

PRO-0088.01 Public 20/03/2024

# Listing new substances under the Stockholm Convention on Persistent Organic Pollutants

### 1. Purpose

This procedure describes the identification of potential persistent organic pollutant (POP) substances by the European Union (EU) for the listing under the Stockholm Convention (SC) (UN XXVII-15) as set in Articles 3 and 8 of Regulation (EU) 2019/1021 of the European Parliament and of the Council on persistent organic pollutants (hereafter the POPs Regulation). It includes:

- the preparatory steps and legislative procedures in the EU preceding the submission of an EU proposal to the SC;
- the organisation of stakeholder consultations in the EU during the various steps of the identification process;
- the drafting or co-drafting of the scientific information in accordance with Annex D to the Convention that is intended to be included in an EU proposal;
- the drafting or co-drafting of the risk profile and the risk management evaluation in accordance with Article 8 of the Convention;
- the listing of a new substance in the Annexes to the Convention and to the POPs Regulation.

This procedure is designed to ensure that:

- deadlines defined by the POPs Regulation and under the SC, in particular as regards the review by the POPs Review Committee (POPRC), are respected;
- the proposal, the risk profile and risk management evaluation contain sufficient and valid information to allow the POPRC to conclude whether the substance is a persistent organic pollutant and whether to recommend its listing in the Convention;
- the communication and co-operation between the competent authorities of the Member States (MSCAs), stakeholders, ECHA, the European Commission and the POPRC is defined.

### 2. Scope

This procedure starts after a notice, stating that a proposal for the listing of a substance (or group of substances) will be prepared by the European Commission, has been published in the ECHA website. The procedure finishes either with the listing of the substance(s) in the Annexes to the Convention and in the Annexes to the POPs Regulation, or with a decision during any of the stages of the listing process that the proposal should not proceed and should be set aside.



PRO-0088.01 Public

20/03/2024

Listing new substances under the Stockholm Convention on Persistent Organic Pollutants

### 3. Description

### 3.1. General

Article 8 of the Convention defines the process for the listing of substances in Annexes A, B and C. The EU, as any other party to the Stockholm Convention, can submit a proposal for listing a substance as POP. The European Commission represents the EU in the work under the SC. The European Commission is assisted by ECHA, which includes the drafting of a proposal for the listing of a substance (Stage 2 below). In accordance with Article 3 of the POPs Regulation, MSCAs may also draft a proposal for POP listing on behalf of the European Commission. The EU proposals are submitted to the Secretariat of the Convention by the European Commission following a Council decision to that effect (Stage 4). The roles of the European Commission, ECHA and MSCAs during the listing process are set out in Articles 3, 8 and 15 of the POPs Regulation.

After a proposal has been submitted to the SC, the POPRC reviews the proposal. The review process consists of three phases, the screening phase (Stage 5), the risk profile (Stage 6 and 7) and the risk management evaluation (Stage 8 and 9). Once the review process is completed, the POPRC recommends the listing of the substance in Annexes A, B and/or C to the Conference of the Parties (COP). The COP decides on the inclusion of the substance in the Annex(es) of the Convention and on potential derogations (Stage 10). Once a substance is listed under the SC, the European Commission can list the substance in the POPs Regulation by adopting a delegated act to amend Annex I, II and/or III of the Regulation (Stage 11).

The identification process in the EU includes three consultations of stakeholders for EU proposals (Stage 3, Steps 11.4 and 12.4), and two for non-EU proposals (Steps 11.4 and 12.4). The respective stakeholder consultations last 8 weeks.

The stages are presented in the flow-chart in section 4.

### 3.2. Detailed description

# Stage 1: Start of the preparation of an EU proposal to list a substance as a POP

The preparation of an EU proposal starts when there has been an agreement among the European Commission and the MSCAs in the 'Competent Authorities expert group for Regulation (EU) 2019/1021 on Persistent Organic Pollutants' (hereafter the POPs expert group)<sup>1</sup> that a substance may fulfil the Annex D screening criteria of the Convention. This stage of the procedure aims to ensure that stakeholders are aware of the European Commission's plans to prepare an EU proposal for a substance (or a group of substances).

