04 June 2026

Joint Communication from HARRPA, H4R Consortium, and PCA regarding the Status of the CLH process for Rosin and Rosin derivatives[1]

H4R, PCA and HARRPA are jointly taking steps to rebut the ongoing CLH proposal to classify Rosin and several of its derivatives as Category 1B and Category 2 reproductive toxicants. Last April 30th H4R submitted updated rebuttals and other documents to the ECHA Secretariat, including the full mechanistic study reports that were finalized in March 2026. Our updated suite of documents demonstrates that effects seen in lab studies are not substance-specific but result from maternal undernourishment as rodents reject rosin-laced feed.

After the 2023 ARN report raised concern on reproductive toxicity, we conducted a thorough review of existing test data. This reconfirmed what we had concluded when REACH testing was completed namely that, except for one substance, the observed effects on fertility (ovulation) and development (pup growth) could be attributed to maternal undernutrition. To prove this with new data, H4R and PCA commissioned two new mechanistic studies. The first, a transiency study, was set up to test whether effects on fertility were transient and reversible. The second, a feed restriction study, was devised to test directly the hypothesis that effects on fertility and development were caused by undernutrition.

The first study provided indication of transiency and demonstrated that that the effects on ovulation were reversible. The second study (feed-restriction study) was inconclusive on fertility effects, as no reduction in corpora lutea and implantation sites counts was observed neither in the feed-restricted dams nor in the rosin-fed dams, compared to the control group of the study. However, the results confirmed that maternal undernourishment was responsible for the retarded pup growth. Indeed, the growth of offsprings from feed-restricted dams was indistinguishable (statistically and biologically) from the offspring of Rosin-exposed dams.

The conclusion is that, for all substances except Rosin Maleated[2], the developmental and fertility effects are caused by maternal undernourishment as rats restrict dietary intake when their food is mixed with unpalatable rosin.

It should be noted that these studies and the refined statistical analysis were not yet available to the Norwegian Environmental Agency at the time of drafting the CLH reports. They have now been made available to the RAC for evaluation. The data from these studies are also presented in a peer-reviewed article published in the Journal Reproductive Toxicity which is publicly available here. The publication is an important milestone in our defence strategy, as it makes new and robust data to support our case publicly available. Furthermore, the learnings on substance-independent maternal undernutrition could benefit the global regulatory toxicology community when similar effects are observed in toxicological studies on other substances.

The RAC is expected to review the submitted data and discuss the classification at RAC 78 CLH WG on 29 June – 1 July, the earliest possible adoption date is the RAC 78 Plenary meeting on 7-11 September. The legal deadline for adoption of the opinions is 24 December 2026. After adoption, ECHA will transfer

[1] Please also see our previous joint public communications : HARRPA_H4R_PCA_Rosin_DU_comm_Nov 2024, HARRPA H4R PCA Rosin Joint Comm Sept 2025 HARRPA H4R , and PCA Rosin Joint Comm Nov 2025

2 For Rosin Maleated regulatory tests indicate effects on development that might not be fully explained by maternal undernutrition.

the dossier to the European Commission, which will then begin its internal process to consider all relevant evidence on the proposed harmonisation of the classification and labelling of Rosin and Rosin derivates.

As part of this process, the European Commission will consult with Member States during the CARACAL meetings in March 2027. In the meantime, HARRPA is actively engaging with Member States to raise awareness of the potential socio-economic and unintended environmental impacts of the proposed classifications, should it be endorsed by the RAC and passed into law by the European Commission.

A Category 1B classification would have immediate consequences, as it triggers an automatic EU-wide ban on the substance in consumer applications. A Category 2 classification, while it does not trigger an automatic EU-wide ban, it may introduce occupational exposure requirements under national Occupational Safety and Health schemes, among other requirements. This would affect not only the rosin industry but also closely linked sectors such as pulp and paper. Reduced demand for rosin could also undermine the health of production forests and increase the risk of forest fires.

Following the Dossier Submitter (Norway) intention to submit such harmonised classification dossiers in 2024, HARRPA commissioned an independent third-party study from Ricardo (WSP Group) to assess the socio-economic impact of such proposal. The Socio-Economic Assessment (SEA) is expected to be finalised end of June 2026.

Important to recall that a RAC opinion, even one supporting classification, is a scientific recommendation rather than the final legislative outcome. The legally binding decision lies with the European Commission and is taken only after consultation with Member States. HARRPA, H4R and PCA will therefore remain fully engaged throughout the remaining stages of the process, ensuring that the conclusions of the SEA, alongside the scientific evidence, are available to inform that decision and that the real-world consequences of any classification are properly understood.

In case you have any questions, please contact us at manager@h4rconsortium.com.

On behalf of the members of HARRPA, H4R Consortium, and PCA.