Proposals for Reform of Authorizations and Restrictions

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Context

- Reform envisaged in the Chemicals Strategy for Sustainability (CSS) announced in October 2020
- Concrete proposals for the reform: paper from CARACAL Meeting of January 27, 2022
  - Includes findings from November 2021 Stakeholders Workshop

Candidate List of Substances of Very High Concern (SVHCs) for Authorization

- The Candidate List of SVHCs now contains 223 entries for chemicals.

Candidate List of substances of very high concern for Authorisation - ECHA (europa.eu)

Substances with the following hazard properties may be identified as SVHCs:

Substances meeting the criteria for classification as carcinogenic, mutagenic or toxic for reproduction (CMR) category 1A or 1B in accordance with the CLP Regulation.

Substances which are persistent, bioaccumulative and toxic (PBT) or very persistent and very bioaccumulative (vPvB) according to REACH Annex XIII.

Substances on a case-by-case basis, that cause an equivalent level of concern as CMR or PBT/vPvB substances, e.g., endocrine disruptors, respiratory sensitizers, persistent mobile toxic and very Persistent/ very mobile substances.

Regulatory Obligations for Candidate List Substances

- Suppliers of substances or mixtures need to update their SDSs to indicate Candidate List Status
- The identification of a substance as an SVHC and its inclusion in the Candidate List can trigger certain legal obligations for the EU importers, producers and suppliers of an article that contains such a substance.
  - Notification of substances in articles (Article 7(2) REACH)
  - Communication in the EU supply chain (Article 33 REACH)
  - Candidate List substances in articles trigger reporting to the SCIP (Substances of Concern In Products) database.
- Candidate List substances may be prioritized for inclusion on the Annex XIV Authorization List.

Proposal for changes in Candidate Listing

- Harmonized classification as Endocrine Disruption (ED), PBT, vPvB, PMT and vPvM: will be sufficient for SVHC listing
- Annual notification obligations by registrants and downstream users of SVHCs of uses, tonnages and exposure/ emission patterns, waste management, possible alternatives
- This information will be used to prioritize substances for further regulatory risk management.
- Could be made publicly available by ECHA (in addition to SCIP database?)
- Initial notification and annual fee for SVHCs payable to ECHA

Authorization

- The authorization process aims to ensure that substances of very high concern (SVHCs) are progressively replaced by less dangerous substances or technologies where technically and economically feasible alternatives are available.
- Suppliers must apply for authorization by the deadline set out in Annex XIV.
- Very complicated and costly process.
- At best suppliers receive a limited period of time (phase-out) to continue marketing the substance.

Restriction

- Annex XVII REACH
- https://echa.europa.eu/substances-restricted-under-reach
- Specific restrictions of use, manufacturing or import of substances on their own, in mixtures or in articles.
- Multi-year process.
- Currently 70 entries
- Only if ‘action on a Community-wide basis is necessary.’
- Restrictions usually include derogations where no substitute is currently available.

Proposal for revision of authorization

- Three possible policy options to reform REACH authorizations and restrictions:
  - ***Option 1**: Simplification of current authorization and restriction system.*
  - ***Option 2**: Merging authorization and restriction.*
  - ***Option 3**: Removing the authorization title from REACH*
- Stakeholder workshop: clear majority of views inclined towards Options 1 and 2. Option 3 'radical'
- Common first action: strengthening the SVHC listing and collection of information on SVHC – see previous slide

Option 1 (Simplification)

Authorization

- ECHA's role in prioritization limited to checking information from DU notifications and gathering information on alternatives
- Removing the Member State Committee (MSC) opinion from the Annex XIV recommendation
- Removing exemptions for uses or categories of uses under Article 58(2)
- Increase efficiency (using experience from upstream applications): reporting standards for applications for authorizations (required level of granularity, level of details…)
- Redefining conditions to grant an authorization (clearer definition of suitability of alternatives)
- In cases an authorization is refused, provide for transitional arrangements (avoiding disposal of the unused substance)
- Introduce completeness/conformity checks of applications

Option 1 (Simplification)

Restrictions – essential use

- Introduce essential use concept for derogations from ‘normal’ restrictions according to Article 68(1) REACH

Option 1 (Simplification)

Restriction: extension of the generic approach to risk management ('GRA')

- GRA restrictions (Article 68(2) REACH) to be extended from CMR substances and consumer uses to further hazard classes (ED, PBT/vPvB, STOT SE,STOT RE, immunotoxic substances respiratory sensitisers and possibly to PMT/vPvM) and uses (consumer & professional).
- Derogations for essential use.
- Restrictions for uses in articles to prioritize articles with exposure to consumers and vulnerable population groups (textiles mentioned specifically).

