

ANSES' conclusions challenge EU's formaldehyde risk assessment: Formacare responds, citing no new evidence

Representing Europe's formaldehyde industry, Formacare, a sector group of Cefic underlines the absence of new scientific evidence in ANSES' [report](#) linking formaldehyde exposure and myeloid leukaemia in humans. These conclusions are at odds with existing EU risk assessments and are not underpinned by new scientific evidence. In light of this, we urge the European Commission and ECHA (European Chemicals Agency) to continue upholding a science-based approach.

The 2023 opinion from ANSES (French Agency for Food, Environmental and Occupational Health & Safety) is based on old scientific evidence. This evidence has since been challenged by more recent studies as demonstrated by two independent assessments, commissioned by Formacare, of the ANSES opinion which have both found significant scientific and methodological shortcomings in the ANSES 2023 report.

Various European bodies, including ECHA's RAC (Risk Assessment Committee), SCOEL (Scientific Committee on Occupational Exposure Limits), and even ANSES itself, have previously concluded that there is no evidence supporting a mode of action explaining an effect of formaldehyde on bone marrow where myeloid leukaemia originates. ANSES' current stance deviates from past assessments, such as its own opinion in [2018](#), its RMOA (Regulatory Management Option Analysis) in [2016](#), the SCOEL's opinion in [2016](#) and the RAC's opinion in [2012](#). Without any new relevant data, this change in position seems unwarranted.

This report could unjustifiably impact the scientific integrity of future EU regulatory measures. Given the potential implications of ANSES' conclusions on the European approach to formaldehyde, we believe it is crucial to initiate a broader scientific discussion involving European experts and relevant stakeholders. The European Union's legislation must be underpinned by robust and consistent scientific assessments.

Formacare acknowledges the 2023 recommendation from ANSES' Scientific Board to enhance collaboration between ANSES and its stakeholders and to fortify the connection between ANSES and research entities. However, neither public consultation nor scientific debate are foreseen in the current scientific assessment process, which does not meet the best practices of expertise.

Formaldehyde is among the most thoroughly studied chemicals worldwide. Formacare supports all European regulations in place. We are committed to rigorously assessing new scientific data and remain available to discuss the existing evidence on formaldehyde safety with authorities.