H4R CONSORTIUM

Toxicity to Reproduction:

EU Harmonized Classification & Labelling (CLH) proposals for Rosin and Rosin derivatives

An overview

Lauren Amable

PCA International Conference,

22nd September 2025

H4R CONSORTIUM

Pine Chemicals ASSOCIATION INTERNATIONAL

Penman Consulting

Terms and *Dramatis Personae*

- **ECHA**: European Chemicals Agency
- ECHA responsible for two primary pieces of legislation:
  - **REACH**
  - **CLP**: Classification, Labelling, and Packaging of Chemicals
- **MSCA**: Member State Competent Authority
- **RAC**: Risk Assessment Committee

- **Toxicity to Reproduction**: Impairment of fertility of humans or development of offspring

Presentation overview

- Regulatory action on Rosin and Rosin Derivatives
- Impact of potential classification
- Timeline – including predicted future key regulatory dates
- Defence strategy
- Industry Call to Action
- Summary

Regulatory action on Rosin and Rosin Derivatives: ARN[1] and CLH[2]

ASSESSMENT OF REGULATORY NEEDS

Assessment of regulatory needs

Authority: European Chemicals Agency (ECHA)

Group Name: Resin and Rosin and its derivatives

General structure: -

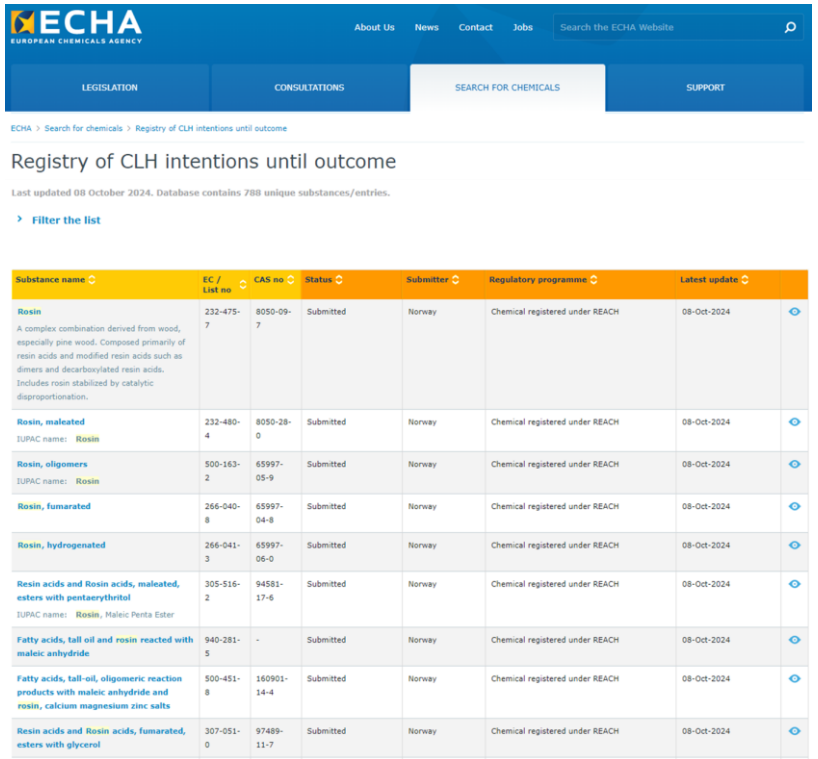
Revision history

Version	*Date*	*Description*
1.0	16 August 2023	

- Note that an ARN is a *screening*, not a formal regulatory, process
  - However, impact of conclusion maybe significant (negative perception)

- ***Suggested* regulatory action**:

Harmonized Classification and Labelling (CLH) as Reprotoxicity Category 1B
for specific Rosin and Rosin derivatives substances (> 25 substances)



ECHA EUROPEAN CHEMICALS AGENCY

About Us | News | Contact | Jobs | Search the ECHA Website

LEGISLATION | CONSULTATIONS | SEARCH FOR CHEMICALS | SUPPORT

ECHA > Search for chemicals > Registry of CLH intentions until outcome

Registry of CLH intentions until outcome

Last updated 08 October 2024. Database contains 788 unique substances/entries.