Option 2 (merge)

Replace Annex XIV listing by restrictions of SVHCs.

- ‘Normal’ restrictions: no changes (just ‘essential uses’ for derogations)
- But: restriction process under REACH Art. 68(2) (GRA) divided into two separate procedures:
  - *Restrictions following GRA (consumer & professional uses) – see extension of this concept described in Option 1*
  - *New: Restrictions for SVHC on the Candidate list for industrial and/or professional and/or consumer uses*

IV. Option 2 (merge)

Restriction of SVHCs

- GRA approach normally applied (subject to ‘sensitivity analysis’)

Derogations (based on essential uses) can be either:

- Proposed by the authorities (part of the Commission restriction proposal)
- Joint derogations requested by industry after the adoption of the restriction (similar to RoHS exemptions); will be applicable generally
  - Lessons learned from current ‘upstream’ applications and RoHS will be considered in implementing such a system
- Individual exemptions applications that will only be applicable to the applicant (equivalent to authorization; new rules would aim at limiting their number)

V. Option 3 (replacement)

- Replacement of authorization by non-REACH processes.
  - Actions under Occupational Safety and Health legislation
  - Actions under Industrial Emissions Directive 2010/75/EU (IED)
- Possibility of introducing national authorisations, export bans

Development of criteria for essential use

- Concept goes beyond REACH (food contact materials, cosmetics and toys mentioned specifically)
- Concept of essentiality in the Montreal Protocol as a starting point
- Two elements are relevant: criticality, alternatives
- Client Earth: luxury, convenience, leisure, cosmetics, toys, or decorative products: not essential
- Environmental benefits, energy efficiency, climate change benefits = Green Deal arguments = likely essential uses
- Still unclear: criticality of a substance, or also of a product?
- **Current status**: Commission has commissioned external study on the 'essential uses' concept, publication of the final report pending
- It will be discussed in a workshop planned for March 2022 and follow up discussions will take place at the next CARACAL meeting.

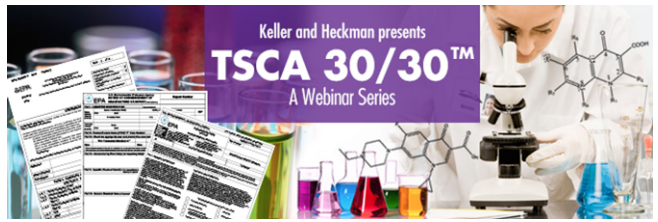
Discussions on grouping for restriction/further scrutiny

- ECHA webinar on assessing groups of chemicals of December 2021
- Elements looked at
  - Hazards
  - Uses/potential for exposure
  - Group boundaries (and need for subgrouping)
  - Potential for substitution
- Main source of information: registration dossiers
- Important: reports on grouping may become publicly available:
  - Cover page (group name, structure, versioning, overview of substances)
  - Overview of the group
  - Justification for the (no) need for regulatory risk management action at EU level

The Next REACH 30/30:
Wednesday, April 13, 2022

For more information on past and future **REACH 30/30** programs, please visit **www.khlaw.com/reach3030** and

Please join us at 1:00 PM Eastern U.S.
Wednesday, Feb 16, 2022
www.khlaw.com/OSHA3030



Please join us at 1:00 PM Eastern U.S.
Wednesday, March 23, 2022
www.khlaw.com/TSCA3030

Please join us at 1:35 PM Eastern U.S.
Wednesday, April 13, 2022
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Thank You

Any Questions?

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