



Regulating Persistent and Mobile substances in Europe: Lessons learned from case processing under CLP, science-policy synergies and stakeholders' engagement

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ZeroPM's 3rd International Workshop: Removal
through Technical Solutions

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Outline

- Recent regulatory developments and ECHA's engagement in ZeroPM
- ECHA update since last ZeroPM workshop and case processing
- ECHA activities on science-policy interactions
- ECHA activities on Stakeholder engagement

Refresher on ECHA's involvement in ZeroPM Project

- Following Project almost from the beginning
- 11/2022: Motivational chat with Project students
- 02/2023: Gothenburg/ Sweden Workshop on **Prevention**
 - Drafting of new CLP Guidance on PM substances, ECHA's expectations from Stakeholders, etc.
- 06/2024: Online Science-Policy Webinar
 - Regulation evolution, ECHA's role under CLP, regulatory processes, criteria, etc.
- 09/2024: Dessau-Roßlau/ Germany Workshop on **Prioritisation**
 - ECHA mandate and vision, mapping of different Regulations managed by ECHA and related synergies, regulatory research needs and challenges, etc.
- 10/2025: Mytilene, Lesvos/ Greece Workshop on **Removal**

Refresher on relevant CLP regulatory developments

- Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures (CLP)
- 10/2020 EU COM Chemicals Strategy for Sustainability (CSS) - towards a toxic-free environment
 - One substance one assessment (1S1A) identifying regulatory need to manage new concern types, including substance with PBT/PMT properties
- Commission Delegated Regulation (EU) 2023/707
 - New hazard classes for PBT/vPvB, PMT/vPvM and ED (ENV and HH) properties
 - CLP Annex I update, followed by 2024 CLP update
- Proposals for harmonised classification (CLH) submitted to ECHA since April 2023
- Updated CLP Guidance published in November 2024

What has happened since 09/2024

- 11/2024: Publishing of amended CLP Guidance on the application of the CLP criteria (Parts 4 and 5)
- 11/2024: Online webinar to introduce the updated CLP Guidance on PBT and PMT hazards
- Spring 2025: Workshops with Member State Competent Authorities
- 05/2025: Stakeholder Event including Industry, NGOs, etc.
- 2024 - present day: P and M discussions under UN GHS and OECD technical groups
- By 10/2025: 8 PBT and PMT CLH proposals submitted to ECHA
 - First case (vPvB) to be discussed in December 75 RAC cycle
 - Several additional registered intentions

First PMT/vPvM CLH cases (N=5)

<u>#</u>	<u>Name</u>	<u>Proposal</u>	<u>P/vP</u>	<u>M/vM</u>	<u>I</u>
1	Trifluoroacetic acid	PMT/vPvM	OECD TG 307 (no degrataion in 120d) Water: non-standard lab and field Sediment: non-standard lab study OECD 301D; 302A [monitoring]	4 OECD 106 studies OECD TG 312 2 QSARs [monitoring]	Repr. 1B
2	[1] sodium trifluoroacetate; [2] and other inorganic salts of trifluoroacetic	PMT/vPvM	As above	As above	As above
3	Benzotriazole [1]; Sodium 1H- benzotriazolide [2]; Potassium 1H-benzotriazolide [3] and inorganic salts [4];	PMT/vPvM	Simulation studies Ready and inherent biodegradability tests Hydrolysis study	OECD TG 106 Literature study QSARs	Repr. 2 ED ENV 1
4	Methyl-1H-benzotriazole [1]; Sodium 4(or 5)-methyl-1H- benzotriazolide [2]; 4(or 5)- methyl-1H-benzotriazole, potassium salt [3]and inorganic salts [4]	PMT/vPvM	Simulation studies Ready and inherent biodegradability tests Hydrolysis study	OECD TG 106 Literature study QSARs	Repr. 2
5	1,3,5-triazine-2,4,6-triamine [Melamine]	PMT/vPvM	Simulation studies Ready and inherent biodegradability tests Hydrolysis study	Several OECD TG 106 Several QSARs [monitoring]	STOT RE 2 Repr. 2

