



NMP Regulatory Status under REACH -- May 2018

On April 18, 2018, the [European Union \(EU\) issued its regulation implementing workplace exposure restrictions for N-methylpyrrolidone \(NMP\) under the European Union's \(EU\) Registration, Evaluation, Authorization and Restriction of Chemicals \(REACH\) regulation.](#) The regulation entered into force on May 9, 2018, the twentieth day following its publication in the Official Journal of the European Union.

Background

In its evaluation of a proposal for restriction submitted by the Dutch Member State in 2013, the European Chemicals Agency's (ECHA) Risk Assessment Committee (RAC) agreed with the proposal for restriction but did not agree with the Dutch derived no effect level (DNEL) for NMP. The RAC proposed a DNEL of ten mg/m³, but this value did not align with the legally binding Indicative Occupational Exposure Limit Values (IOELV) of 40 mg/m³ established by the European Scientific Committee on Occupational Exposure Limit Values (SCOEL). As such, the RAC and SCOEL were advised to come to an agreement on what the occupational exposure limit (OEL) for NMP should be, but were unable to do so.

Because the RAC and SCOEL could not reach an agreement, the European Commission (EC) stepped in to make a decision.

Current Status

As articulated in the regulatory language, the EC agreed that a restriction establishing DNEL thresholds was the most appropriate measure to protect workers exposed to NMP.

The regulation restricts the sale, manufacture, or use in the EU of products containing NMP in concentrations of 0.3 percent or more unless the manufacturers, processors, and users take the appropriate risk management measures, including operational conditions, to ensure that workers are not exposed to concentrations above the established DNEL values which are 14.4 mg/m³ for inhalation exposures and 4.8 mg/kg/day for dermal exposures.

Industry stakeholders have a two-year period, until **May 9, 2020**, to implement the restriction. The Commission provided an extended timeframe for industry stakeholders selling or using NMP as a solvent or reactant in wire coating, until **May 9, 2024**. By the established deadlines, companies will need to calculate new exposure scenarios and implement additional risk minimization measures if necessary to meet the new DNEL values.

The European trade group representing NMP manufacturers have agreed to proceed with adoptions of REACH registration dossiers and updated safety data sheets to promote early implementation of risk management measures.