### Step 1: Discussion in the meeting of the POPs expert group

Substances which have been identified as potential POPs are discussed in the meetings of the POPs expert group. Agreement is sought among the Commission and the MSCA to proceed with the preparation of an EU proposal for a substance which is likely to meet the

<sup>&</sup>lt;sup>1</sup> https://ec.europa.eu/transparency/expert-groups-register/screen/expert-groups/consult?do=groupDetail.groupDetail&groupID=1656&Lang=EN



PRO-0088.01 Public

20/03/2024

Listing new substances under the Stockholm Convention on Persistent Organic Pollutants

Annex D criteria of the Convention, with the aim to subsequently submit the proposal to the SC.

### Step 2: Publish a notice that an EU proposal will be prepared

Once there has been an agreement to proceed with the preparation of an EU proposal for a substance(s) ECHA publishes a notice in its website in accordance with Article 8 (d) of the POPs Regulation. The notice entails that the substance(s) is added to the "List of substances proposed as POPs" in the ECHA website<sup>2</sup> and this disseminates information that the substance is under POP assessment in the "Substance Infocard".

Notices for non- EU proposals are published in the ECHA website when the submission of a non-EU proposal is published in the SC website. The same dissemination principles as for EU proposals apply.

### Stage 2: Preparation of an EU proposal

This stage is to ensure that the scientific information contained in the proposal is prepared in accordance with the criteria in Annex D to the Convention. The proposal should contain all the relevant information needed to allow the POPRC to conclude on the fulfilment of the Annex D criteria for the substance. The screening comprises the following four criteria: persistence, bioaccumulation, potential for long-range environmental transport and adverse effects.

#### Step 3: Prepare the draft proposal

The European Commission can request ECHA to prepare the scientific information in accordance with Annex D of the Convention for an EU proposal. MSCAs can also draft the scientific information of a proposal that may subsequently be submitted by the European Commission (following a positive decision by the Council).

The proposal shall contain the information specified in Annex D of the Convention to allow the POPRC to conclude on the fulfilment of the Annex D criteria for the substance. This comprises information on substance identity, persistence, bioaccumulation, potential for long-range environmental transport and adverse effects (human health and environment). The guidance "Handbook for effective participation in the POPs Review Committee under the Stockholm Convention" (UNEP/POPS/POPRC-20180206) explains the POPs review process and can be consulted when drafting the proposal.

The most relevant information in accordance with Annex D should be summarized in approximately 20 pages, excluding the references. The Secretariat of the SC prepares the translation of the proposal into the official (working) languages of the UN (Arabic, Chinese, English, French, Russian and Spanish). The proposal may contain supporting information compiled in an information document ("INF document"). The information document will not be translated.

### **Step 4: Discussion in ECHA's PBT Expert Group**

The draft proposal may be brought for discussion to ECHA's PBT Expert Group in order to get informal scientific advice about the potential PBT /vPvB and long-range environmental transport potential of the substance being proposed as a POP.

<sup>&</sup>lt;sup>2</sup> <a href="https://echa.europa.eu/list-of-substances-proposed-as-pops">https://echa.europa.eu/list-of-substances-proposed-as-pops</a>



PRO-0088.01
Public
20/03/2024

Listing new substances under the Stockholm Convention on Persistent Organic Pollutants

### Stage 3: Consultation of interested parties in the EU on the proposal

An EU-wide consultation is organised, and the comments are published in the ECHA website. The aim of this stage is to provide an opportunity for stakeholders to provide input on the proposal under preparation. The comments received may be used for the revision of the information contained in the draft proposal in accordance with Annex D.

### Step 5. Launch a consultation of interested parties in the EU

A consultation on the draft proposal is launched by ECHA to invite all interested parties to provide comments and information. The consultation runs for eight weeks.

#### **Step 6: Publish comments**

After the closing of the consultation of interested parties, the comments received are published in the ECHA website.

# Stage 4: Decision of the Council of the European Union on the submission of the EU proposal to the Stockholm Convention

This stage concerns the submission of a European Commission proposal for a Council Decision on the submission of an EU proposal for the listing of a substance under the SC, and in the case that the decision is adopted by the Council of the European Union, the subsequent submission of the EU proposal to the Secretariat of the SC.

