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NMP Regulatory Status under REACH -- April 2017

Background

In 2013, the Dutch Member State submitted a proposal to the European Chemicals Agency (ECHA) to restrict manufacturing, and all industrial and professional uses of NMP under the European Union's (EU) Registration, Evaluation, Authorization and Restriction of Chemicals (REACH) regulatory program. The proposal included a recommended occupational exposure level of five mg/m³, based on the Dutch calculation of a derived no effect level.

In November 2014, ECHA's Risk Assessment Committee (RAC) reviewed the Dutch dossier. The RAC agreed with the restriction proposal but determined that the DNEL for NMP should be ten mg/m³, not five mg/m³ as proposed by the Dutch. The Socio-Economic Assessment Committee (SEAC) also agreed that restriction is the best risk management approach for NMP.

The DNEL of ten mg/m³ from ECHA RAC was not in alignment 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 for NMP should be, but were unable to do so.

On March 2, 2017, ECHA published a draft recommendation that NMP go through Authorization. While the ECHA action to publish a recommendation that NMP go through authorization seems to contradict its RAC agreement that restriction is the best risk management option, the authorization recommendation is not entirely surprising, as ECHA is simply following its internal procedures, which includes recommending any substance on the candidate list in the order of its priority score.

Current Status

Because the ECHA RAC and SCOEL could not come to a consensus on the occupational exposure limit, the European Commission (EC) must make a decision on the original restriction proposal of the Dutch with the five mg/m³ limit. The EC is not limited in its consideration of the suggested occupational exposure levels. It could adopt the Dutch proposal of five mg/m³, the RAC proposal of ten mg/m³, the IOELV of 40 mg/m³, or any other level it views as appropriate. The Committee review of the NMP restriction is ongoing.

It is very important to note that a substance cannot simultaneously undergo restriction and authorization. Because the EC is currently considering the Dutch restriction proposal, the ECHA authorization recommendation is on hold. Furthermore, it is the EC that

NMP Regulatory Status under REACH – April 2017

Page 2

will make any final decision regarding NMP authorization or restriction. ECHA does not have any legislative power to amend an annex of REACH regulation.

European industry stakeholders continue to believe that NMP restriction is still the most likely outcome for NMP. The CEFIC Butanediol (BDG) Sector Group, which represents the European NMP manufacturers, is urging the EC to end this period of regulatory uncertainty by amending Annex XVII to include NMP restriction.

Opportunities for Advocacy

Industry groups can weigh in on support for the restriction approach as part of the ECHA authorization comment period, ending on **June 2, 2017**. Comments should be made to both ECHA and the EC. The NMP Producers Group can provide further instructions to groups interested in engaging in advocacy on this issue.