24 May 2013

Questions to MEPs European Parliament hearing with Geert Dancet (ECHA)

Topic	Question	Background
1. Candidate List	How could the Commission and ECHA avoid the 'black list' effect associated with the candidate list?	As noted by the Commission, the 'black list effect' of the candidate list is real. Indeed, downstream users have the perception that a listing on the candidate list means a future ban and the need for substitution. Several retailers and service providers have demonstrated over the last five years that they consider the Candidate List a black list and react to it immediately, long before a decision is taken on what the appropriate outcome of such a listing may be. ***It is therefore critical for the Commission and ECHA to add, in relevant communications on the candidate list, a clear and visible explanation that if a substance is on the list it does not mean that it is banned***; it can continue to be used and be present in articles until and unless subject to a ban pursuant to an authorisation and/or restriction process. Some national authorities have been proceeding this way for some

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		time. As example of such best practice is that of the French authorities, who publish an 'avis' explaining that the listing of a substance is not a ban on the Official Journal of the French Republic.
2. RMO Transparency	We welcome the Commission's emphasis on Risk Management Options (RMO) analyses in choosing how to manage the risk of substances. However, we have heard many echoes that this process, as currently run by Member States, lacks in transparency. What could the Commission and ECHA do to ensure stakeholders, particularly industry (and including downstream users), are consulted in this process?	In its SVHC Roadmap, the Commission states that '*in general RMO is not meant to be made public and no consultation of stakeholders is foreseen. However, the Authority drafting the RMO can consider if the publication and consultation of stakeholders is appropriate*'. The same Roadmap states that around 160 RMO analyses have been made since 2009, and yet, none of these results have ever been shared. We believe that industry, including downstream users, should always participate in the RMO analysis stage. This is key to ensure the transparency and efficiency of the RMO process and to ensure all the relevant information is collected. Previous experience has shown how important it is to collect information on the value chain, and on the different uses of substances. Such data collection would obviously be easier if industry were involved in this process at the earliest stage. ***The decision about whether to seek public consultation should not be left to national authorities alone. The Commission should recommend early involvement***

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		of industry, including actors of the supply chain, in the RMO analyses run at national level.
3. Fast Track Restrictions for Substances in Articles	How can the Commission and ECHA establish criteria to ensure that the 'fast track' restriction procedure of Article 68.2 of REACH is applied only in exceptional circumstances, e.g. in cases where there are known uncontrolled risks to consumers requiring urgent action.	Industry is greatly concerned about the possible broad application of Article 68(2) to articles containing CMRs 1A and 1B that would introduce yet another layer of uncertainty for many European businesses. The Commission has launched a stakeholder consultation on certain CMR 1A and 1B substances in articles. The declared objective of this project is to elaborate criteria for the implementation of the 'fast track' restriction process mentioned in article 68(2) of REACH. The Commission consultation is entitled 'The potential impact on industrial competitiveness of restrictions on certain CMR 1A and 1B substances in articles' but it only requires market/use information. Industry is afraid that a fast track restriction process could be instigated on substances in articles on the basis of mere use/content, without demonstrating that the use, ***or presence of that substance in consumer articles, actually represents an unacceptable risk to human health or the environment that can only be addressed at the EU level***. Industry considers that the fast-track restriction procedure of Article 68(2) should only be used in exceptional circumstances e.g. in cases

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		where there are known uncontrolled risks to consumers requiring urgent action. For CMR in Articles, a complete analysis of the impact of any restriction should be performed on an individual substance basis including the need for robust scientific background and socio-economic evaluation, as well as the availability of alternatives as foreseen in REACH Article 68(1).
4. REACH and RoHS	Can the Commission and ECHA take positive steps to ensure regulatory coherence between REACH and RoHS and a predicable regulatory environment favouring investment and innovation in EEE products?	Regulatory coherence between the different European regulatory texts is of the utmost importance for industry. We have made significant investments both financially and in terms of knowledge building (and its dissemination along the value chain) to comply with these regulations and will continue to do so in the future. The RoHS II Directive mandates that the list of restricted substances must be 'coherent' with REACH, (take account of its Annex XIV and XVII), 'maximise synergies' and reflect the 'complementary nature' of the work carried out under REACH. We therefore recommend a close link with REACH and the tools that REACH provide for the assessment and restrictions of substances (Annex XVII). We also encourage the different Commission units and DGs which are responsible for REACH and RoHS to collaborate closely on this issue.

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5. Downstream Users	Can the Commission and ECHA take positive steps to ensure that Downstream Users, receive appropriate assistance from authorities to (i) comply with REACH, (ii) ensure continued supply of critical substances and (iii) yet maintain or enhance their competitiveness and innovation potential?	The REACH Review is only very partially addressing the concerns of downstream users, notably in terms of the impact of REACH on to cause supply chain disruptions and hamper business continuity. The supply of critical chemicals (especially where substitutes do not exist) is a major concern of many of Europe's industry sectors (such as electronics, automotive, aerospace, healthcare and toys), especially where very low volumes of chemicals are used in critical applications. Another concern is the protection of intellectual property, for example, where manufacturers of articles are obliged to share sensitive information with competitors and suppliers. Downstream users would like a system that is predictable and provides legal certainty, which in turn will foster innovation and competitiveness. Unfortunately, REACH in its current form cannot be considered as a stable regulatory environment that encourages inward investment to the EU and associated economic growth and jobs. The Commission should also undertake a comprehensive assessment of the impact of REACH on downstream user industries as a matter of top priority.

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		Several concrete measures could be taken in this respect, including: - Requiring consistent interpretations of the Regulation across Member States - More application of Art. 58 (2) granting specific exemptions for chemicals for specific industrial uses in tightly controlled environments - More risk-based decision-making versus hazard. For example, Annex XV proposals to add a substance to the SVHC list should take into account whether there are any risks associated with the use of a substance. - Intellectual property rights more effectively protected. - Improvement of existing technical guidance and the introduction of new guidance where gaps exist.
6. Substance Identity	Can the Commission/ECHA take positive steps to ensure that only well-defined 'substances' according to the substance definition in REACH and ECHA guidelines on substance identity are proposed by regulators e.g. for inclusion in the	REACH includes a definition of a 'substance' that also applies to substances in articles. Also the ECHA has developed guidelines containing criteria for the identification of substances that are requested to be applied by Industry, notably when submitting registration dossiers. By contrast, in some instances, regulatory authorities have not applied the same rules when

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	Candidate List?	identifying substances for listing on the candidate list[i]. It is important that only well-defined 'substances' according to the substance definition in REACH and ECHA Guidelines on Substance identity should be proposed by regulators e.g. for inclusion in the Candidate List. To the extent possible, substance identification should be provided by both the EC and the CAS Registry Number. Considering the seriousness of REACH compliance and the resources that industry is already investing to ensure compliance, regulators should also undertake upfront research to fully define substances that are subject to regulatory action.

[i] Example from the December 2012 List:
4-(1,1,3,3-tetramethylbutyl)phenol, ethoxylated [covering well-defined substances and UVCB substances, polymers and homologues]

Example from the substance list published for consultation in March 2013:
4-Nonylphenol, branched and linear, ethoxylated [substances with a linear and/or branched alkyl chain with a carbon number of 9 covalently bound in position 4 to phenol, ethoxylated covering UVCB- and well-defined substances, polymers and homologues, which include any of the individual isomers and/or combinations thereof]

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