Filter the list

Substance name	EC / List no	CAS no	Status	Submitter	Regulatory programme	Latest update
Rosin A complex combination derived from wood, especially pine wood. Composed primarily of resin acids and modified resin acids such as dimers and decarboxylated resin acids. Includes rosin stabilized by catalytic disproportionation.	232-475-7	8050-09-7	Submitted	Norway	Chemical registered under REACH	08-Oct-2024
Rosin, maleated IUPAC name: Rosin	232-480-4	8050-28-0	Submitted	Norway	Chemical registered under REACH	08-Oct-2024
Rosin, oligomers IUPAC name: Rosin	500-163-2	65997-05-9	Submitted	Norway	Chemical registered under REACH	08-Oct-2024
Rosin, fumarated	266-040-8	65997-04-8	Submitted	Norway	Chemical registered under REACH	08-Oct-2024
Rosin, hydrogenated	266-041-3	65997-06-0	Submitted	Norway	Chemical registered under REACH	08-Oct-2024
Resin acids and Rosin acids, maleated, esters with pentaerythritol IUPAC name: Rosin, Maleic Penta Ester	305-516-2	94581-17-6	Submitted	Norway	Chemical registered under REACH	08-Oct-2024
Fatty acids, tall oil and rosin reacted with maleic anhydride	940-281-5	-	Submitted	Norway	Chemical registered under REACH	08-Oct-2024
Fatty acids, tall-oil, oligomeric reaction products with maleic anhydride and rosin, calcium magnesium zinc salts	500-451-8	160901-14-4	Submitted	Norway	Chemical registered under REACH	08-Oct-2024
Resin acids and Rosin acids, fumarated, esters with glycerol	307-051-0	97489-11-7	Submitted	Norway	Chemical registered under REACH	08-Oct-2024

- CLH Assessment (Norwegian MSCA)

9 Rosin and Rosin Derivatives substances listed
(8 managed by H4R) – see next slide

H4R CONSORTIUM

Pine Chemicals ASSOCIATION INTERNATIONAL

[1] ARN: Assessment of Regulatory Needs
[2] CLH: Harmonized Classification and Labelling

