses to comments

In cases where the Annex XV SVHC dossier is prepared by an MSCA, the case responsible extracts the Proposal and Justification (Part I) from the Annex XV report and gives it the format of the draft Support Document (SD). This SD is then made available to the DS. Once comments have been received, the case responsible gathers them in a Response to Comments (RCOM) table and makes this available to the DS. The case responsible requires the DS to prepare responses to the comments received and to take them into account when revising the SD. The case responsible retrieves from the DS the finalised RCOM table and SD.

Step 13 – Prepare support document and responses to comments

In cases where the Annex XV SVHC dossier is prepared by ECHA, the case responsible prepares responses to the comments received and reviews part I (Proposal and Justification) of the Annex XV SVHC report, taking into account the comments received. The SVHC-PC reviews RCOMs and SDs to ensure consistency between the different ECHA dossiers. Legal Affairs Unit may be requested to provide legal support.

Stage 4: MSC process

This stage is to ensure that the Annex XV SVHC dossier is referred to the MSC and that MSC is sufficiently supported to seek unanimous agreement. In cases where no unanimous agreement is reached, the MSC-S prepares the MSC opinion, which is referred to the European Commission. This stage only applies when comments received are relevant for the identification of the proposed SVHC and trigger MSC involvement. The MSC Chairman decides in consultation with case responsible and process owner, whether to refer an Annex XV proposal to the MSC and how to address it for MSC agreement seeking, based on the relevance of the comments received for the identification of the substance as an SVHC. If no comments relevant for the identification have been received, the process proceeds directly to stage 5. WIN-0031 applies for this stage.

Step 14 – Referral to the MSC for seeking unanimous agreement

If comments, relevant for the identification of the substance as SVHC have been received, the MSC-S refers the proposal to the MSC to seek unanimous agreement. The MSC-S provides the MSC with the original proposal, the comments received during public consultation together with the responses from the DS, the draft SD (as amended if relevant by the DS) and a draft of the possible agreement. The MSC-S supports the MSC during the agreement seeking process.

Step 15 – Prepare and handle MSC opinion

In cases where the MSC cannot reach unanimous agreement on the proposal for identification of the substance as an SVHC, the MSC-S prepares an opinion document, based on the majority view(s) of the MSC, as given in the respective MSC meeting and/or written

procedure. This opinion document add the minority position(s) of disagreeing Members should provide sufficient information to allow the European Commission to come to an informed decision on an SVHC proposal.

Step 16 – Referral of an opinion to the Commission

The Deputy Executive Director, subject to delegation by the Executive Director (ED/58/2018), refers the proposal together with the MSC opinion, minority position(s) of disagreeing members, the comments received during public consultation including the responses of the DS, as well as the support document and the draft agreement brought for the MSC vote to the European Commission. The final decision on identification of the substance is then taken in accordance with the procedure referred to in Article 133(3).

Stage 5: Follow-up process

This stage ensures a correct update of the Candidate List for substances identified as SVHCs. In any case, the dossier submitter is informed about the outcome of the process. For this stage, see WIN-0073.

Step 17 – Prepare decision for the inclusion of the substance in the Candidate List

In cases where no relevant comments have been received (Art. 59(6)) or the substance has been identified as an SVHC, either through unanimous agreement of the MSC (according to Article 59(8)) or through the Commission procedure referred to in Article 133(3) (according to Article 59(9)), the SVHC-PC prepares the decision to include the substance(s) on the Candidate List.

Step 18 – Finalise and sign decision to include substances in the Candidate List

Legal Affairs Unit, Head of Unit(HoU), Director and the Executive Office (HoU) revise the decision to ensure legal correctness and consistency. The Deputy Executive Director, subject to delegation by the Executive Director, signs the decision to include substances on the Candidate List.