### Step 7: Discussion in the meeting of the POPs expert group

The draft scientific information in accordance with Annex D is presented and discussed in the meeting of the POPs expert group. Agreement is sought among the MSCAs on whether the Annex D criteria is likely to be fulfilled and whether the EU should submit the proposal to the SC.

# Step 8: Adoption of a European Commission proposal for a Council Decision on the submission, on behalf of the EU, of a proposal for the listing of a substance in the Annex(es) to the Convention

After the EU proposal is finalised, DG ENV initiates an inter-service consultation on a Commission proposal for a Council decision on the submission of a proposal for the listing of additional substance(s) in Annex A, B and/or C to the Convention. The interservice consultation lasts for two weeks. After having addressed the comments of the other services, the European Commission may proceed to adopt formally the proposal for a Council Decision. The adopted Commission proposal is published in the Official Journal of the European Union and submitted to the Council of the European Union.

# Step 9: Council decision on the submission of an EU proposal for listing a substance under the SC

Once submitted, the Commission proposal remains with the Council of the European Union for consideration. It is discussed in the Working Party for the Environment. After agreement a Council Decision on the submission, on behalf of the EU, of a proposal for the listing of substance(s) in the Annex(es) of the Convention is formally adopted. The decision gives the European Commission the mandate to submit a proposal for the listing of substance(s) to the SC on behalf of the EU. The adopted Council decision is published in the Official Journal of the European Union and in the ECHA website.



PRO-0088.01
Public
20/03/2024

Listing new substances under the Stockholm Convention on Persistent Organic Pollutants

## **Step 10: Submission of an EU proposal to the Secretariat of the Stockholm Convention**

Based on the Council Decision, the European Commission submits, on behalf of the EU, the proposal for the listing of a substance in the Annex A, B and/or C to the Convention to the Secretariat of the SC.

### Stage 5: Review of the proposal against the Annex D criteria by POPRC

The POPRC examines the proposal and decides on whether the substance meets the screening criteria specified in Annex D to the Convention and in so doing gives the reason for its decision as part of the report of the meeting. If the POPRC decides that the screening criteria are fulfilled, the proposal moves to the risk profile phase (in accordance with paragraph 4 (a) of Article 8 of the Convention). If the decision is negative, the proposal is set aside (in accordance with paragraph 4 (b) of Article 8). Any Party may resubmit a proposal to the POPRC. The resubmission may include any considerations of the Party, as well as a justification for why these additional considerations should be discussed in the POPRC. If, following this procedure, the POPRC again sets the proposal aside, the Party may challenge the decision of the POPRC, and the COP shall consider the matter at its next session. The COP may decide, based on the screening criteria in Annex D and taking into account the evaluation of the POPRC and any additional information provided by any Party or observer that the proposal should proceed.

The European Commission, supported by ECHA and/or the MSCAs, presents the EU proposal in the POPRC meeting and provides any additional information or clarifications requested during the meeting.

### Stage 6: Preparation of the risk profile

This stage is to further review the proposal by preparing the risk profile in accordance with Annex E to the Convention. The risk profile should contain all the relevant information needed to allow the POPRC to decide whether the substance is likely, as a result of its long-range environmental transport, to lead to significant adverse human health and/or environmental effects such that global action was warranted. In addition, the POPRC takes into account any relevant additional information submitted by Parties and observers for the preparation of the risk profile.

#### Step 11: Prepare the risk profile

After the POPRC has decided that the screening criteria for the proposed substance have been fulfilled, the POPRC establishes an intersessional working group (IWG) to review the proposal further and to prepare a draft risk profile. The IWG collects information specified in Annex E to the Convention from Parties and observers, as well as technical comments throughout the drafting process and by taking those comments into account, the IWG completes the risk profile. In the IWG, the drafter of the risk profile is normally the submitter of the proposal. For EU proposals, ECHA and/or MSCA may draft a risk profile on behalf of the European Commission.

The risk profile shall contain the information specified in Annex E to the Convention. This comprises information about sources (production data, uses and releases), about hazard



PRO-0088.01 Public 20/03/2024

Listing new substances under the Stockholm Convention on Persistent Organic Pollutants

assessment for ecological and human health endpoints, environmental fate data (persistence, environmental transport and bioaccumulation), monitoring data, exposure information (in local areas and as a result of long-range transport), hazard classification and labelling, as well as information about national and international risk assessments for the substance and the status of the substance under international conventions. The template and POPRC document "Risk profile outline", which specifies some information requirements for various sections, shall be used to write risk the (UNEP/POPS/POPRC.1/10/Annex IV). The guidance "Handbook for effective participation in the POPs Review Committee under the Stockholm Convention" (UNEP/POPS/POPRC-20180206) should be consulted when drafting the risk profile.