Lessons learned from processing of first PMT CLH proposals

- Early notification of Member State intention to start working on a proposal beneficial
- Identification of related work and/or conclusions in other regulatory programmes on same or related substance(s)
- Early engagement with relevant experts (e.g. ECHA Secretariat, PBT EG, MSs, Industry, other data holders)
- Acquaintance with the CLH process and CLP Guidance before submission
- Ensuring information generation has been completed before submission; after that, new information can be provided/ used only during the consultation
- Use the ECHA template for the recording of all reliable and relevant information; conclude, within a Weight-of-evidence (WoE) determination

ECHA activities promoting science-policy synergies

- Transparent and proactive communication of ECHA's scientific work ("ECHA Science")
 - How acquired data and knowledge on chemicals meet EU legal and policy goals
- Publication of annual reports on key areas of regulatory challenge (needs)
 - Protection against harmful chemicals, addressing chemical pollution, shift away from animal testing, improve availability of chemical data, promote circularity
- Publication of ECHA strategy statement 2024-2028
 - Be a trusted chemicals agency, respond to emerging challenges, communicate & engage, lead on chemical knowledge and expertise, invest in organisational excellence
- Building and sharing scientific expertise also by use of Framework contracts (calls for tender)
 - For more details, please consult the "Business opportunities" section of the ECHA website

ECHA activities relating to science-policy synergies

- Webinars, trainings, staff visits & exchanges, speaker requests, scientific conferences (e.g. SETAC) and missions
- Publication of key work findings in peer-reviewed journals
- Encouragement of scientific activities developing models, methodologies and generating chemicals' data
 - Screening, identification and prioritisation of most relevant substances
- Engagement in integrated projects
 - PARC (Partnership for the Assessment of Risks from Chemicals)
 - ZeroPM

ECHA activities relating to Stakeholder engagement

- ECHA Stakeholder Engagement Approach
 - Prioritise identification and mapping of Stakeholders, encourage proactive, open and tailor-made interaction
 - Enhance mutual understanding on ECHA's role, responsibilities and mandate
 - Increase the impact of ECHA's outputs by inviting for early feedback and other consultations
- Regular co-ordination meetings with relevant policy makers, for example, the European Institutions
- Formal and informal discussions with Member State Competent Authorities and other policy actors, also via their participation in ECHA Committee and Forum activities
- Workshops, webinars, trainings, videoconferences, bilaterals with ECHA's Accredited Stakeholders (Industry Associations, NGOs, trade unions, academia, etc.)

Concluding remarks

- ECHA appreciates the opportunity to follow the progress of the Project => many thanks to Project co-ordinators
- Identifying, screening and prioritising relevant substances for regulatory action essential
- Communication of ECHA's mission, processes (e.g. documentation, actors, timelines, volumes, etc.) and priorities/ research needs helps to bridge any gaps on science-policy integration
- Looking forward to Project climax and any potential follow-ups

Key links

- ECHA website: <https://www.echa.europa.eu/>
- Chemicals strategy for sustainability: https://environment.ec.europa.eu/strategy/chemicals-strategy_en
- CLP Legal text (09/2025): <https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:02008R1272-20250901>
- CLP Delegated Act (03/2023): <https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32023R0707>
- CLP Guidance (11/2024): https://echa.europa.eu/documents/10162/2324906/clp_parts4-5_en.pdf/56ed0738-f7e9-6a6f-e9ca-c13af265ec6b?t=1730718888268
- 11/2024 online webinar: <https://echa.europa.eu/-/introduction-to-echa-s-guidance-on-new-clp-hazard-classes> and https://echa.europa.eu/documents/10162/92636068/241121_clp_new_hazard_classes_webinar_qa_en.pdf/32365dea-58cd-69e2-bdea-176224ef06dd?t=1739946958845
- CLH process: <https://echa.europa.eu/regulations/clp/harmonised-classification-and-labelling>
- RAC opinions: <https://echa.europa.eu/registry-of-clh-intentions-until-outcome>
- 2025 key areas of regulatory challenge: https://echa.europa.eu/documents/10162/17228/key_areas_regulatory_challenge_2025_en.pdf/da33bf25-2b75-1fe9-c308-53043f9b9a28?t=1749466525527
- ECHA strategy statement 2024-2028: https://echa.europa.eu/documents/10162/17209/echa_strategy_2024-2028_en.pdf/936c121f-9ba0-e677-40e1-d27c0cbdbacb?t=1706600415618

Thank you

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