Penman Consulting

Rosin and Rosin Derivatives substances – CLH report outcome

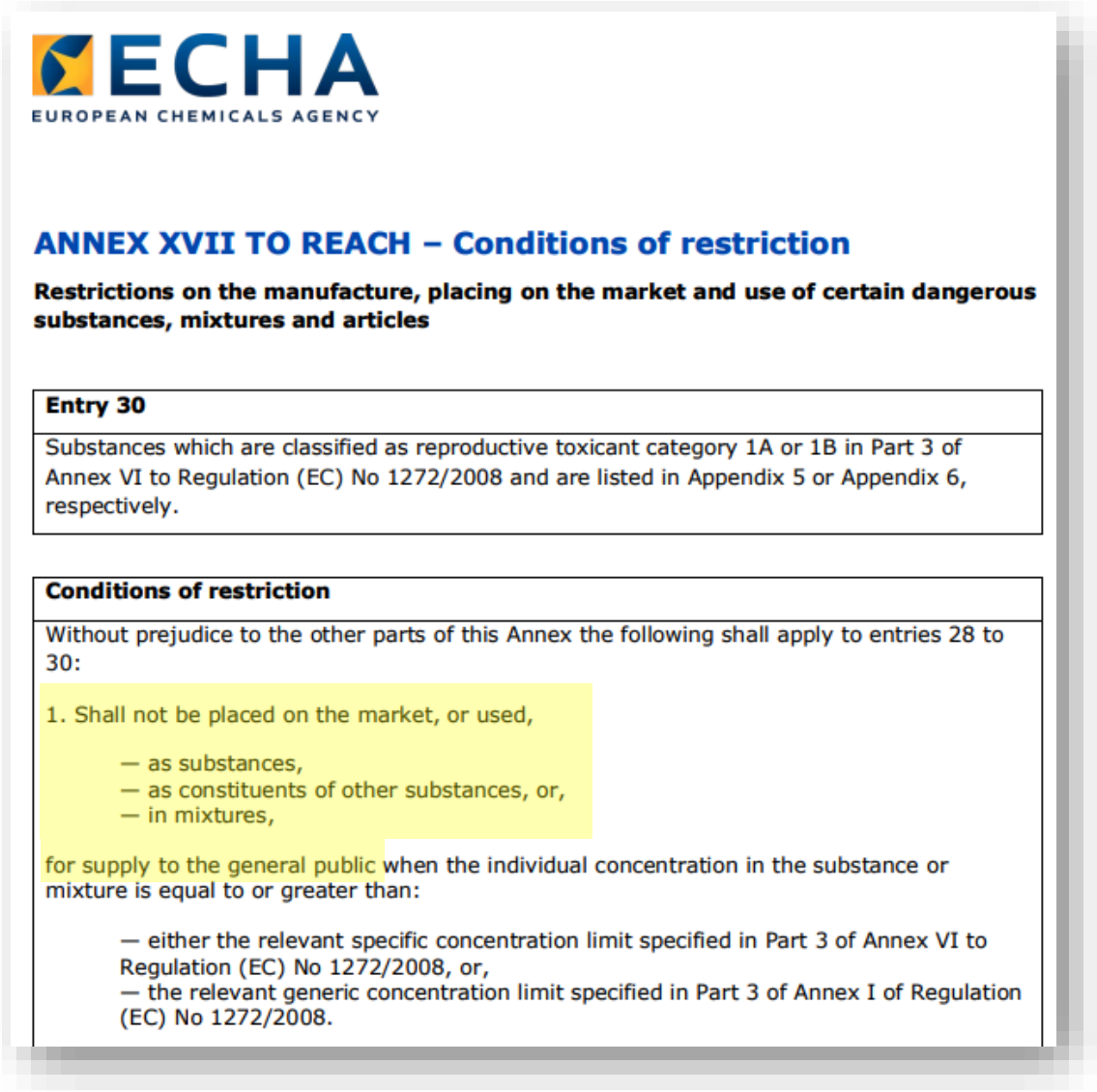
Table 1. Rosin and rosin derivatives of CLH reports as published by ECHA on the 1st September 2025

CAS	EC	Substance	H4R Category	Proposed harmonised classification of CLH reports (Updated 1st September 2025)	Hazard code
8050-09-7	232-475-7	Rosin; colophony	1	Repr. Cat. 1B	H360Df
65997-05-9	500-163-2	Rosin, oligomers	1	Repr. Cat. 1B	H360Df
65997-06-0	266-041-3	Rosin, hydrogenated	1	Repr. Cat. 2	H361f
65997-04-8	266-040-8	Rosin, fumarated	3	Repr. Cat. 2	H361f
8050-28-0	232-480-4	Rosin, maleated	3	Repr. Cat. 1B	H360D
	500-451-8	Fatty acids, tall oil, oligomeric reaction products with maleic anhydride and rosin, calcium magnesium zinc salts	Cease of Manufacture / No Active registrations	Repr. Cat. 2	H361f
94581-17-6	305-516-2	Resin acids and Rosin acids, maleated, esters with pentaerythritol	4	Repr. 2	H361fd
97489-11-7	307-051-0	Resin acids and Rosin acids, fumarated, esters with glycerol	4	Repr. 2	H361d

Simple Rosin Esters out of scope of current assessment

Why is this important?