The most relevant information in the risk profile should be summarized in approximately 20 pages, excluding the references. Supporting information, example data tables and details of studies, can be presented in an information document. The information document will not be translated.

The POPRC agrees on a workplan for the intersessional period between the yearly POPRC meetings, which defines the activities and related deadlines for completing the risk profile. The main activities can be grouped into four sub-steps which are described below.

### Step 11.1 - Prepare the 1st draft of the risk profile

The POPRC invites Parties and observers to submit to the Secretariat information specified in Annex E for the first draft of the risk profile see "Additional explanatory notes for Annex E information submission Form" (UNEP/POPS/POPRC.5/10/Annex VI). After the information specified in Annex E to the Convention has been provided by Parties and observers, the drafter analyses the information submitted and incorporates the relevant information into the risk profile. The drafter collects other relevant information for the risk profile and completes the first draft, which is then submitted to the Secretariat of the SC according to the deadline in the intersessional work plan.

# Step 11.2 – Prepare the 2<sup>nd</sup> draft of the risk profile and the responses to comments

The members of the IWG may submit comments on the first draft. The drafter reviews the comments, revises the dossier, and completes the second draft of the risk profile, as well as a compilation of responses to those comments (RCOM). These documents are then submitted to the Secretariat of the SC according to the deadline in the workplan.

#### Step 11.3: Call for information by the Secretariat of the SC

The Secretariat of the SC invites Parties and observers to the SC to review and submit comments on the 2nd draft of the risk profile. The commenting period usually lasts about six weeks.

#### Step 11.4: Launch a consultation of interested parties in the EU

Simultaneously to the invitation by the Secretariat of the SC to review and submit comments on the 2<sup>nd</sup> draft of the risk profile, ECHA launches a consultation of interested parties in the EU on the same draft (for both EU and non-EU proposals), inviting all interested parties to provide comments and information.

The aim of the consultation is to gather stakeholder input about the risk profile and any interest that EU stakeholders may have in the context of the potential listing of the



PRO-0088.01 Public 20/03/2024

Listing new substances under the Stockholm Convention on Persistent Organic Pollutants

substance in the Convention. That input will inform the EU internal discussion on the listing. The comments received may also be used for the revision of the risk profile.

### **Step 11.5: Publish comments**

See step 6.

## Step 11.6 – Prepare the 3<sup>rd</sup> draft of the risk profile and the response to comments

The drafter reviews the comments received during the call for information (step 11.3), revises the dossier and completes the third draft of the risk profile, as well as a compilation of responses to those comments (RCOM). The 3<sup>rd</sup> draft of the risk profile and the RCOM are then submitted to the SC Secretariat of the SC according to the deadline in the work plan.

# Step 11.7 – Prepare the 4<sup>th</sup> and final draft of the risk profile and the responses to comments

The members of the IWG submit comments on the third draft. The drafter reviews the comments, revises the dossier, and completes the fourth and final draft of the risk profile, as well as a RCOM. The RCOM and the final draft are submitted to the Secretariat of the SC according to the deadline in the working plan. The Secretariat of the SC sends the final dossier for translation. Information in a support document or Appendix will not be translated.

### Stage 7: Review and adoption of the risk profile by the POPRC

The POPRC reviews the draft risk profile prepared by the IWG and adopts a decision on whether the chemical is likely, as a result of its long-range environmental transport, to lead to significant adverse human health and/or environmental effects such that global action is warranted in accordance with paragraph 7 (a) of Article 8 of the Convention. If the risk profile is adopted, the proposal proceeds to the risk management evaluation stage. However, the POPRC may decide that the proposal should not proceed and sets the proposal aside in accordance with paragraph 7 (b) of Article 8 of the Convention. If the proposal is set aside, a Party may request the COP to consider instructing the POPRC to invite additional information from the proposing Party and other Parties during a period not to exceed one year. After that period and on the basis of any information received, the POPRC shall reconsider the proposal. If, following this procedure, the POPRC again sets the proposal aside, the Party may challenge the decision of the POPRC and the COP shall consider the matter at its next meeting. The COP may decide, based on the risk profile and taking into account the evaluation of the POPRC and any additional information provided by any Party or observer that the proposal shall proceed.

