EUROPEAN COMMISSION
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REACH AND THE STOCKHOLM CONVENTION AS WELL AS THE UNECE POP PROTOCOL

A COMMON UNDERSTANDING

INTRODUCTION

The Stockholm Convention on Persistent Organic Pollutants (the "POP Convention") requires its Parties to prohibit and/or eliminate the production, use, import and export of chemicals listed in Annex A thereto and to restrict the production and use of chemicals listed in Annex B, in accordance with the provisions of the Convention[1]. All Parties may submit proposals for listing chemicals in Annex A or B.

The 1998 Protocol to the 1979 Convention on Long-Range Trans-boundary Air Pollution on Persistent Organic Pollutants (the "POP Protocol") has the same objective and similar mechanisms.

The European Union is a Party to both international instruments. The POP Convention and POP Protocol are implemented in the Union, *inter alia*, by means of Regulation (EC) No 850/2004 (the "POP Regulation"). Although this paper focuses on the interaction between REACH and the POP Convention, the conclusions reached are equally applicable to the interaction between REACH and the POP Protocol.

Article 14 of the POP Regulation requires the Commission to amend Annex I or II to that Regulation whenever a substance is listed in the POP Convention. Article 3(1) of the POP Regulation prohibits the production, placing on the market and use of substances listed in Annex I. Article 3(2) restricts the production, placing on the market and use of substances listed in Annex II in accordance with the conditions set out therein.

Pursuant to Article 22(3)(b) and (4) of the POP Convention, if the Union is "unable to accept" an amendment of an Annex to the POP Convention (the listing of a substance), it must notify the Secretary General of the UN within one year of communication to the Parties of the adoption of the amendment[2]. In this paper the term "opt out" is used to describe this

[1] It is also conceivable that the listing of a substance in Annex C to the POP Convention could interface with REACH in that Article 5(c) of the Convention obliges the Parties, where they deem it appropriate, to require the use of substitute or modified materials, products and processes to prevent the formation and release of chemicals listed in Annex C.

[2] See Article 2 of Council Decision 2006/507/EC concerning the conclusion, on behalf of the Union, of the POP Convention.

notification. In the absence of such notification by a Party, the amendment enters into force for that Party and must be implemented.

Article 2 of Council Decision 2006/507/EC, concerning the conclusion on behalf of the Union of the POP Convention, states that when an amendment to Annex A or B to the Convention is not implemented in the Annexes to the POP Regulation or other relevant Union legislation within one year from the date of communication by the depositary of the adoption of the amendment, the Commission shall notify the depositary in accordance with Article 22 of the Convention. Where an amendment is implemented after such a notification, the Commission shall withdraw the notification without delay.

This paper examines the relationship between the POP Convention, POP Regulation and REACH in the areas of

A. restrictions; and

B. the authorisation requirement

in order to set out a common understanding on how best to manage chemicals subject to the POP Convention in EU legislation. It will be reviewed in the light of experience and changing circumstances.

A RESTRICTIONS

1. A substance is already listed under the POP Convention and not restricted by REACH

In the absence of notification by the Union of its inability to accept an amendment of the POP Convention, the amendment enters into force for the Union and must be implemented. In the Union this is done by amending the relevant Annex(es) to the POP Regulation.

In principle, once this has been done, it is not desirable that REACH be used to alter the implementing measures taken under the POP Regulation (although any Annex XV dossier presented under REACH must be processed). In the case of a full ban under the POP Convention, where the Annexes to the POP Regulation have been amended accordingly, the conditions for the preparation of a proposal for a restriction laid down in Article 69 of REACH would not be met. The risk to human health or the environment, presented by the substance, would be adequately controlled and would not need to be addressed. An Annex XV dossier would be unable to demonstrate that action was necessary on a Union-wide basis, beyond measures already in place. Where the POP Convention creates exemptions, the Union may implement the Convention more strictly. This should be done under the POP Regulation[3] albeit possibly on the basis of risk analysis done under REACH following the submission of an Annex XV dossier, and if confirmed in the opinions of RAC and SEAC.

[3] Article 14(3)

2. Annex XVII to REACH already contains a restriction in relation to a substance which is subsequently listed under the POP Convention

In these circumstances, the practice is to implement the listing in the POP Convention by means of amending the appropriate Annex(es) to the POP Regulation and to remove the restriction from Annex XVII to REACH (examples of this are PFOS, SCCPs and Penta-DBE). Article 131 of REACH provides the enabling power for the Commission Regulation amending Annex XVII[4].

The entry in the appropriate Annex to the POP Regulation should cover at least the bans under the Stockholm Convention and existing restrictions in Annex XVII to the REACH Regulation.

3. Substance not yet listed in POP nor restricted under REACH

In the case of a possible listing of a substance under the POP Convention before, or soon after, a Member State or the Commission (via ECHA) has initiated a restriction procedure under REACH, the action to be taken will depend to a great extent on timing.

The procedure to include a substance in one of the Annexes to the POP Convention takes a minimum of three and a half years and often longer[5]. The REACH restriction procedure can be concluded in less than three years with an amendment of Annex XVII.