- If CMR classification adopted, it is very likely that the substance becomes a "**S**ubstance of **V**ery **H**igh **C**oncern"
- Leads to Restricted uses in the European market and stigmatization
  - Consumer and professional uses
  - Industrial use and articles needs further assessment
- Existential threat to the pine chemicals industry
  - Source material producers
  - Pine chemicals producers
  - Industry manufacturing products using them
- Other Rosin substances are likely to be evaluated following this first CLH proposals (including Tall oils)



ECHA
EUROPEAN CHEMICALS AGENCY

ANNEX XVII TO REACH – Conditions of restriction

Restrictions on the manufacture, placing on the market and use of certain dangerous substances, mixtures and articles

Entry 30
Substances which are classified as reproductive toxicant category 1A or 1B in Part 3 of Annex VI to Regulation (EC) No 1272/2008 and are listed in Appendix 5 or Appendix 6, respectively.

Conditions of restriction
Without prejudice to the other parts of this Annex the following shall apply to entries 28 to 30: 1. Shall not be placed on the market, or used, — as substances, — as constituents of other substances, or, — in mixtures, for supply to the general public when the individual concentration in the substance or mixture is equal to or greater than: — either the relevant specific concentration limit specified in Part 3 of Annex VI to Regulation (EC) No 1272/2008, or, — the relevant generic concentration limit specified in Part 3 of Annex I of Regulation (EC) No 1272/2008.

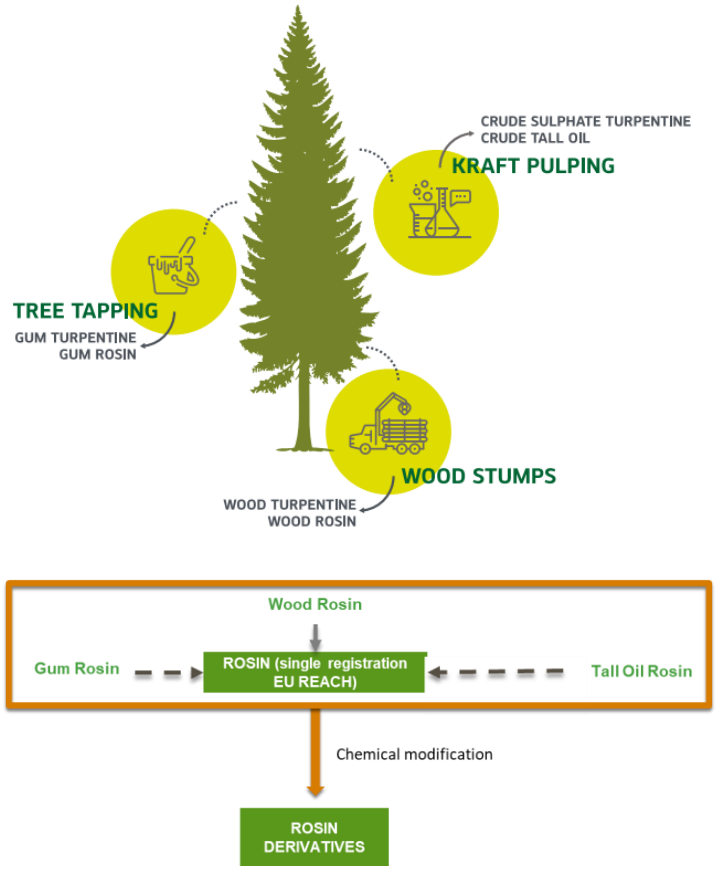
H4R CONSORTIUM

Pine Chemicals ASSOCIATION INTERNATIONAL

Penman Consulting

Why is this important?

Impact of restriction will be detrimental



"Pine chemical products, extracted from pine trees, are used in a wide array of consumer goods including paints, inks, adhesives, perfumes, flavors in soft drinks and food, fragrances in soaps and household cleaners, food additives, vitamins, automobile tires, and many more applications.