In case of an EU proposal, an expert from the European Commission, supported by ECHA and/or MSCAs, presents and defends the risk profile on the substance(s) in the POPRC meeting.



Public 20/03/2024

PRO-0088.01

Listing new substances under the Stockholm Convention on Persistent Organic Pollutants

### Stage 8: Preparation of the risk management evaluation (RME)

This stage is to prepare the risk management evaluation in accordance with Annex F of the Convention. The proposal should contain all the relevant information needed to allow the POPRC to decide on a recommendation whether the chemical should be considered by the COP for listing in the Annex A, B and/or C to the Convention.

#### Step 12: Prepare the RME

After adoption of the risk profile, the POPRC prepares a risk management evaluation that includes an analysis of possible control measures for the chemical. The POPRC establishes an IWG and agrees on a workplan for the intersessional period between the yearly POPRC meetings to complete the draft RME. The Secretariat collects information specified in Annex F from Parties and observers, as well as technical comments received throughout the drafting process and makes everything available to the IWG, so that it is taken into account when drafting the RME.

In the IWG, the drafter of the RME is normally the submitter of the proposal. For an EU ECHA and/or MSCA may draft the risk management evaluation on behalf of the European Commission.

The RME shall contain the information specified in Annex F of the Convention. This comprises information about efficacy and efficiency of possible risk reduction control measures, alternatives (products and processes), societal impacts of implementing control measures, waste and disposal implications, access to information and public education, status of control and monitoring capacity and national and regional control actions and risk management. The template and POPRC document "Revised risk management evaluation outline (UNEP/POPS/POPRC.3/20/Annex II) outlines the sections of the RME. The guidance "Handbook for effective participation in the POPs Review Committee under the Stockholm Convention" (UNEP/POPS/POPRC-20180206) should be consulted when drafting the risk management evaluation.

The most relevant information in the RME should be summarised in approximately 20 pages, excluding the references. Supporting information can be presented in an information document, which will not be translated.

The POPRC agrees on a workplan for the intersessional period between the yearly POPRC meetings, which defines the activities and related deadlines for completing the RME. The main activities can be grouped into four sub-steps below.

### Step 12.1- Prepare the 1st draft of the RME

After the adoption of the risk profile in a POPRC meeting, the POPRC invites Parties and observers to submit to the Secretariat information specified in Annex F for the first draft of the RME, see "Additional explanatory notes for Annex F information submission Form" (UNEP/POPS/POPRC.5/10/Annex VII). After the information specified in Annex F has been provided, the drafter analyses that information and incorporates the relevant information into the draft RME. The drafter collects other relevant information for the RME and completes the first draft of the RME, which is submitted to the Secretariat of the SC according to the deadline in the intersessional work plan.

### Step 12.2- Prepare the 2<sup>nd</sup> draft of the RME and the responses to comments

The members of the working group may submit comments on the first draft. The drafter reviews the comments, revises the dossier and completes the second draft of the RME, as



PRO-0088.01
Public
20/03/2024

Listing new substances under the Stockholm Convention on Persistent Organic Pollutants

well as a RCOM. The 2<sup>nd</sup> draft and the RCOM are then submitted to the Secretariat of the SC according to the deadline in the work plan.

### Step 12.3: Call for information by the Secretariat of the SC

The Secretariat of the SC invites Parties and observers to the SC to review and submit comments on the 2nd draft of the RME. The commenting period usually lasts about six weeks.

### Step 12.4: Launch the consultation of interested parties in the EU

See step 11.4. Note that for step 12.4 the relevant file is the RME.

**Step 12.5: Publish comments** 

See step 6.

### Step 12.6- Prepare the 3<sup>rd</sup> draft of the RME and the responses to comments

The drafter reviews the comments received during the call for information (step 12.3), revises the dossier and completes the third draft of the RME, as well as a RCOM. The  $3^{\rm rd}$  draft of the RME and the RCOM are submitted to the SC Secretariat and the IWG according to the deadline in the work plan.