Accordingly, even in the knowledge that a proposal for listing under the POP Convention has been submitted (or is imminent), it will often be desirable to go ahead with a restriction under REACH in order to benefit from an earlier time period of restriction of a substance presenting an unacceptable risk in the Union before it is superseded by a listing in the POP Convention (and subsequent amendment of the POP Regulation) and is then removed from Annex XVII to REACH. Moreover, such an approach would facilitate the development of the EU position for the Conference of Parties when the listing of the substance is decided.

Moreover, the result of the assessment under the POP Convention could be that the substance does not fulfil the criteria for a POP. Yet, the substance could pose an unacceptable risk in the Union due to other properties.

Considering the foregoing, it would be good practice for the Member States or the Commission to initiate a restriction procedure under REACH following a nomination for listing of a substance under the POP Convention.

Where, following the listing in Annex XVII to REACH, the substance is also listed under the Convention, the REACH restriction should - in principle - be removed.

[4] Examples are Commission Regulation (EU) No 207/2011 and Commission Regulation (EU) No 126/2013.

[5] HBCDD took around four and a half years.

B REACH AUTHORISATION REQUIREMENT

1. A substance is listed under the POP Convention before a procedure has begun to include the substance in Annex XIV to REACH

Article 58(7) of REACH states that "substances for which all uses have been prohibited under Title VIII or by other Union legislation shall not be included in Annex XIV . . .". Although the POP Convention and the POP Regulation do not necessarily prohibit "all uses" (since there can be exemptions for certain specified uses), it is clear that REACH should neither depart from nor duplicate the rules fixed by the POP Regulation. Therefore, if a substance that is already regulated under the POP Regulation (EC) is included in Annex XIV to REACH, authorisations may only be granted under REACH in relation to uses exempted under the POP Regulation.

In principle, any risks related to the exempted uses of that substance should be addressed though adaptation to technical progress under the POP Regulation[6] and, therefore, the REACH authorisation requirement should only be superimposed on the provisions of the POP Regulation if there are good reasons for doing so[7].

2. Annex XIV to REACH already includes a substance which is then listed under the POP Convention

The tool for implementing the POP Convention is the POP Regulation and, once implementation has been effected, the REACH authorisation requirement should not normally be superimposed on the provisions of the POP Regulation.

The question arises how to manage the interests of economic operators and achieve at the same time a smooth implementation of Union's international obligations through the POP Regulation. The right balance must be found between the prompt-as-possible implementation by the Union of a new listing in the POP Convention and safeguarding the legitimate interests of applicants for/holders of authorisation for the substances concerned.

In this context, it is helpful to look separately at cases where the listing in the POP Convention is adopted before or during the transitional period under REACH for existing uses (i.e. from listing in Annex XIV to the sunset date) and cases where the listing in the POP Convention is adopted afterwards.

A) The listing in the POP Convention is adopted before the sunset date/date when a decision is taken on applications received by the latest application date.

[6] Article 14(3) of the POP Regulation

[7] For example in the case of substances listed in Annex B to the Convention where the Convention allows for 'acceptable purposes', the Convention does not exert pressure to substitute as the acceptable purposes are not limited in time. If an alternative to such substance is not yet readily available in the EU, the REACH authorisation process, whilst permitting the use on socio-economic grounds, could provide the pressure to substitute. If the alternative is readily available in the EU the entry in the POP Regulation should be adapted to the technical progress and the relevant exemption should be removed.

The decision to include the substance in Annex XIV to REACH specifies a latest application date and a sunset date. Article 56(1)(c) and (d) of that Regulation automatically allow continued use of a substance newly included in Annex XIV up to the sunset date or date of decision on the application, whichever is later.

However, the Commission could nevertheless implement the POP Convention by amending the POP Regulation. According to Article 61(6) of REACH the Commission shall withdraw an authorisation for a use of a substance if that use is subsequently prohibited or otherwise restricted in the POP Regulation. REACH therefore gives priority to decisions taken under the POP Convention and implemented through the POP Regulation. As a consequence, an authorisation holder cannot legitimately expect that his authorisation will remain valid regardless of action taken pursuant to the POP Convention. Arguably, by extension, an applicant for authorisation under REACH who is either preparing his application or waiting for a decision on his application by the Commission has no legitimate expectation that his application will bear fruit where action is taken to implement the POP Convention. Once a use is prohibited in the POP Regulation, not only should all existing authorisations be withdrawn but all applications for authorisation should be refused.

If the one year deadline for notifying inability to accept an amendment to the POP Convention expires before either the sunset date or the date of decision on the application, the Union will have to make a policy choice. It can decide to implement the POP Convention through the POP Regulation and refuse applications (in the spirit of Article 61(6)) or to opt out of the amendment of the POP Convention[8] (and not amend the POP Regulation) at least until the sunset date or the date of decision on the application.

If the one year deadline expires after both of those dates, the Commission can take its decision on applications for authorisation before deciding whether to opt out. However, if the one year deadline expires soon after the sunset date or the date of decision on the application, for the sake of consistency the Commission should not approach the decisions on the authorisations and on the opt out separately, but consider them in conjunction.