Step 19 – Prepare and publish the update of the Candidate List

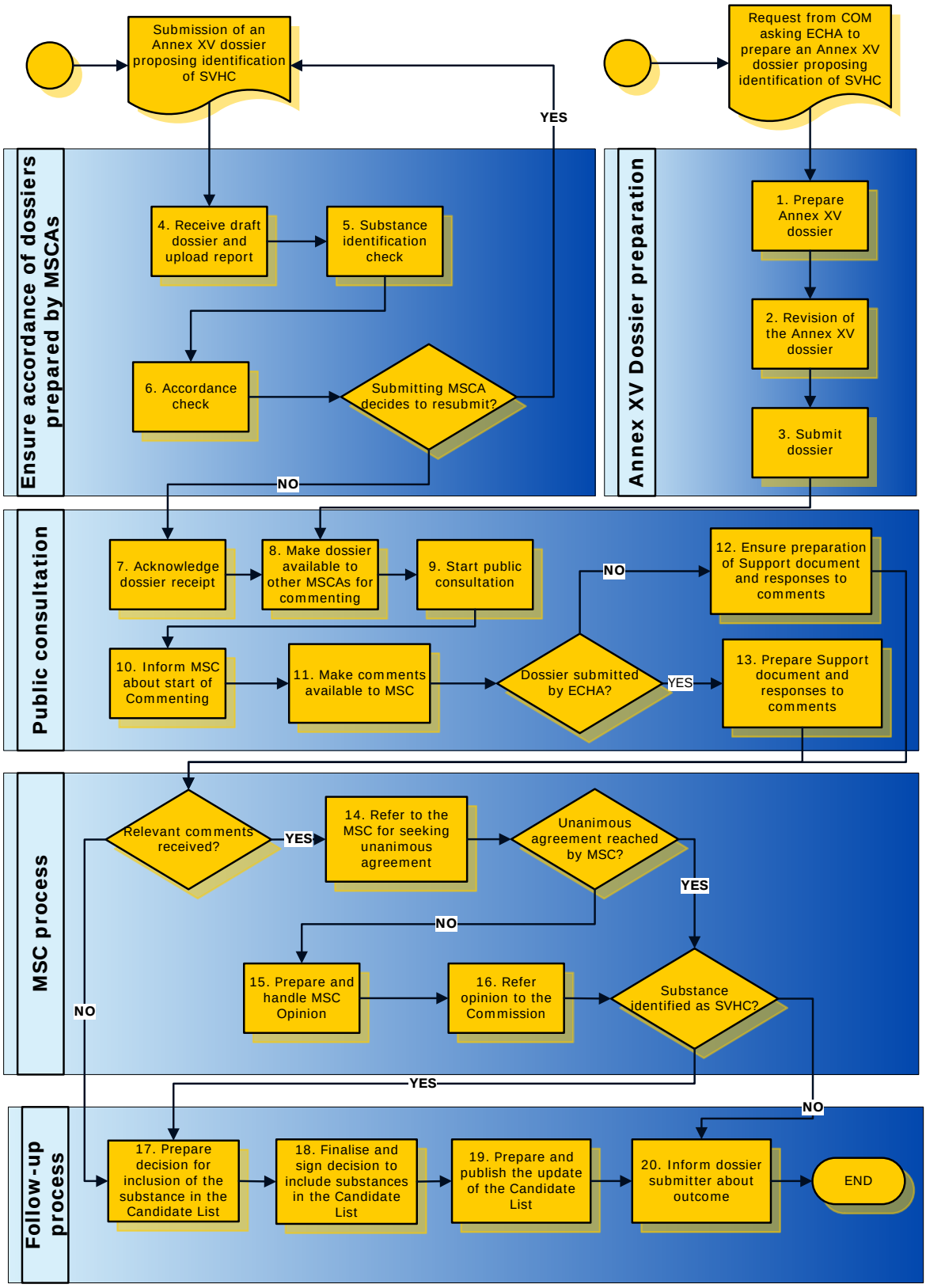
In cases where no relevant comments have been received or the substance has been identified as SVHC through the European Commission procedure referred to in Article 133(3), the case responsible prepares RCOM and SD for publication. In cases where the substance is identified as SVHC through unanimous agreement of the MSC, the MSC-S prepares the MSC agreement, RCOM and SD for publication.

The SVHC-PC prepares the update of the Candidate List, and ensures its publication on ECHA's website.

Step 20 – Inform about the outcome of the SVHC process

The SVHC-PC together with relevant colleagues and the press team, prepares a press release to inform about the outcome of the SVHC identification process.

