NEWSLETTER APRIL 2018

REACH

NMP restriction published

COMMISSION REGULATION (EU) 2018/588 of 18 April 2018 amending Annex XVII to Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorization and Restriction of Chemicals (REACH) as regards ***1-methyl-2-pyrrolidone***

Foreward

On August 9th 2013, the Netherlands submitted to the ECHA a dossier pursuant to Article 69(4) of Regulation (EC) No 1907/2006 ('the Annex XV dossier' (2)), proposing to restrict ***1-methyl-2-pyrrolidone*** (NMP). The Annex XV dossier demonstrated that action on a Union-wide basis was necessary to address risks to the health of workers exposed to NMP. The Netherlands based its hazard assessment of NMP on the effects of the substance on several human health endpoints. Developmental toxicity was considered the most critical of those endpoints and was used to determine a level (the derived no-effect level or 'DNEL') above which workers should not be exposed to NMP by inhalation. Regulation (EC) No 1272/2008 of the European Parliament and of the Council (3) provides that, where NMP is present in mixtures in a concentration of 0,3 % or higher, they are to be classified as toxic for reproduction, category 1B. The restriction should apply in relation to such mixtures, as well as to the substance on its own.

On June 5th 2014, the Agency's Risk Assessment Committee (***RAC***) adopted its opinion, confirming that developmental toxicity was the most critical health endpoint. RAC considered, however, that a different assessment factor from that used by The Netherlands should be applied to calculate the DNEL for NMP. This resulted in a level twice as high as that proposed by The Netherlands for exposure of workers to NMP via the inhalation route. RAC also calculated a DNEL for exposure of workers to NMP via the dermal route, which had not been proposed by The Netherlands.

RAC confirmed that overall exposure to NMP above those two DNELs poses a risk to the health of workers and that the proposed restriction, based on those two DNELs, is the most appropriate Union-wide measure to reduce that risk in terms of its effectiveness.

On November 25th 2014, the Agency's Socio-Economic Assessment Committee (***SEAC***) adopted its opinion, concluding that the proposed restriction, as modified by RAC, is the most appropriate Union-wide measure to reduce the risk to the health of workers arising from NMP in terms of its socioeconomic benefits and socioeconomic costs. SEAC recommended a five year general deferral of application of the restriction, in line with the period proposed in the Annex XV dossier, to allow stakeholders to take the necessary compliance measures. SEAC considered that a longer deferral period might be appropriate for the wire coating sector, which was identified by The Netherlands as the sector on which the proposed restriction could have the greatest impact in relation to costs. The Agency's Forum for Exchange of Information on Enforcement, referred to in Article 76(1)(f) of Regulation (EC) No 1907/2006, was consulted during the restriction process and its recommendations have been taken into account.

On December 9th 2014, the Agency submitted the opinions of RAC and SEAC (1) to the Commission. On becoming aware of a discrepancy between the DNEL for exposure to NMP via the inhalation route proposed by RAC in its opinion and the indicative occupational exposure limit for NMP established under Council Directive 98/24/EC (2) following a scientific opinion of the Scientific Committee on Occupational Exposure Limits for chemical substances (SCOEL), the Commission asked RAC and SCOEL to work together to resolve the issue in accordance with Article 95(3) of Regulation (EC) No 1907/2006. As a result of this, on 30 November 2016 RAC proposed a modified DNEL for exposure of workers to NMP via the inhalation route. Based on the opinions of RAC and SEAC, the Commission considers that there is an unacceptable risk to the health of workers during the manufacture and use of NMP which needs to be addressed on a Union-wide basis. A restriction establishing DNELs for exposure of workers to NMP via both the inhalation and the dermal routes is the most appropriate Union-wide measure to address that risk. Such a restriction would be more appropriate than the indicative occupational exposure limit for NMP established under Directive 98/24/EC for the following reasons: the overall risk characterization ratio is based on quantified DNELs for inhalation and dermal exposure to NMP; the harmonization of the chemical safety report in the registration dossier via harmonized DNELs can only be established under Regulation (EC) No 1907/2006; downstream users will have the same time period as manufacturers and importers to put in place the appropriate risk management measures and operational conditions in order to ensure that exposure of workers to NMP is below the two DNELs; the safety data sheets will include those DNELs in the appropriate specific sections. Therefore, the proposed restriction is the most appropriate Union-wide measure to address the risk to the health of workers from exposure to NMP. DNELs are to be applied when conducting the chemical safety assessment of a substance under Regulation (EC) No 1907/2006 in order to help determine the measures that need to be taken to manage the risk presented by the substance in particular exposure scenarios. Where manufacturers, importers or downstream users intend to place NMP as a substance on the market on its own or in mixtures in a certain concentration, that assessment should be made available to users of the substance by means of chemical safety reports and safety data sheets. Manufacturers and downstream users should ensure that the DNELs are complied with when the substance is manufactured or used, on its own or in a mixture. Stakeholders should be allowed sufficient time to take appropriate measures to comply with the proposed restriction, particularly in the wire coating sector, where the costs of implementing the restriction will be particularly high. Therefore, taking into account the SEAC recommendation, the application of the restriction should be deferred. The deferral period should have regard to the delay in the restriction process due to the collaboration between RAC and SCOEL

