



The Global Resource for
the Pine Chemicals Industry

H4R / HARRPA / PCA CLH Update

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Key Regulatory Events beyond the EU

- **China MEE 12 Overhaul (currently in Draft / Consultation Phase)**
 - Cosmetics, Pharmaceuticals and Food Additives are amongst the Sectors that are not exempted anymore from Registration
 - Exact Data / Registration Requirements as new Chemicals / new Use not clear yet
 - Registration only allowed by Chinese Entities (Only Representative of Foreign Companies not allowed anymore)
- **Vietnam new Chemical Framework – Custom Challenges**
 - Companies report frequent Issues with Customs insisting on 100% Composition Information
 - Compromising Business Confidential Information, impossible for UVCB's

PCA works closely with ACC RAIN: Consultation Input, UVCB One-Pager

Key Regulatory Events beyond the EU (II)

- **China adopts new Mandatory National Standard for Cosmetic Safety**
 - Draws upon EU Cosmetic Products Regulation (EC No 1223/2009)
 - Will be implemented January 1, 2028
- **Terpene Polymers in Japanese Positive List for Food Contact Materials**
 - Terpene monomers are listed in Annex 14, but unclarity on the MW>1000 clause
- **US FDA proposes to make GRAS Notifications Mandatory for Food Substances**
 - Transition for existing substances marketed under self-affirmed GRAS Conclusions
 - Consultation running until December 9, 2026
- **Global Registration / Notification / Dossier Management**
 - 2026 / 2027: Turkey, Brazil, Colombia, Chile, India, Peru, Taiwan, Thailand, Ukraine, UK

PCA globally supports and defends Market Access of Pine Chemicals



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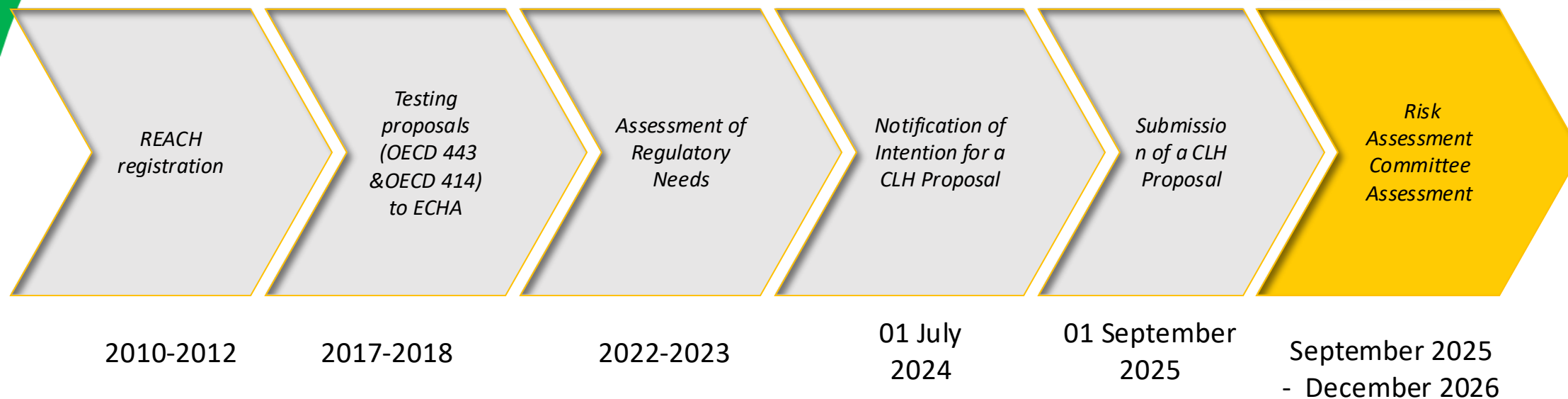
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The CLH process for Rosins and derivatives. How we got here.

- **Public consultation:**
Sept-Dec 2025: H4R,
HARRPA and PCA
submitted two new studies

- **RAC-78 CLH WG**
29 June 2026
- **RAC-78 Plenary**
8 September 2026



REACH Regulation: Registration Evaluation Authorisation of Chemicals
CLH Process : Harmonised Classification and Labelling
RAC: Risk Assessment Committee

Testing shows that Rosins and their derivates are not reprotoxic

Exception Rosin, Maleated

Studies		H4R Position
REACH dossiers in 2024 Regulatory OECD 422 and OECD 414 studies [2010-2017]		- Fertility effects are caused by undernutrition resulting from diet unpalatability. - Development effects are non-specific secondary to underweight pregnancies - Not described in the REACH dossier because it was considered to be a well known mechanism. - Screening studies only. Testing proposal made to close remaining data gaps (2017 – 2018), unanswered by ECHA as of September 2026
Additional Investigative studies	Transiency/Reversibility [2026]	- Indication of transiency on fertility effect observed - Evidence of reversibility on fertility effect observed
	Pair-Fed Feed restriction [2026]	Supports the hypothesis that undernourishment retards pup growth

