EU POP Regulation Recast: An opportunity to improve POP management in the EU

Executive summary

The European Commission's intention to recast the Persistent Organic Pollutants (POP) Regulation while assigning new tasks to the European Chemicals Agency (ECHA) provides a unique opportunity to improve the EU's approach to the implementation of the Stockholm Convention, in particular the process for nomination of new substances by the EU. There is a need for a clear, scientifically-driven, inclusive process to evaluate potential POP candidates. The European Commission should conduct an in–depth impact assessment prior to submission to the Convention and subsequent global ban.

The Commission must enhance the transparency, justification and predictability of EU processes for managing POP substances, including the interrelationship with REACH.

The American Chamber of Commerce to the European Union (AmCham EU) stresses the need for an open policy debate that takes stock of the experience gained so far and proposes concrete improvement actions.

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AmCham EU speaks for American companies committed to Europe on trade, investment and competitiveness issues. It aims to ensure a growth-orientated business and investment climate in Europe. AmCham EU facilitates the resolution of transatlantic issues that impact business and plays a role in creating better understanding of EU and US positions on business matters. Aggregate US investment in Europe totalled more than €2 trillion in 2016, directly supports more than 4.5 million jobs in Europe, and generates billions of euros annually in income, trade and research and development.

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POSITION PAPER

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Introduction

The Stockholm Convention, ratified by 180 Parties and based on the precautionary principle, is a global treaty that provides a legal framework to eliminate the production, use, import and export of Persistent Organic Pollutants (POPs). It also aims to secure their safe handling, disposal and eliminate or reduce releases.

The European Union has been a Party to the Convention since 2005 and as such, has committed to introduce measures to reduce releases of POPs into the environment to lower human and wildlife exposure. The EU has been very active in nominating new substances under the Convention. Regulation (EC) No. 850/2004 is the legal instrument that implements the EU and its members' commitment under the Convention.

The American Chamber of Commerce to the European Union (AmCham EU) understands that the Commission plans to recast the EU POP Regulation. The reasons are the need to update the obsolete regulatory procedures in the EU POP regulation, to align them with the Lisbon Treaty, as well as revise a number of cross-references to outdated EU legislation. This is also the opportunity to propose a new role for the European Chemicals Agency (ECHA) in this process.

Improvement needs based on industry's experience with the nomination process

Recent industry experience with the nomination of new substances by the EU to the Stockholm Convention highlighted a number of procedural flaws. Given the far-reaching consequences of a POP nomination, namely substance deselection from the beginning of the process, any uncertainties should be minimised and robust scientific justification provided.

AmCham EU calls for the improvement and clarification of the process by which REACH-assessed substances are scientifically evaluated and nominated under the Stockholm Convention.

The European Commission generally considers that all persistent, bioaccumulative and toxic substances (PBTs) under REACH constitute a pool of POP candidates, provided the potential for long-range transport exists. The outcome of an environmental assessment carried out under EU chemicals legislation (e.g. REACH PBT assessment confirmed by ECHA committees) can serve as a starting point for further consideration. However, this first step must be complemented by:

- **An in-depth scientific assessment of the long-range transport properties** of the substance as well as its potential for re-deposition in remote regions, as required under Annex D of the Convention;
- A **Risk Management Options analysis** (RMOA) that clearly documents the risk to be managed and assesses whether the Convention is the most appropriate instrument for controlling it;
- **A stakeholder consultation** followed by involvement of **ECHA's scientific committees**;
- **A full impact assessment conducted prior to a nomination** to avoid a disproportionate impact on the EU economy and industry.

The role of ECHA

The Commission's intention to involve ECHA in the process is a step in the right direction, as it can be reasonably expected that this would increase transparency, strengthen the scientific debate and ensure that the roles of the Commission (policy making) and ECHA (scientific and technical assessment) are separated. This should also provide opportunities for stakeholder consultation and clarify relationships between REACH and the Convention.

In addition, the experience gained by ECHA with the management of REACH processes, particularly with the Authorisation and Restriction processes, could be useful for improving POP management processes.