### Step 12.7 - Prepare the 4th draft of the RME and the responses to comments

The members of the IWG may submit comments on the  $3^{rd}$  draft. The drafter reviews the comments, revises the dossier and completes the  $4^{th}$  and final draft of the RME, as well as a RCOM. The  $4^{th}$  draft of the RME and the RCOM are then submitted to the Secretariat of the SC according to the deadline in the work plan. The Secretariat of the SC sends the final dossier for translation. Information in a support document or Appendix will not be translated.

### Stage 9: Review and adoption of the RME by the POPRC

The POPRC recommends based on the risk profile and the RME whether the chemical should be considered by the Conference of the Parties for listing in Annexes A, B and/or C, in accordance with paragraph 9 of Article 8 of the Convention.

In case of an EU proposal, the expert from the European Commission, supported by ECHA and/or MSCAs, presents and defends the RME on that substance in the POPRC meeting.

#### Stage 10: Listing of the substance under the Stockholm Convention.

# Step 13: Decision by the COP on the listing of a new substance and the amendment of the Annexes to the Convention

The COP, taking due account of the recommendations of the POPRC, including any scientific uncertainty, shall decide, in a precautionary manner, whether to list the proposed chemical, and specify its related control measures, in Annexes A, B and/or C of the Convention.

The position to be taken on behalf of the EU at the COP meeting as regards an amendment of the Annex(es) to the Convention to list a new substance is established by means of a Council decision. That Council decision is based on a European Commission proposal to that



PRO-0088.01
Public
20/03/2024

Listing new substances under the Stockholm Convention on Persistent Organic Pollutants

effect. Before adoption of such proposal, the responsible European Commission service consults the POPs expert group, where the MSCAs and stakeholders are represented.

In its decisions, the COP adopts amendments to Annexes A, B and/or C to list new chemicals that have been found to meet the criteria under the Convention. The chemicals are listed for elimination without any exemptions, or with specific exemptions (Annex A), or for restriction with acceptable purposes or specific exemptions (Annex B). Additionally, or alternatively, a chemical can also be listed in Annex C to reduce or eliminate unintentional production.

The Secretariat of the SC publishes a depositary notification about the adoption of the amendments to the Annexes. The amendments enter into force one year after the communication by the depository of the adoption of the amendment for all Parties, unless a Party is not able to accept the amendments and has submitted a notification in accordance with paragraphs 3 (b) of Article 22 of the Convention, or has made a declaration with respect to any amendment to those Annexes in accordance with paragraph 4 of Article 22 and paragraph 4 of Article 25. That declaration reserves the right of a Party to accept each individual amendment, which would enter into force for the Party only after the deposit of its instrument of ratification, acceptance, approval or accession of such amendment.

## Step 14: Update the regulatory status of the substance that has been listed as a POP

ECHA updates the information in the "list of substances proposed as POPs" in the ECHA website to reflect the listing of the substance in the Convention. This disseminates information that the substance is a recognised POP in the "Substance Infocard.

### Stage 11: Listing of the substance in the POPs Regulation

Once the COP decides to amend the Annex(es) to the Convention to list new substances, the decision needs to be transposed in EU law by amending Annex I, II and/or III to the POPs Regulation. These amendments are done by delegated acts on the basis that the EU has supported the change concerned by means of a Council decision. The adoption of such a delegated act requires the European Commission to consult the representatives of the MSCAs in the POPs expert group. Relevant stakeholders are present in the expert group as observers. In addition, the European Commission organises a four-week public consultation on the draft delegated acts.

In the case that a listing of a new substance in the Annex(es) to the Convention is not accepted by the EU, a written notification of non-acceptance is sent to the depositary within one year from the date of communication by the depositary of the adoption of the amendment to the Annex(es) pursuant to Article 22 paragraph 3 (b) of the Convention, and in line with the declaration of competence submitted at the moment of ratification by the EU in accordance with Article 25 paragraph 3 of the Convention. A notification of non-acceptance can be withdrawn at any time and the annex shall thereupon enter into force.