Therefore the following entry is added to the Annex to XVII of Reach regulation:
1-methyl-2-pyrrolidone(NMP), CAS No 872-50-4, EC No 212-828-1

1. Shall not be placed on the market as a substance on its own or in mixtures in a concentration equal to or greater than 0,3 % after May 9th 2020 unless manufacturers, importers and downstream users have included in the relevant chemical safety reports and safety data sheets, Derived No-Effect Levels (DNELs) relating to exposure of workers of **14,4 mg/m3** for exposure by inhalation and **4,8 mg/kg/day** for dermal exposure.

2. Shall not be manufactured, or used, as a substance on its own or in mixtures in a concentration equal to or greater than 0,3 % after May 9th 2020 unless manufacturers and downstream users take the appropriate risk management measures and provide the appropriate operational conditions to ensure that exposure of workers is below the DNELs specified in paragraph 1.

3. By way of derogation from paragraphs 1 and 2, the obligations laid down therein shall apply from May 9th 2024 in relation to placing on the market for use, or use, as a solvent or reactant in the process of coating wires.

SECOND REVISION OF APPLICATION of REACH REGULATION

We reports here the conclusion of the document "COMMUNICATION FROM THE COMMISSION TO THE EUROPEAN PARLIAMENT, THE COUNCIL AND THE EUROPEAN ECONOMIC AND SOCIAL COMMITTEE Commission General Report on the operation of REACH and review of certain elements: Conclusions and Actions"

The REACH Evaluation concludes overall that REACH is addressing today's citizens' concerns about chemical safety. REACH is effective but opportunities for further improvement, simplification and burden reduction have been identified, which can be achieved by delivering the actions outlined in the report. Those should be implemented in line with the renewed EU Industrial Policy Strategy, Circular Economy Action Plan and the 7th Environment Action Program. REACH is found to be generally coherent with other EU legislation concerning chemicals and delivers the international goals as intended. Implementation is still on-going in all areas, with some key milestones, such as the last registration deadline, still to be completed by June 2018. Many of the costs of REACH have been incurred and benefits are starting to materialize. The REACH evaluation has concluded that the legal requirements and obligations are well tuned to achieving the needs and objectives pursued. While this communication has identified a number of actions that will further improve REACH, there is currently no need to change its enacting terms.

Sixteen (16) actions has been identified by the Commission for the REACH refit in the next future. Those in blue bold are, in our opinions, the most relevant for industry:

Action n. 1: encourage updating of registration dossiers
Action n. 2: improve evaluation procedures
Action n. 3: improving the workability and quality of extended Safety Data Sheets
Action n. 4: tracking substances of concern in the supply chain
Action n. 5: promote substitution of SVHCs
Action n. 6: simplification for a more workable authorization process
Action n. 7: early socio-economic information for possible regulatory measures
Action n. 8: improve Restriction Procedure
Action n. 9: Further enhance Member State involvement in the restriction procedure
Action n. 10: Frame the application of the precautionary principle
Action n. 11: Interplay between authorisation and restriction
Action n. 12: Interface REACH and OSH (Occupational, Safety and Health) legislation
Action n. 13: Enhance enforcement
Action n. 14: Support compliance by SMEs
Action n. 15: Fees and the future of ECHA
Action n. 16: Review of registration requirements for low tonnage substances and polymers

RAC recommends an occupational exposure limit for benzene

At its March meeting, the Committee for Risk Assessment (RAC) also recommended occupational exposure limits (OELs) for two other substances: nickel and its compounds, benzene and acrylonitrile. These opinions conclude the response to the European Commission, which for the first time asked RAC to assess the scientific basis for setting OELs.