Consumers touch, smell, and consume pine chemical products every day"

H4R CONSORTIUM

Pine Chemicals ASSOCIATION INTERNATIONAL

Sources:
- Prof Eckhard Weidner et al., "Analysis Of The European Crude Tall Oil Industry – Environmental Impact, Socio-economic Value & Downstream Potential", Fraunhofer Umsicht, for PCA.
- Dr. Smita Bhatia, Lakshmikumaran & Sridharan, "Global Impact of the Modern Pine Chemical Industry", PCA

Penman Consulting

Why is this important?

Examples of application/critical sectors impacted by classification:

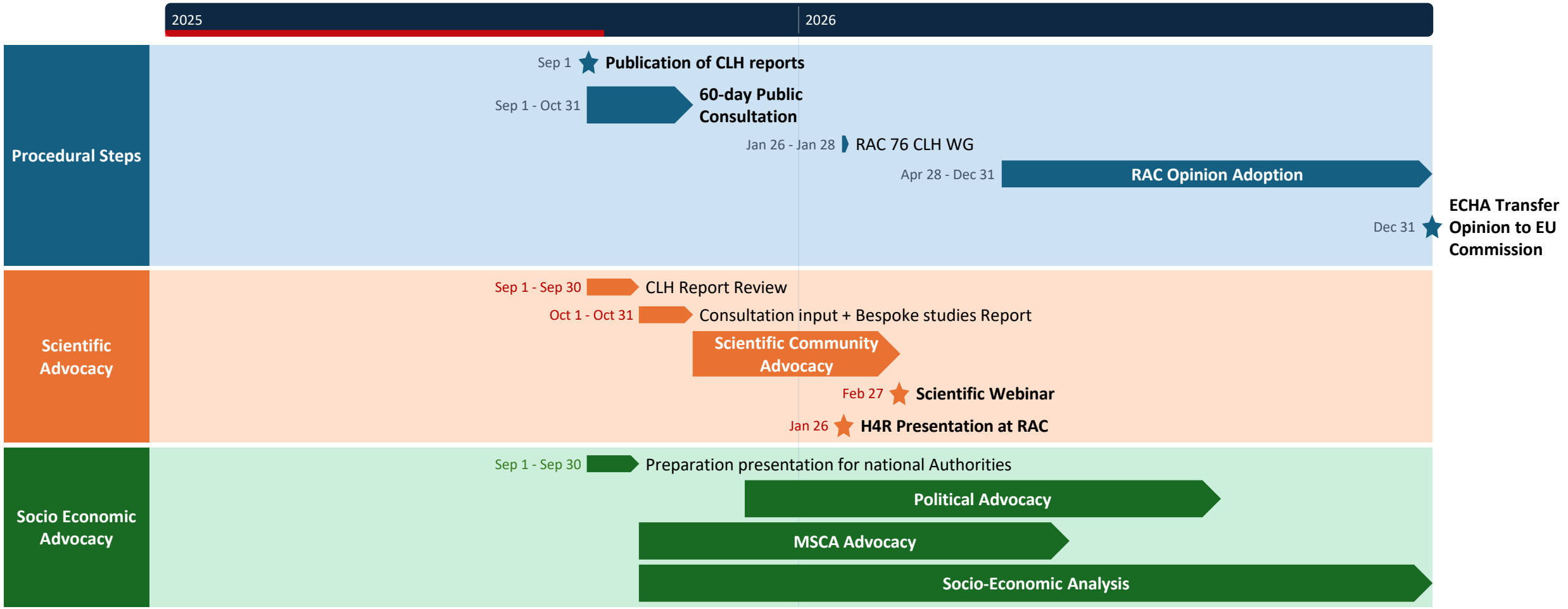
- Flooring Adhesive, Coating/**Construction**
- Soldering Fluxes/**Electronic**
- Tyre Modifications, Rubber emulsifier, Rubber Productions/**Automotive**
- Adhesive/**Smart phones**
- Casting waxes/**Defence**
- Depilatory waxes/**Health and Beauty**
- Paper sizing, Pigment coating, Gravure inks, Offset inks / **Media, packaging**
- Adhesives/**All sectors**

