Refinables Project

Consequence of one or several of the Refinable constituents being listed on the Candidate List and/or prioritised for Authorisation

BACKGROUND

The authorisation process consists of four steps. Manufacturers have legal obligations in step 1 (inform users one selected) and in step 3 requesting applications while users may require application requests in absence of manufacturers action. However, all interested parties have the opportunity and are highly encouraged to provide inputs in steps 1 and 2.

Step 0: Registry of Intentions (ROI)
ECHA regularly publishes updates of its "Registry of Intentions", listing the willingness of a Member State or the Commission to launch an Annex XIV drafting process as well as the date by which the report will be submitted to ECHA-Member State Committee (MSC).

Step 1: Identification of Substances of Very High Concern (SVHC) or Candidate Listing (by authorities)
SVHC will be identified by Member State Competent Authorities (MSCA) or the Agency (on behalf of the European Commission) by preparing a dossier in accordance with Annex XV. Interested parties can comment on substances for which a dossier has been prepared (first consultation). The outcome of this identification process is a list of identified substances, which are in theory candidates for authorisation or restriction (the "Candidate List").

Step 2: Prioritisation process (by ECHA-MSC)
The substances on the Candidate List are prioritised on an annual basis to determine which ones should be included in the List of Substances Subject to Authorisation (Annex XIV of the REACH Regulation or "Authorisation List"). Prioritisation is done in two tiers:

1) scoring on the basis of PBT/vPvB properties, wide dispersive use potential, and volumes;
2) reviewing the regulatory effectiveness of a potential Authorisation or Restriction using a verbal approach.

Interested parties are invited to submit comments on ECHA's draft recommendation of priority substances to be included in Annex XIV (during the second public consultation). After the public consultation the Member State Committee issues its opinion on the (update) draft recommendation, which considers the comments, submitted during the public consultation. ECHA will take into account the opinion of the Member State Committee when recommending to the Commission priority substances that should be included in Annex XIV.
At the end of the prioritisation process, the following decisions are taken:

- whether or not the substance will be subject to authorisation or restriction;
- which uses of the included substances will not need authorisation (e.g. because sufficient controls established by other legislation are already in place) (generic or specific exemptions);
- the "application date" by which applications must be received by ECHA;
- the "sunset date" by when a substance can no more be used without authorisation;
- while the MSC can set a review period for all or for specific uses this is left so far to the Commission.

Step 3: Applications for authorisation (by industry)
Applications for authorisation need to be made within the set application deadline and for each use that is not exempted from the authorisation requirement. They must include among others:

- a Chemical Safety Report (CSR) covering risks related to those properties that caused the substance to be included in authorisation system (unless already submitted as part of the registration; in such case the CSR should be updated);
- an analysis of possible alternative substances or technologies (AoA), including information on research and development foreseen or already in progress to develop such alternatives.

If the analysis of alternatives reveals that a there is a suitable alternative, the applicant must submit a substitution plan, explaining how he intends to replace the substance by the alternative. The suitability of available alternatives is assessed taking into account all relevant aspects, including whether the alternative results in reduction of overall risks and is technically and economically feasible.

While the above listed documentation is required in all cases, a Socio-Economic Analysis (SEA) or an extensive Demonstration of Safe Use depend on if the substance is recognised as a non-threshold or PBT or respectively as a threshold substance.
An applicant should include a SEA in his application in case of a non-threshold or a PBT substance and may do this in support of a threshold substance. An extensive documented demonstration of "adequate control of risks" is required for threshold substances.
A fee has to be paid by application request that can cover only one use. However, the use descriptor (in the case of authorisation called: Broad description of Uses) can be defined narrow or broad allowing the applicant some flexibility. Applications can be submitted individually per legal entity, jointly per substance/use or even jointly for several substances for the same use application.
For all applications, the Agency Committees (SEAC and RAC) will provide expert opinions. The applicant can comment on these opinions.
A Public Consultation to solicit "knowledge on alternatives" from third parties is part of the process.

Step 4: Granting of authorisations (by the European Commission)
Authorisations will be granted if the applicant can demonstrate that the risk from the use of the substance is adequately controlled.
Downstream users may only use such substances for uses that have been authorised. For this they must either:

- obtain the substance from a company that was granted an authorisation for that use. They must stay within the conditions of that authorisation. Such downstream users must notify the Agency that they are using an authorised substance, within 3 months of first supply.
- apply themselves for authorisations for their own uses.

Uses exempted from authorisation relevant to PM Refinables
Certain uses of substances are exempted from the authorisation process by a generic or a specific exemption clause.
Generic exemptions cover: intermediate and waste status and in case of mixtures uses below the classification cut off for the relevant SVHC hazard properties, or below the Specific Concentration Limits as listed in Annex VI of the CLP:

- According to article 2.8, intermediates (on-site isolated intermediates and transported isolated intermediates) are not subject to authorisation. An intermediate does not need to be manufactured and used under Strictly Controlled Conditions (SCC) to be exempted from authorisation. However, it must fulfil all criteria related to intermediates including being "completely consumed" into the new substance, does not lead to extensive waste generation and not be subject to the direct manufacturing of an article.
- Also exempted is the use of substances when present in mixtures below a concentration limit of 0.1% by weight for C or M properties or 0,3 % for R properties, or a Specific Concentration Limit as listed in Annex VI of the CLP (e.g. Borate 5%).