Benzene is a genotoxic carcinogen, known to cause leukaemia. RAC is of the opinion that a threshold based on the indirect (i.e. not directly DNA-damaging) genotoxic effects of benzene in workers can be used to derive a new occupational exposure limit. The proposed ***OEL = 0.05 parts per million*** will protect workers from leukaemia as well as other adverse health effects. Exposure to benzene occurs in the petroleum and chemical industries and also as a result of gasoline engine emissions and combustion products.

RAC also proposed an ***OEL = 0.45 parts per million*** for acrylonitrile, a monomer used in many plastics.

For nickel and its compounds, it proposed ***OELs = 0.005 mg/m3*** for respirable dust and ***0.03 mg/m3*** for inhalable dust. The proposals are based on the latest scientific evidence and were subject to public consultation. In addition, industry and trade unions were able to attend the RAC plenary sessions and provide further comments on the Committee's draft opinions.

These opinions follow the European Commission's request in March 2017 for RAC to provide within a year scientific opinions on five OELs for chemicals under Occupational Safety and Health legislation for the consideration of the Commission's Advisory Committee on Health and Safety at Work. The scientific advice from RAC will help the Commission to amend exisiting or add new OELs to the Carcinogens and Mutagens Directive and better protect workers from cancer-causing chemicals.

OELs set the maximum concentration for such substances in the air at workplaces in the EU.

Latest events

SCA, Food-Contact Substances, and FDA Seminar
8-10 May 2018 * Keller and Heckman LLP * Omni Chicago Hotel, USA

SETAC Europe 28th Annual Meeting
13-17 May 2018 * SETAC Europe * Rome, Italy

3 Days Hazard Communication Workshop (CLP, SDS, eSDS)
15-17 May 2018 * Yordas * Lancaster, United Kingdom

Introduction to OSPAR and REACH
23 May 2018 * Yordas * Lancaster, United Kingdom

Global Food Contact Chemical Safety & Compliance Seminar
24 May 2018 * Intertek * Arlington Heights, IL, United States

OECD QSAR Toolbox V 4.2 training: Basic (June 11-12) and Advanced Practical (June 13-15)
11-15 June 2018, Reach Monitor SL and LMC OASIS, World Trade Center, Barcelona, Spain

Chemspec Europe 2018
20-21 June 2018, Mack Brooks Exhibitions , Cologne, Germany

TSGE Prague Biocide Conference 2018, Prague
Focus on SMEs - Keeping up with the progress on active substance approvals
Date: 21 - 22 June 2018, ***Two Chemsafe lectures***

ITALY

Piano nazionale dei controlli 2018 (National inspection plans fir 2018)

The Italian Ministry Of health has published the National plano f Inspection for 2018. It can be downloaded form the MoH web site under Reach pages.

CHEMSAFE: PARTICIPATION TO EVENTS

In the frame of our pharmaceutical/medical health activity, we are now engaged in organizing two workshop during the Italian ***AFI*** (Associazione Farmaceutici Industria) Symposium in Rimini on 6-8 June 2018.
The first workshop will be focused on ***Medical Devices*** and the second one on ***ERA*** (Environmental Risk Assessment) of medicines. 8 Chemsafe experts will be directly involved as speakers; we expect also to have external guests from companies. Both workshop will be held on Wednesday June 6, 29018 in the morning session. The participation is free; you are all welcome!!

Chemsafe will sponsor and participate as speaker at the **TSGE Prague Biocide Conference 2018**: *Focus on SMEs - Keeping up with the progress on active substance approvals*
Date: 21 - 22 June 2018
Venue: Hotel Occidental Praha (formerly known as Barceló Praha Hotel), Prague
TSGE Forum's annual biocide conference will be returning to the Occidental Praga Hotel, Prague for the fourth consecutive year. Suitable for those involved in the biocides industry, the conference is ideal for meeting a wide range of EU regulators, experts and industry participants from across Europe. The 2018 program will focus on the experience and challenges of SMEs in respect to Mutual Recognition procedures and further progress made in active substance approvals. In addition latest developments in data protection issues, BPR enforcement, borderline cases with other EU legislations and EU guidances will be discussed.
As with previous conferences, the event will offer plenty of networking opportunities, including a drinks reception.

Confirmed speakers include:
Dr Mandy Osterloh - Dow Microbial Control
Product Authorization: Industry Experience with Union Authorization
Thomas Raas - Redebel Regulatory Affairs
Dr. Antonio Conto - Chemsafe Srl
BPR Dossier Project Management, regulatory and management challenges
Dr. Francesca Fasano - Chemsafe Srl
Risk Assessment of Disinfection By-Products
Tatjana Röder - aquagroup AG