Examples of Regulation/Guidance on CMR (ban, substitution, restriction):

- Cosmetic (1223/2009/EC (Art. 15))
- Food and food packaging / Drinking water
- Packaging inks (Swiss Ordinance, German Ink Ordinance, EuPIA's Exclusion Policy for Printing Inks and Related Products)
- Medicinal products (89/79/EC)
- Pharmaceuticals / Drug use
- Automotive industry
- Toy Safety Directive (2009(48/EC)
- German Ink Ordinance

Timeline of key REACH activities

From CLH report publication (September 2025) to transition period (2029)



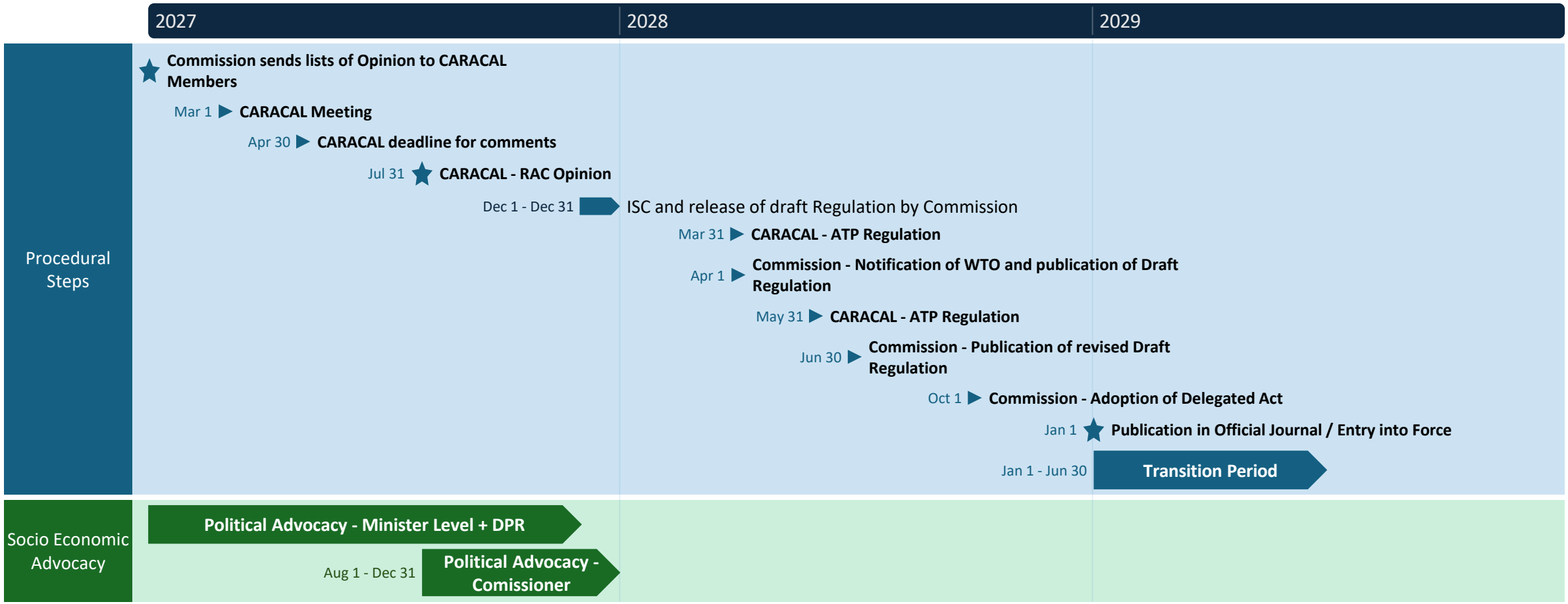
H4R CONSORTIUM

Pine Chemicals ASSOCIATION INTERNATIONAL

Penman Consulting

Timeline of key REACH activities

From CLH report publication (2025) to transition period (2029)