The tasks of ECHA and the role of its committees should be clearly described in the legal text of the POP Regulation in a similar manner to the Regulation on Prior Informed Consent (which implements the Rotterdam Convention into EU law, see Article 6) or other EU chemical regulations that rely on ECHA for certain tasks (REACH, CLP, Biocidal Products Regulation). Specific suggestions are proposed further down.

Link between REACH and the Stockholm Convention

Serious questions have been raised about the link between REACH and the Stockholm Convention. The Commission and Member States developed a 'Common Understanding Paper' to clarify the interlinkages with the Restriction and Authorisation processes. In summary, this paper states the following:

Once restricted under REACH, a nomination under the Convention is a mechanism to 'internationalise' a REACH Restriction. At the end of the Convention review process, the listing in the POP Convention supersedes the REACH Restriction. For substances listed under Annex XIV of REACH and subject to Authorisation, similar alignment processes are foreseen, whereby the measures accompanying a listing under the Convention ultimately superimpose REACH Authorisations (depending on the sunset date). In other words, once a use is prohibited or otherwise restricted under the Convention and implemented in the EU POP regulation, all existing REACH authorisations would be withdrawn and new applications refused.

While consistency between regional and international policy is highly desirable, AmCham EU cautions against promoting or establishing automatic links between REACH and the Convention. The objective and the scope of these two instruments have nothing in common: the Convention is global by nature and aims at eliminating a POP chemical in all its lifecycle stages. REACH is more balanced in that it aims at protecting human health and the environment while enhancing competitiveness and innovation. Where a risk has been identified, targeted restrictions are possible under REACH, which is not the case under the Convention.

Concrete recommendations for the recast of the POP regulation

AmCham EU members would like to see the following elements clarified and included in the EU POP Regulation on the occasion of its recast.

- Process clarity:
  - A description of the process by which the EU identifies, evaluates and proposes substances for POP nomination;
  - A description of the process by which the EU runs and coordinates subsequent assessments in the POP process (risk profile, risk management, etc.);
  - A description of the process by which the Commission and Member States provide input to the EU-designated experts on the POP Review Committee (POPRC) about the key subsequent steps during the listing process, and about the positions that EU observers take during the key POPRC meetings that follow a nomination (risk profile, risk management, etc.);
  - A description of the process by which the EU coordinates in advance of and during the meetings of the Conference of the Parties.

- A list of tasks expected from ECHA:
  - Establish and train a dedicated team of scientific and regulatory experts within ECHA;
  - Create a POP Expert Group with Member States and stakeholders to assess the need for and review data supporting new nomination proposals. The group would also manage the procedural steps following this nomination (e.g. analytical methods for Unintentional Trace);
  - Develop general guidance on POPs which explains the function and the methods for applying the regulation;
  - Develop specific guidance on the process for selecting candidate substances, including: a structured scientific proposal, an assessment of uses, socioeconomic considerations, justification for international action and consultation with industry. Such guidance could also address the steps that follow a nomination initiated by the EU: drafting of screening dossiers, risk profiles, alternatives assessment and risk management evaluations;
  - Similar to the REACH Restriction process, consult stakeholders to inform on the impact of proposed additions of substances to the Annex I (prohibitions) and Annex II (restrictions), whether these additions are individual, in mixtures or articles, as well as the exemptions from the use control measures;
  - Develop scientific guidance on long-range transport assessment, chemical redeposition and what constitutes an 'adverse outcome';
  - Clarify relationships between the Stockholm Convention and REACH processes and examine thoroughly if/when REACH may not be sufficient to control risks and POP nomination might be justified;
  - Coordinate among Member States prior to POPRC meetings and clarify the roles of the EU and national experts in the POPRC to ensure full independence of experts.

- A requirement to establish transparent procedures for POP draft nominations, including public consultation, as is the case with other procedures where ECHA is involved (REACH, CLP harmonised classification proposals, Biocides, etc.).

- A requirement for ECHA committees (Risk Assessment Committee and Socioeconomic Committee) to deliver an opinion on nomination proposals before the European Commission seeks a mandate to nominate from the European Council and, later, an opinion on risk profiles and alternatives assessments.