A general decision could simply be made that all such applications will always be treated in a given way (transpose or opt out), or individual decisions could be taken on a case by case basis. In the latter event, various factors would come into play, such as the economic importance of the use of the substance to the Union versus the desire on the part of the Union to act in accordance with prevailing international opinion.

If the Commission decides to opt out at least until the sunset date or the date of decision on the application the permutations are -

1) No applications are received = the Union can implement the POP Convention.

[8] To be noted: Any decision not to accept an amendment of the POP Convention and amend Regulation (EC) No 850/2004 accordingly (i.e. a decision to 'opt out') must be taken in consultation with the Member States in the appropriate Council Working Group.

2) Applications are received but do not satisfy Article 60(2) or (4) = no authorisations are granted and the Union can implement the POP Convention through the POP Regulation.

3) Authorisations are granted for uses that are in line with POP Convention exemptions = the Union can implement the POP Convention through the POP Regulation, including the exemptions. However, applying the principle of not lowering the level of the environmental protection in the EU and in recognition of the investment of operators who have applied for authorisation, the relevant entry in the POP Regulation should make it clear that the exemption is limited to use by operators who have been authorised under REACH. The duration of such authorisation should be for the time period specified in the authorisation decision (which cannot exceed that allowed by the POP Convention); renewal of the REACH authorisation should not be possible unless there was a prior decision to prolong the exemption under the POP Regulation).

4) Authorisations are applied for but for uses not exempted under the POP Convention listing = the Union can either -

   a) implement the POP Convention through the POP Regulation and not grant authorisations (in the spirit of Article 61(6)); or

   b) grant authorisation and opt out of the POP Convention.

The same considerations as those mentioned above in relation to the initial decision whether to implement or opt out of the POP Convention also apply here.

The approach to applications for authorisation for new uses (which may be received after the latest application date) depends whether the use is in line with the specific exemption under the Convention. Authorisation could be granted if the use concerned is in line with an exemption under the POP Convention that has been implemented in the POP Regulation as described in 3) above. If the new use is not in line with an exemption under the POP Regulation, the application for authorisation should be refused in the spirit of Article 61(6) of REACH. If, on the basis of the considerations referred to above, the Union has not implemented the POP Convention, authorisations could be granted.

B) The listing in the POP Convention is adopted after the sunset date/date when a decision is taken on applications received by the latest application date

Here, the decision whether to grant or refuse applications for authorisation should already have been taken. In relation to any authorisations granted, the two possibilities are -

1) The POP Convention does not exempt any uses = the Union must either implement the POP Convention (and the REACH authorisations must be withdrawn under Article 61(6)) or opt out within the one year deadline;

2) The POP Convention creates exemptions for certain uses –

a) where the REACH authorisations are in line with exemptions under the POP Convention, the Union can implement the POP Convention via the POP Regulation. Once again, in recognition of the principle of not lowering the level of the environmental protection in the EU and the investment of operators who have applied for authorisation, the relevant entry in the POP Regulation should make it clear that the exemption is limited to use by operators who have been authorised under REACH. As above (in A.3)), the duration of such authorisation should be for the time period specified in the grant decision (which cannot exceed that allowed by the POP Convention); renewal of the REACH authorisation should not be possible unless there was a prior decision to prolong the exemption under the POP Regulation.

b) where the REACH authorisations are not in line with exemptions under the POP Convention, the Union must either implement the POP Convention (and the authorisations must be withdrawn under Article 61(6)) or opt out.

As in A), the approach to applications for authorisation for new uses (received after the latest application date) depends whether they are in line with the exemptions provided under the Convention and whether the Convention has been implemented.

3. Substance not yet listed in the POP Convention nor included in Annex XIV to REACH

The procedure for including a substance, which is already on the candidate list, in Annex XIV to REACH takes around two years[9] (If the substance is not even on the candidate list, at least six months can be added). To that, a transitional period of at least three years should be added (until the later of the sunset date or the date on which a decision is taken on applications submitted by the latest date for applications) As indicated above the POP Convention procedure takes a minimum of three and a half years).

Since the procedure for listing a substance in the POP Convention is shorter than the REACH authorisation procedure (including the transitional period) there is little to be gained from adding a substance to Annex XIV if a Party to the POP Convention has already submitted a proposal for its listing in the Convention. Therefore, the process for subjecting a substance to the authorisation procedure under REACH should be terminated if that substance is proposed for listing under the POP Convention at any time up until a decision by the Commission to include the substance in Annex XIV. Then, the analysis in section B.2 above applies.

The question then arises, what action should be taken pending the outcome of the proposal procedure under the POP Convention. As the REACH restriction procedure is considerably quicker than the POP Convention and it may be desirable to introduce risk management measures in the Union in the form of a restriction under REACH which would apply until superseded by the POP Convention and the POP Regulation.

This is the approach currently being taken in relation to decaBDE.

[9] One year for the ECHA recommendation and one year for inclusion in Annex XIV.