H4R CONSORTIUM

Pine Chemicals ASSOCIATION INTERNATIONAL

Penman Consulting

Scientific and regulatory action to mitigate the risk of potential classification

Twin-track Approach

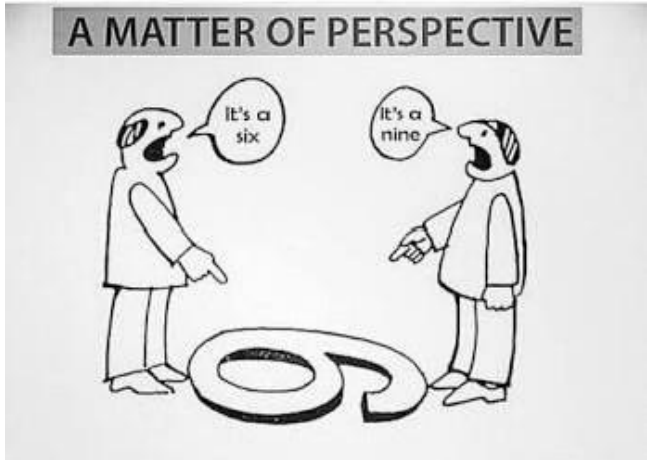
- **Scientific [PCA/H4R]**:
  - Provide evidence that there is NO hazard to reproduction

- **Socio-economic [HARRPA]**:
  - Even if the substances were hazardous, they are NOT risky
  - Provide a benefit to society (essential **uses**?)
  - Example of a sustainable industry

Scientific (1)

- **Rosin and Rosin derivatives should not be classified for reproductive toxicity** since the observed (minimal) effects are not linked to the chemistry of the substances

- **Fertility** effects are caused by under-nutrition secondary to diet unpalatability
  - *This is a **beneficial adaptive** response.*
  - ***Not adverse** and therefore should not lead to classification*
- **Development** effects are secondary to **non-specific maternal toxicity**
  - *Therefore, should not lead to classification*



- Review of CLH report ongoing
  - Rebuttal documents will be prepared and submitted during Public Consultation period

Scientific (2)

- PCA and H4R are sponsoring 2 additional **Mechanistic studies** to substantiate the hypotheses
  1. **Bespoke study to investigate transiency of fertility effect:**
     - Some evidence of transiency were observed under the conditions of the study.
     - Effect of Rosin was rapidly reversible following cessation of treatment.

  2. **Feed restriction study to investigate the underlying mechanism**

     (*i.e.*, the causal relationship between undernutrition and fertility)
     - The data strongly support the hypothesis that the developmental effects of dietary Rosin are caused by undernourishment.
     - Feed restriction study was not conclusive on the fertility issue as unexpectedly, dietary Rosin did not lower fertility.

The 2 additional mechanistic studies were not considered by the Norwegian Authorities in the preparation of the CLH reports but will be submitted during the public consultation period.

Scientific (3)

- External double-blind peer-review of all relevant studies submitted in the H4R dossiers by SciPinion - currently ongoing
  - Expected completion date: December 2025

Socio-economic arguments

- A survey on EU tonnages & uses for the 7 CLH substances was initiated and sent to all EU REACH registrants.
  - Aim is to strengthen overall dossier quality, remove unrealistic uses and ensure there are no inconsistencies in information (especially since dossiers are under regulatory scrutiny)

