COMMISSION REGULATION (EU) No 109/2012 of 9 February 2012 amending Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) as regards Annex XVII (CMR substances)

Restriction of Nickel containing chemicals classified as CMR cat 1A and 1B in the 1st ATP

Introduction

REACH foresees a restriction process to regulate the manufacture, placing on the market or use of certain substances, either on their own or in mixtures or articles, within the EU territory if they pose an unacceptable risk to health or the environment. Such activities may be limited or even banned, if necessary. The restriction is designed to manage risks that are not addressed by the other REACH processes or by other EU legislation.

The restriction process is regulated by Title VIII of the REACH Regulation (EC) N° 1907/2006 of the European Parliament and of the Council of 18 December 2006[1] as amended by Commission Regulation 552/2009[2] and some provisions of Annex XVII to REACH Regulation. In 2009, the European Commission launched a "fast track" Restriction process for nickel containing chemicals included in the 1st ATP. This "fast track" procedure is based on Article 68(2)[3] of REACH and does not require an Annex XV dossier. Under Article 68(2), the Commission can amend Annex XVII via the "comitology" procedure (i.e. the Regulatory Procedure with Scrutiny). Under this procedure, the legislative act is adopted by the Commission following an opinion of the EU REACH Committee and a three-months scrutiny period by the European Parliament and the Coouncil of EU.

In this context, in September 2011, the EU REACH Committee expressed a favorable opinion (by qualified majority vote) on a package of restrictions for substances placed on Annex VI of the CLP Regulation with a harmonised classification of category 1A or 1B carcinogen under the first Adaptation to Technical Progress (ATP) in 2009. Under the procedure, the restriction of substances with such a classification will apply to consumer applications under Annex XVII (sections 28-30) of REACH. This package of restrictions covers those nickel containing chemicals which are included in the 1st ATP and are classified as CMR cat 1A and 1B. The

[1] *OJ L 396, 30.12.2006, p. 1.*
[2] *OJ L 164, 26.6.2009, p. 7.*
[3] *For a substance on its own, in a preparation of in an article which meets the criteria for classification as carcinogenic, mutagenic or toxic in reproduction, category 1A or 1B, and could be used by consumers and for which restrictions to consumer use are proposed by the Commission, Annex XVII shall be amended in accordance with the procedure referred to in Article 133(4). Articles 69 to 73 shall not apply.*

Regulation has been published on 10th February 2012 in the Official Journal[4]. The legislation shall enter into force on the 20th day following its publication and it shall apply three months after its entry into force.

What are the consequences for the Nickel Industry and its Downstream Users?

The proposed Regulation will amend REACH Annex XVII providing that the Nickel containing chemicals covered by the restriction "shall not be placed on the market or used as substances, as constituents of other substances, or, in mixtures, for supply to the general public […]". In other words, the Restriction of nickel containing chemicals will focus on consumer use of these substances on their own or in preparations. 138 Nickel containing chemicals are covered by this Restriction. However, it should be noted that only 23 of them have been registered under REACH. Moreover, these chemicals have been registered in EU as intermediates or as substances without any identified consumer use. This means that none of the nickel containing chemicals included in the Restriction process are sold (or should be) to the consumers in EU.

Overall, the impact of the restriction of the nickel containing chemicals to consumer use on the Nickel Industry and its Downstream Users is negligible. Furthermore, the restriction may even have positive implications as it can give to the Nickel industry the opportunity to reiterate that the use of nickel containing chemicals is already highly regulated. This could influence positively the listing & authorization process and especially the prioritization of the substance before inclusion into Annex XIV.

Next steps

The Institute continues to be committed to supporting the downstream users of commercial nickel containing chemicals. It is also committed to ensuring that regulatory decisions in the EU and globally are risk-based, using sound science and rigorous processes. Through its different activities and its REACH Authorisation management programme, the Nickel Institute will continue to minimise the likelihood of key nickel containing chemicals being subject to Authorisation and limit to the extent possible, other downstream regulatory consequences within the EU and globally.

For Further Information

Mrs. Veronique Steukers, Director, Global Government Affairs & Advocacy

Mrs. France Capon, Senior Advisor, Chemicals Management

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[4] *OJ L37/1, 10.02.2012: http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2012:037:0001:0049:en:PDF*