Specific exemptions can be requested if it can be demonstrated that substance specific EU-wide risk management legislation applies for all stages of the use (manufacturing-use-end of life).

RELEVANCE TO REFINABLES WG

PM Refinables are complex (UVCB) isolated intermediates resulting from a primary and/or secondary refining stream containing amongst others, precious metals.

Borax is used in PM refining as a flux which promotes melting. Selected Borates are on the Candidate List of SVHC but are not yet prioritized for authorisation. The prioritisation of the selected Borates will be postponed with a year to allow for grouping with other borates. A new selection procedure starts in February 2012 with a public consultation over summer and final vote in December 2012. Action by the users will be required from April 2012 on.
It is further possible that Hydrazine will be prioritised for Annex XIV listing in 2012 and Pb oxide in 2013 or 2014. Hydrazine is used in the PM refinement process while Pb oxide is used as a reagent (carrier) and is quite regularly available as a component in the UVCB.
Arsenic oxides were already prioritised and can like Pb oxides be part of the ingredients included in the Refinables.

A clear longer-term strategy seems justified given several Refinable constituents are and can in the coming years be listed on the Candidate List and/or are prioritised for Authorisation.

Although intermediates are not subject to Authorisation obligations under REACH (and burdensome and costly REACH Authorisation duties could be avoided if intermediate-type use can be confirmed), there may be:

- direct consequences if refining or reagent agents would be included in the Authorisation list (Hydrazine, Pb oxide, …);
- indirect consequences if any of the Refinable constituents should require Authorisation, as uncertainties about security of supply might occur (suppliers might be denied Authorisation, requiring phase-out of supply).

FUTURE STEPS

Action ECHA	Action PMC Refinables WG	Comments
	Eurométaux regularly checks the registry of intentions published by ECHA (http://echa.europa.eu/chem_data/reg_intentions_en.asp) and updates its members.	The aim of the public registry of intentions is to allow interested parties to be aware of the substances for which the authorities intend to submit Annex XV dossiers and therefore facilitates timely preparation of the interested parties for commenting later in the process.
Hypothesis 1: Constituent of PM Refinable is published in the Registry of Intentions - Proposal for SVHCs and an Annex XV dossier is submitted.	• Check possibility of categorisation as intermediate-type use (reaction behaviour / transformation): check if all uses of the Refinable can for sure be confirmed as intermediate. • If intermediate-type use cannot be confirmed, there is the possibility in this step to submit a dossier within the deadline set for comments (via http://echa.europa.eu/consultations/authorisation/svhc/svhc_cons_en.asp).	If intermediate-type use can be confirmed, then the use is exempt from Authorisation.
Hypothesis 2: Constituent of PM Refinable is published in the Candidate List for Authorisation (http://echa.europa.eu/chem_data/authorisation_process/candidate_list_table_en.asp).	Verify communication obligations along the supply chain (Article 33). There are no communication obligations for a confirmed intermediate!	As soon as a substance is listed in the Candidate list for Authorisation, duty of communication applies. Article 33(1) states that producers, importers and other suppliers of articles containing SVHC, which are on the Candidate List for Authorisation with a threshold above 0.1% (w/w), have to provide information available to them about the substances to the recipients (does not include consumers) of the articles.
Hypothesis 3: Constituent of PM Refinable is prioritised for Annex XIV inclusion (Authorisation List) and ECHA's draft Annex XIV recommendation is published on the ECHA website (http://echa.europa.eu/consultations/authorisation/draft_recommendations/recommendations_en.asp).	If intermediate-type use cannot be confirmed, there is the possibility in this step to submit comments via webform within 3 months of the date of publication, in particular on uses that should be exempt from the Authorisation requirement.	Article 58(2) of REACH: possible to exempt from the Authorisation requirement some uses or categories of uses provided that based on existing specific EU legislation imposing minimum requirements for protection of human health & environment the risk is properly controlled.

Hypothesis 4: Constituent of PM Refinable is included in Annex XIV (Authorisation List) (http://echa.europa.eu/reach/authorisation_under_reach/authorisation_list_en.asp).	If constituent use is not intermediate-type and not exempt from Authorisation: • Send a notification of intent (indicating the Annex XIV substance which will be the subject of the application and providing a general description of the use(s) for which an authorisation will be sought) to ECHA (echa_application_for_authorisation@echa.europa.eu) • Prepare and submit an Application for Authorisation. Prepare the dossier in the most suitable format for submission: a) based on CSR, show that risks are adequately controlled, that tonnage is not of high concern, that there is no wide dispersive use and env=no PBT/nor=vPvB; b) analysis of alternatives; c) if there are alternatives, submit a substitution plan; d) based on more socio-economic evaluation, show that there are no alternatives, benefits outweigh the cons (socio-economic analysis or SEA). See also http://guidance.echa.europa.eu/docs/guidance_document/authorisation_application_en.pdf.	• There is no tonnage threshold for a substance to be subject to Authorisation. • Authorisation will be granted if the registrant can show: a) Adequate control of risks or b) Social economic benefits outweigh the risks and no substitution is possible. • If suitable alternatives are available, the application for Authorisation is unlikely to be granted. • A fee has to be paid for each Authorisation application. • All Authorisations will be reviewed after a certain time-limit which will be set on a case-by-case basis, and industry must re-apply (with the appropriate fee).