4. Flowchart


Submission of an Annex XV dossier proposing identification of SVHC
Request from COM asking ECHA to prepare an Annex XV dossier proposing identification of SVHC
YES
Ensure accordance of dossiers prepared by MSCAs
4. Receive draft dossier and upload report
5. Substance identification check
6. Accordance check
Submitting MSCA decides to resubmit?
NO
Annex XV Dossier preparation
1. Prepare Annex XV dossier
2. Revision of the Annex XV dossier
3. Submit dossier
Public consultation
7. Acknowledge dossier receipt
8. Make dossier available to other MSCAs for commenting
9. Start public consultation
10. Inform MSC about start of Commenting
11. Make comments available to MSC
Dossier submitted by ECHA?
NO
YES
12. Ensure preparation of Support document and responses to comments
13. Prepare Support document and responses to comments
MSC process
Relevant comments received?
YES
NO
14. Refer to the MSC for seeking unanimous agreement
Unanimous agreement reached by MSC?
YES
NO
15. Prepare and handle MSC Opinion
16. Refer opinion to the Commission
Substance identified as SVHC?
YES
NO
Follow-up process
17. Prepare decision for inclusion of the substance in the Candidate List
18. Finalise and sign decision to include substances in the Candidate List
19. Prepare and publish the update of the Candidate List
20. Inform dossier submitter about outcome
END

5. Definitions

Term or abbreviation	Definition
Annex XV dossier for SVHC	Annex XV report
Annex XV report	A report covering the information set out in the Annex XV of REACH.
COM	European Commission
DEG	Dossier Expert Group
DS	Dossier submitter
EC	European Communities
HoU	Head of Unit
MSC	Member State Committee
MSC-S	Member State Committee Secretariat
MSCA	Member State Competent Authority
RCOM	Response to comments
SD	Support Document (for identifying a substance as SVHC)
SID	Substance identification
SID unit	Unit responsible for Substance identification and Data Sharing
SVHC	Substance of very high concern
SVHC-AST	SVHC Assistant
SVHC-PC	SVHC Process Coordinator

6. Records

Record name	Security level	Comments
SVHC_AXVPrep_COM	Internal	Request from the European Commission asking ECHA to prepare an Annex XV dossier proposing the identification of a SVHC
N/A	Internal	Communication exchanged with the Commission on the request to prepare an Annex XV dossier
SVHC_AXVREP	Public	Annex XV dossier (including the Report and annexes) proposing identification of SVHC prepared by MSCAs or ECHA
SVHC_ACCHECK_LTR	Internal	Accordance check letter informing the DS whether the submitted Annex XV dossier is in accordance with Annex XV and contains sufficient information to conclude on the identification of the substance as SVHC
SVHC_Receipt	Internal	Letter, acknowledging the receipt of a final dossier, proposing the identification of a substance as SVHC, sent to Dossier Submitter.
SVHC_INVITMSCA	Internal	Invitation to MSCA' for submitting comments
SVHC_MSC_PublConsultStart	Internal	Note sent to the MSC informing them about the start of the public consultation on the Annex XV dossier
SVHC_MSC_NoCommentsNote/ CommentsReceivedNote	Internal	Note sent to MSC concerning comments or no comments received during the public consultation
SVHC_COMMENT	Internal	Comments on Annex XV SVHC dossiers received from consulted interested parties and the MSCAs (via the ECHA public consultation)
SVHC_RCOM	Public	(Draft) Table of comments on Annex XV SVHC dossiers received from consulted interested parties and the MSCAs (via the ECHA public consultation), including the replies from DS

Record name	Security level	Comments
SVHC_SUPDOC	Public	(Draft) Support document for the identification of the SVHC
SVHC_MSC_Agreement	Internal/Public	(Draft) MSC Agreement
SVHC_MSC_Opinion	Public	(Draft/Final) MSC Majority Opinion and minority views (only in case MSC fails to reach a unanimous agreement on the identification of the SVHC)
SVHC_MSC_Opinion_ReferralLetter	Internal	Referral of the MSC Opinion to the Commission
SVHC_DECISION	Public	Decision to include a substance on the Candidate List (for substances identified as SVHC)

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
EC No 1272/2008	Regulation (EC) No 1272/2008 on classification, labelling and packaging (CLP-Regulation)
EC No 45/2001	Regulation (EC) 45/2001 of the European Parliament and of the Council of 18 December 2000 on the protection of individuals with regard to the processing of personal data by the Community institutions and bodies and on the free movement of such data
ED/58/2018	Delegation of signature power to sign decisions and communications to the Deputy Executive Director
ED/32/2010	Tasks, duties and powers of the Data Protection Officer and the Data Controllers
MB/07/2014	Review of the policy for Managing potential Conflicts of Interests
N/A	Guidance on chemical safety report (section 11 on how to perform a PBT/vPvB assessment)
N/A	Guidance document for the preparation of an Annex XV dossier on the identification of SVHCs

8. Annexes

N/A