A ban in consumer uses has been avoided, except for Rosin Oligomers

More is needed to protect continued use in EU applications

- ✓ H4R and PCA commissioned two modified OECD 421 tests on rosin.
 - One test proved that the effects observed on fertility were reversible.
 - A second, a feed-restriction study, proved that maternal undernutrition caused repro effects.
 - ✓ In addition, an independent scientific review was commissioned to SciPinion which aligned with our position not to classify, and a Socio-Economic Analysis was commissioned to Ricardo by HARRPA
 - ✓ For Rosin and Rosin Maleated, the proposed classification were moved from “presumed” to “suspected” reproductive toxicant.
 - Preventing a scenario in which rosin would have faced an outright ban in consumer uses.
- !! However, further testing is required to provide evidence that there is no substance-dependent effect.
- !! Industry is proactive in data generation and wants to accelerate regulatory testing, depending on ECHA’s approval

CLH Process – status of Classification

Substance (CAS)	Dossier submitter proposal	RAC CLH WG	HARRPA / H4R / PCA position
Rosin	Cat 1B 	Cat 2	No classification
Rosin, hydrogenated	Cat 2	Cat 2	No classification
Rosin, oligomers	Cat 1B	Cat 1B	No classification
Rosin, maleated	Cat 1B 	Cat 2	No objection
Rosin, fumarated	Cat 2	Cat 2	No classification
Fatty acids, tall-oil, oligomeric reaction products with maleic anhydride and rosin, calcium magnesium zinc salts	Cat 2	Cat 2	No classification
RARA, fumarated, esters with glycerol	Cat 2	Cat 2	No classification
RARA, maleated, esters with pentaerythritol	Cat 2	Cat 2	No classification
Reaction products of tall oil fatty acids and tall oil rosin with maleic anhydride	Cat 1B	Cat 1B	n/a

Rosin and Rosin, Maleated CLH Proposal changed from Cat 1b to Cat 2
H4R/ HARRPA / PCA position: no classification is warranted except for Rosin, Maleated

Next steps in the Rosin CLH process



*Potential delays, see next slide

Next steps for HARRPA, H4R and PCA

- Targeted and intentional engagements with authorities to ensure that results of full testing proposals are considered before any decision is taken on the harmonised classification of Rosins and their derivatives.
- Proactive Testing data generation:
 - New OECD TG 422 by oral gavage to be started Q4 2026. This additional testing serves two purposes:
 - Generation of additional evidence demonstrating safety.
 - Provide scientific rationale for pausing regulatory process until such time as a complete dataset is available to inform the assessment

Obligations and Impact of Current (RAC WG) Opinion - EU

Reprotox 2 Classification

- CMR 2 are Substances of Concern (ESPR, PPWR)
- Registration Dossier Management
 - Update Chemical Safety Assessment (CSA) with (Consumer) Exposure Scenarios/Assessments
- Revise Hazard Communication
 - Update SDS, eSDS, CLP
 - Mixtures must be Classified as Reprotox 2 if concentration of Classified Substance is $\geq 3\%$
- Evaluate Workplace Safety Controls
- Validate Applicability of Sector-Specific (voluntary) Restrictions
 - Includes **Cosmetics, Ecolabel Certified Products, Inks**, Toys, specific Food Contact Materials

Obligations and Impact of Current (RAC WG) Opinion - EU

Reprotox 1b Classification (Rosin, Oligomers)

- CMR 1b are Substances of Concern (ESPR, PPWR), **SVHC Candidate**
- **Entry nr 30 of Annex XVII of REACH: Restricts placing on the market for general public (limited Derogation is possible)**
- REACH Registration Dossier Management
 - Update Chemical Safety Assessment (CSA) with Exposure Scenarios
 -
- Revise Hazard Communication
 - Update SDS, eSDS, CLP
 - Mixtures must be Classified as Reprotox 1b if concentration of Classified Substances is $\geq 0.3\%$
- Implement Workplace Safety Controls (**as per CMRD**)
 - **Including up to 40 years of record keeping**
 - **Mandatory Effort to Substitute, Minimize/Eliminate Exposure**
- Validate Applicability of Sector-Specific (voluntary) Restrictions
 - Includes **Cosmetics, Ecolabel Certified Products, Inks**, Toys, Food Contact Materials

REACH Annex VI Classification

Impact Beyond the EU

Legally binding only in the EU, but globally seen as important Benchmark

- **Global SDS and Hazard Classification Impacts**
 - Multiregional suppliers / customers may update their documentation regardless of the region
- **Customer / Industry / Supply Chain Impacts**
 - Entry into Declarable / Restricted Substances Lists
- **Possible Evaluations by non-EU agencies and institutions (e.g. IARC, EPA, FDA, NIOSH)**
 - Evaluations can lead to new Regulatory Considerations (e.g. California Prop 65)
- **Higher Priority in Evaluations in non-EU / Emerging Chemical Management Processes**
 - Canada / China / Australia / UK / Korea / Turkey and new REACH like legislation (LATAM, Eurasia etc)

Global Industry Advocacy is needed to defend the Regulatory Status of Rosins