### Step 15: Prepare the draft delegated act for amending the POPs Regulation

The European Commission prepares the draft delegated act based on the listing of the substance in the Annex(es) to the Convention, and by taking into account the information contained in the risk profile and the risk management evaluation adopted under the SC. In addition, the European Commission considers all information that is available at EU level, including any potential existing authorisations or restrictions of the substance according to



PRO-0088.01 Public 20/03/2024

Listing new substances under the Stockholm Convention on Persistent Organic Pollutants

the REACH Regulation (EC No 1907/2006) or any other pieces of legislation that may apply to that substance.

#### Step 16: Consult the POPs expert group

When preparing the delegated act, the European Commission consults the representatives of the MSCAs in the POPs expert group. Relevant stakeholders are present in the expert group as observers. In addition, the draft final text of the delegated act is presented and discussed in a meeting of the POPs expert group.

### Step 17: Launch a public consultation on the delegated act

The European Commission launches a four-week public consultation on the draft delegated act, during which citizens and stakeholders can provide feed-back. That feedback is considered by the European Commission and may result in modifications of the draft delegated act.

### Step 18. Adopt the delegated act

The European Commission adopts the Delegated Regulation amending Annex I, II and/or III to the POPs Regulation. Adopted acts generally contain an 'explanatory memorandum' summarising the reasons for measures contained in the act and the feedback received and how it was used. After the adoption by the European Commission, the Delegated Regulation is submitted to the European Parliament and to the Council of the European Union so that both institutions can exercise their right of objection, which lasts two months, with a possible extension of two months at the initiative of any of these institutions. If there are no objections, the Delegated Regulation is published in the Official Journal of the European Union and normally enters into force on the 20<sup>th</sup> day after its publication. In some cases, there can be a deferral in the entry into application of some of the provisions in the Delegated Regulation, for example to allow for an easy adaptation from duty holders.

# Step 19. Update the regulatory status of the substance that has been listed as a POP

ECHA updates the information in the "List of substances proposed as POPs" in the ECHA website to reflect the listing of the substance in the POPs Regulation. The substance is then also included in the "List of Substances subject to the POPs Regulation".

Document code: Security level:

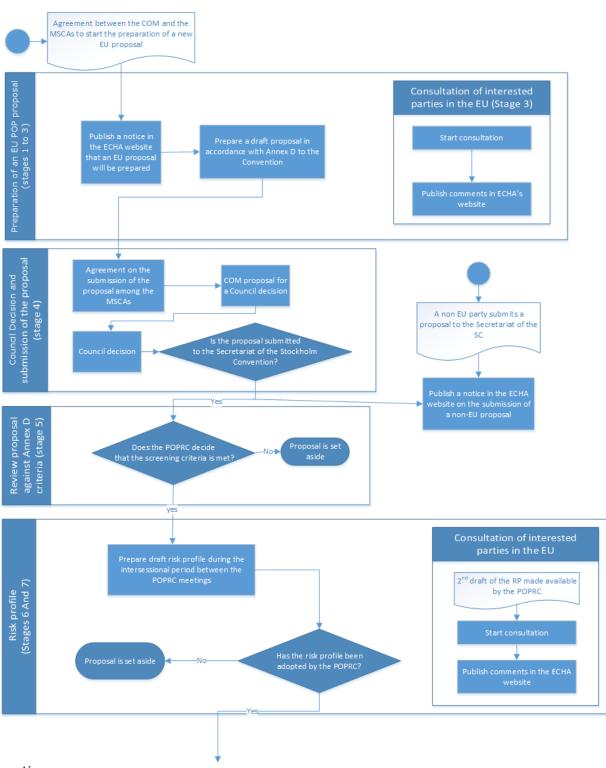
Public 20/03/2024

PRO-0088.01

Listing new substances under the Stockholm Convention on Persistent Organic Pollutants

Effective date:

### 4. Flowchart





Document code: Security level:

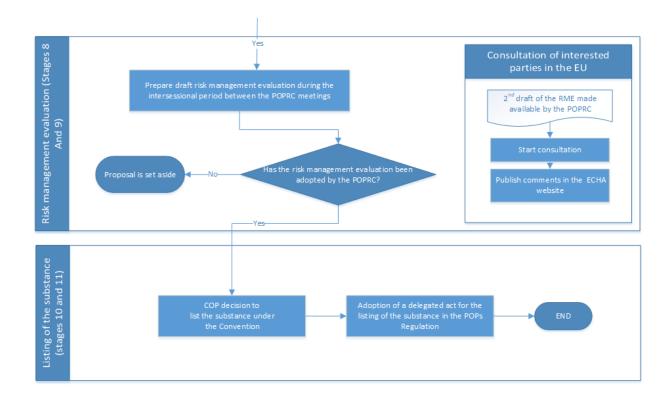
Effective date:

Public

20/03/2024

PRO-0088.01

Listing new substances under the Stockholm Convention on Persistent Organic Pollutants





PRO-0088.01 Public 20/03/2024

Listing new substances under the Stockholm Convention on Persistent Organic Pollutants

### 5. Definitions

Term or abbreviation	Definition
Proposal	Scientific dossier prepared in accordance with the Annex D to the Convention
СОМ	European Commission
DG ENV	Directorate-General for Environment
СОР	Conference of the Parties to the Stockholm Convention
MSCA	Competent Authority of the Member State
POPs expert group	Competent Authorities expert group for Regulation (EU) 2019/1021 on Persistent Organic Pollutants (POPs)
SC	Stockholm Convention
POP	Persistent Organic Pollutant
POPRC	Persistent Organic Pollutant Review Committee
RP	Risk profile
RME	Risk management evaluation
IWG	Intersessional working group
PBT/vPvB	Persistent, Bioaccumulative and Toxic / very Persistent and very Bioaccumulative
RCOM	Responses to comments

### 6. Records

N/A

### 7. References

Associated document code	Document name
POPs Regulation EU No 2019/1021	Regulation (EU) 2019/1021 of the European Parliament and of the Council of 20 June 2019 on persistent organic pollutants
,	https://eur-lex.europa.eu/legal-content/EN/TXT/HTML/?uri=CELEX:02019R1021-20200704#tocId2



Public 20/03/2024

PRO-0088.01

Listing new substances under the Stockholm Convention on Persistent Organic Pollutants

Associated document code	Document name
REACH Regulation EC No 1907/2006	Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH)
UN XXVII-15	Stockholm Convention on Persistent Organic Pollutants <a href="http://chm.pops.int/TheConvention/Overview/TextoftheConvention/tabid/22">http://chm.pops.int/TheConvention/Overview/TextoftheConvention/tabid/22</a> 32/Default.aspx
n/a	Handbook for effective participation in the POPs Review Committee under the Stockholm Convention 2009. <a href="http://chm.pops.int/TheConvention/POPsReviewCommittee/OverviewandMandate/tabid/2806/Default.aspx">http://chm.pops.int/TheConvention/POPsReviewCommittee/OverviewandMandate/tabid/2806/Default.aspx</a>
UNEP/POPS/POPRC.1/10/Ann ex IV	Risk profile outline <a href="http://chm.pops.int/TheConvention/POPsReviewCommittee/OverviewandMandate/tabid/2806/Default.aspx">http://chm.pops.int/TheConvention/POPsReviewCommittee/OverviewandMandate/tabid/2806/Default.aspx</a>
UNEP/POPS/POPRC.3/20/Ann ex II	Revised risk management evaluation outline <a href="http://chm.pops.int/TheConvention/POPsReviewCommittee/OverviewandMandate/tabid/2806/Default.aspx">http://chm.pops.int/TheConvention/POPsReviewCommittee/OverviewandMandate/tabid/2806/Default.aspx</a>
UNEP/POPS/POPRC.5/10/Ann ex VI	Additional explanatory notes for Annex E information submission form <a href="http://chm.pops.int/TheConvention/POPsReviewCommittee/OverviewandMandate/tabid/2806/Default.aspx">http://chm.pops.int/TheConvention/POPsReviewCommittee/OverviewandMandate/tabid/2806/Default.aspx</a>
UNEP/POPS/POPRC.5/10/Ann ex VII	Additional explanatory notes for the Annex F information submission form <a href="http://chm.pops.int/TheConvention/POPsReviewCommittee/OverviewandMandate/tabid/2806/Default.aspx">http://chm.pops.int/TheConvention/POPsReviewCommittee/OverviewandMandate/tabid/2806/Default.aspx</a>

### 8. Annexes

N/A