- Socio-Economical assessment by HARRPA/Ricardo Group

Industry Call to Action

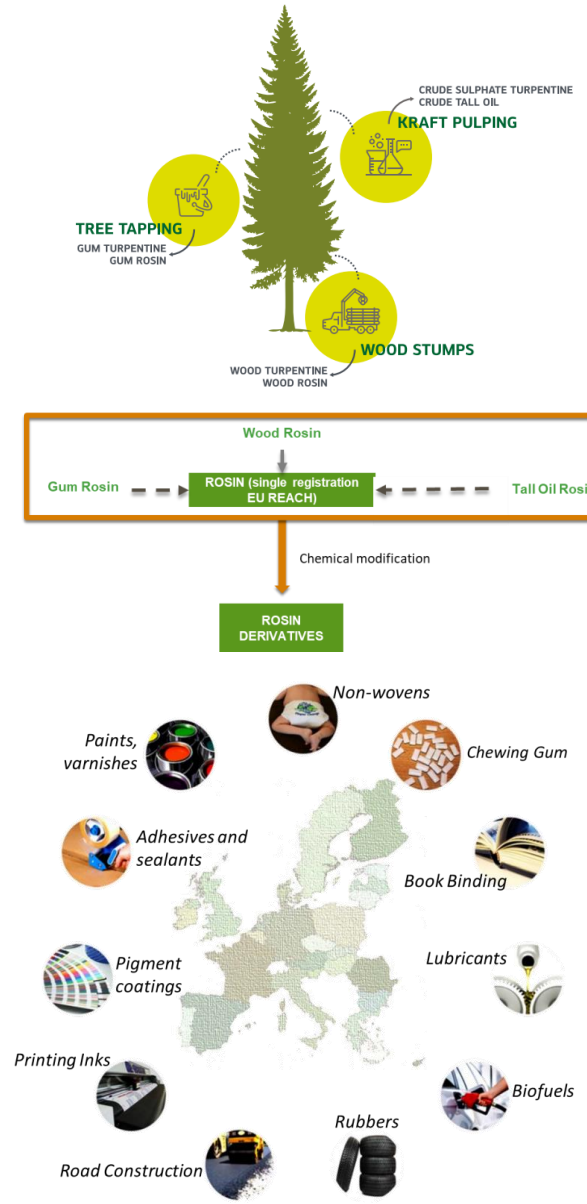
- *Scientific defense*:
  - Contribute during Public Consultation Phase **(Deadline 31st October 2025)**
    - Any scientific data we are unaware of?

    (This phase should focus on science and hazard)
    - Contribution to EU tonnages & uses survey for the 7 CLH substances
    - Complementary PCA/H4R/HARRPA joint webinar and Q&A session on following steps and guidance: **14th October 2025 15:00 CET/09:00 EDT**

- *Socio-economic defense*:
  - Identification of 'real-world' Uses
  - Which Uses might be considered **essential**?
  - Argumentation around sustainability

In summary

- Potential Repro (1B and 2) classification for Rosin and certain Rosin derivatives will have **a detrimental impact up and down the supply chain**
- H4R and PCA have been conducting additional studies to prove CLH is unwarranted
- H4R, with support from HARRPA, continues engaging with European authorities
  - Ensuring a balanced view and level playing field
- Stakeholder input needed during the public consultation (01st Sep - 31st Oct 2025)
  - Focus on the science / intrinsic hazard properties
- Further engagement will be needed later in the process (14th Oct 2025)
  - Socio-economical, political, sustainable value, regrettable substitution
- Timeframe: continuing through to late 2026
- Need to speak with one voice / Joint statement available on respective website
  - Stay engaged throughout the process and include your regulatory teams
  - Your contribution will be needed



H4R CONSORTIUM

Image sources:
- Prof Eckhard Weidner et al., "Analysis Of The European Crude Tall Oil Industry – Environmental Impact, Socio-economic Value & Downstream Potential", Fraunhofer Umsicht, for PCA.
- Dr. Smita Bhatia, Lakshmikumaran & Sridharan, "Global Impact of the Modern Pine Chemical Industry", PCA

Thank you for your attention

Complementary PCA/H4AR/HARRPA joint webinar and Q&A session scheduled

14th October 2025 15:00 CET/09:00 EDT