

Summary of the Presentation:
Controversial Issues in Applying REACH: How to comply with some non-precise Legal Duties?
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The Cases:

- **Case 1:** J, the Japanese manufacturer of chemicals, intends to entrust his subsidiary J-GmbH with the assumption of the duties of an OR (Only Representative); it is contemplated that the J-GmbH will also act on behalf of other foreign manufacturers of the same substance: Can this result in a disadvantage for the Japanese manufacturer J? The Chinese enterprise C is not a manufacturer but a distributor of chemicals: What are the possibilities of C to be represented in the EC's REACH process?
- **Case 2:** The German varnishing handicraft enterprise V learns that M, the manufacturer of a varnish (in the sense of REACH: the formulator of a preparation) he uses for painting of cars, has forgotten to include this application in its registration. What obligations does V now have: Is he obliged to pre-register and register with ECHA or is he only obliged to submit a chemical safety report? Is there a difference if V is an SME with only 50 employees? Can V demand that the manufacturer M takes over his obligations?
- **Case 3:** The tyre manufacturer R uses substance X for the production of his tyres and textile manufacturer T uses substance Y for the production of his t-shirts, both in quantities exceeding 1 tonne per year. The automobile manufacturer A uses the chemical substance Z (exceeding 0.1 % w/w) for the production of his passenger vehicles in quantities exceeding 1 tonne per year. What actions are R, T and A required to take?

Results concerning the Cases:

Result 1: For non-Community manufacturers the appointment of an OR has the advantage that it is always ensured that he can supply his products directly to all his EC customers. In addition, the non-Community manufacturer has better control over the registration process, and this way is more customer-friendly. By contrast, it will legally not be allowed that a non-Community manufacturer directly supplies a customer in the EC (e.g. a German customer) with REACH substances of 1 t/year, if the substances delivered to the German customer are neither covered by the OR's registration nor by the German customer's registration as importer. The German subsidiary of a Japanese manufacturer can resume the responsibility of an OR. Without appointment of an OR, the risk is high that the Japanese manufacturer will lose his clients in the EC, if the clients are not willing to register the substances as importers. If an OR represents several non-Community manufacturers of the same substance, he must submit separate registration dossiers for each of them; in such case in the OR contract due care should be given to the confidentiality of business information. A Chinese *distributor* of chemicals is not allowed appointing an OR or a TPR (Third Party Representative). If this distributor is not able to engage or found a company in the EC which

assumes the REACH obligations, he finally may no longer export substances, preparations or articles to the EC which are subject to registration obligations. Such discriminating effects may be solved in the future, if the EC and Japan are willing to apply the principle of mutual recognition of the REACH legislation of both the EC and Japan to each other, so that the registration is possible either in the EC or in Japan.

Second Result: A DU is any commercial “user” of substances in the EC in the sense that he is processing, consuming, storing, or treating the substance for commercial activities. If the manufacturer or importer of substances, who has done the pre-registration and registration for the uses in three formulations, has forgotten to register also the use of a few DUs for a fourth formulation of this substance, this DU is not permitted to use or sell this fourth formulation. The affected DUs may possibly try to make a late pre-registration under Art.28 para.6 REACH, however, in principle this is only possible if they in the future intend also to manufacture or import this formulation. If none of the exceptions under Art.37 para.4 REACH applies, this DU must prepare and hold available a chemical safety report for the non-registered use (there are no exceptions foreseen for SME), without being able to force the manufacturer to register this new use. Because of the risk of losing clients or of damage claims, the DU may be able to transfer the duty of preparing the chemical safety report to the manufacturer. The DU should provide information about intended uses as early as possible to the manufacturer.

Third Result: An “article” should be assumed if the processing of the material has been completed and no further significant processing steps are to be undertaken, so that the shape, surface and design is more important than the chemical composition. One could assume that in case of tyres a release of substances “under normal or reasonably foreseeable conditions” would take place, however due to EChA guidance, unintended but unavoidable releases such as the friction wear of tyres is outside of the scope of duty for registration of substances in articles. Even in this EChA guidance, the drawing line between “foreseeable” and non-foreseeable conditions is very thin and not free of contradictions, so that the question of a release of substances in the sense of Art.7 REACH should be double-checked. In case that substances are included in the article which belong to the candidate list of substances of very high concern (Annex XIV), the producer or importer of articles must send notifications to EChA (if more than 1 t/year and concentration value is 0.1 % w/w) and must answer requests from consumers (if concentration value is 0.1% w/w).

Time Schedule under REACH:

- Pre-registration from 1 June 2008 until 1 December 2008.
- Commencing 2 December 2008: prohibition of the marketing and sale of non pre-registered substances prior to their registration.
- By 1 June 2010: Registration of CMR substances in quantities exceeding 1 tonne per year, for substances posing a hazard to water in quantities exceeding 100 tonnes per year and for other substances in quantities exceeding 1,000 tonnes per year, provided they were pre-registered until 1 December 2008 (otherwise registration is already required as of 2 December 2008)
- By 1 June 2013: Registration for other substances in quantities exceeding 100 tonnes per year, provided they were pre-registered until 1 December 2008 (otherwise registration is already required as of 2 December 2008)
- By 1 June 2018: Registration for other substances in quantities exceeding 1 tonne per year provided they were pre-registered until 1 December 2008 (otherwise registration is already required as of 2 December 2008).

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- **Customs law** (tariff classification, legally binding tariff decisions, customs procedures, AES/ATLAS, preferences, origin of goods, market regimes etc, application for AEO certification in all EC Member States)
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