REACH OCTOBER 2018 UPDATE

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Today's Topics

1. U.K. Government notice on regulating chemicals if there is no Brexit deal
2. Recent ECHA Board of Appeals decisions
3. Open ECHA consultations

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UK Notice: IF NO BREXIT DEAL

- On October 1, 2018, the UK Department for Environment Food & Rural Affairs issued a notice explaining how UK chemical companies would be affected if the UK leaves the EU in March 2019 with no deal.
- According to the UK Government: “Negotiations are progressing well and both we and the EU continue to work hard to seek a positive deal. However, it’s our duty as a responsible government to prepare for all eventualities, including ‘no deal’, until we can be certain of the outcome of those negotiations.”

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After March 2019 If There's No Deal

- UK would:
  - Ensure UK legislation replaces EU chemicals legislation via the EU Withdrawal Act.
  - Establish a UK regulatory framework and build domestic capacity to deliver the functions currently performed by ECHA.
  - The legislation would preserve REACH as far as possible, while making technical changes that would need to be made because the UK has left the EU.
- The Health and Safety Executive (HSE) would act as the lead UK regulatory authority, from the day the UK leaves the EU.
- Registration of new chemicals through a UK IT system that is similar to the existing REACH-IT system
- In a 'no deal' scenario, the UK would not be legally committed to medium- or long-term regulatory alignment with the European Economic Area (EEA).

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What Does This Mean?

- Companies registered under REACH would no longer be able to sell into the EEA market without transferring their registrations to an EEA-based organization.
  - Appoint EEA Only Representative (OR)? Will ECHA waive fees?
  - Transfer Registrations to EEA importer? Will ECHA allow manufacturer to importer or manufacturer/importer to OR transfers?
  - What about where the UK company served as Lead Registrant?
- UK downstream users currently importing chemicals from an EEA country would face new UK registration requirements.
- UK downstream users of authorizations would no longer be able to rely on authorization decisions addressed to companies in the remaining EEA countries.

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What Will the UK Do to Ensure Continued Access to UK Markets

- Carry across existing REACH registrations held by UK-based companies directly into the UK's replacement for REACH, legally 'grandfathering' the registrations into the UK regime.
- Set up a transitional light-touch notification process for UK companies importing chemicals from the EEA that don't hold a REACH registration before the UK leaves the EU. This would mean that those UK companies could continue to buy those chemicals from the EEA without any break.
- Carry into the UK system all existing authorizations to continue using higher-risk chemicals held by UK companies.

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What Would UK Companies Need to Do?

- Companies with existing EU REACH registrations being automatically grandfathered into the UK regime or authorizations would have to validate their existing registration with the HSE, open an account on the new UK IT system and provide some basic information on their existing registration within 60 days of the UK leaving the EU.
- Companies with grandfathered registrations would have two years from the day the UK leaves the EU to provide the HSE **with the full data package** that supported their original EU registration and is held on the ECHA IT system.
- Businesses that imported chemicals from the EEA before the UK leaves the EU (but who did not have an EU REACH registration), would need to notify the UK authority and provide some basic data on the chemicals within 180 days of the UK leaving the EU, instead of having to undertake a full registration immediately.
- This would be an **interim arrangement for those importers and they would need to move to full registration at a later date** following a review of this approach.

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Special Arrangements

- Special arrangements with Ireland, Norway, Iceland and Liechtenstein are being contemplated.

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ECHA Board of Appeals

- The Board of Appeals is responsible for deciding appeals lodged against certain decisions of the ECHA taken under the REACH Regulation and the Biocidal Products Regulation.
- In the case of REACH, these include: failures during completeness check; test proposal decision; compliance check decisions; substance evaluation decisions; decisions by ECHA to grant or deny access to data to potential registrants. Note that appeals have suspensive effect.
- Although the Board of Appeals is part of the Agency, it makes its decisions independently.
- The Board of Appeals consists of a Chairman and two members (one legally qualified and one technically qualified).
- The Board of Appeals is assisted in the performance of its functions by the Registry.

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Statistics

- 113 cases have been lodged before the Board of Appeals
- 91 final REACH decisions
  - 22 dismissed the Appeal
  - 25 upheld the Appeal
  - 44 cases resulted in Withdrawal because ECHA rectified their decision

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REACheck Solutions GmbH (A-011-2017) Decided 23 March 2018

- Case involved a Potential Registrant opting-out completely from the Lead Registrant (LR) Dossier
- Dispute over price for the “token”
- The ECHA granted the token for free because it decided the LR has not negotiated in good faith
- Board of Appeals dismissed the case as inadmissible because the granting of a token was outside of the Board’s remit, but observed:
  - Potential registrant in a full opt-out situation can bypass the LR and ask ECHA directly for the token;
  - But a full opt-out registrant takes its chances as its dossier will be a high priority for completeness check.

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SI Group UK Ltd et. al. (Case A-006-2016) Decided 6 June 2018

- In the context of substance evaluation, ECHA has authority to require monomer registrants to provide information they have in their possession on the polymers produced from the monomers and the level of monomer impurities and degradants.
- ECHA can not order monomer registrants to provide information on downstream polymers if that information is not in their possession.

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Cosmetic Regulation Cases

- Several cases concerning the intersection between REACH and the animal testing ban under the Cosmetics Regulation
- Cases involve cosmetic use-only substances
- The ECHA Board of Appeals held in BASF Personal Care and Nutrition GmbH, Germany (Case A-013-2016) that ECHA must take a position on the interpretation of the Cosmetics Regulation insofar as this is necessary to interpret and apply the REACH Regulation.
- In Symrise AG, Germany (Case A-009-2016) the Appellant raised the cosmetics regulation issue for the first time at the oral hearing, so the Board did not consider this issue.
- Symrise AG (Case A-010-2018) is a pending case that raises this issue again

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ECHA Consultations – BPA

- 4,4‘-isopropylidenediphenol (bisphenol A; BPA) – Recommendation for inclusion on the Annex XIV Authorisation List.
- BPA is proposed for listing on Annex XIV on the basis of human health (reproductive toxicity and endocrine disruption) and environmental effects (endocrine disruption)
- Normally food-contact uses are exempt from authorization **but only if the basis for listing is human health effects**
- Article 58(2) could provide a basis for exemption but very difficult to achieve

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Article 58(2) REACH

- According to Article 58(2) of the REACH Regulation, “uses or categories of uses may be exempted from the authorisation requirement provided that, on the basis of the existing specific Community legislation imposing minimum requirements relating to the protection of human health or the environment for the use of the substance, the risk is properly controlled”.
- ECHA considered that the following must be true:
  - There is existing EU legislation (*i.e.* Regulations and Directives adopted by the EU institutions) addressing the use (or categories of use) that is proposed to be exempted. Only existing EU legislation is relevant in the context to be assessed (not national legislation).
  - The existing EU legislation must properly control the risks to human health and/or the environment from the use of the substance arising from the intrinsic properties of the substance that are specified in Annex XIV.
  - The existing EU legislation imposes minimum requirements for the control of risks of the use throughout the life cycle of the substance.

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Implications

- Placement on the EEA market and use of BPA or mixtures containing BPA at 0.1% w/w or more.
- Imported articles exempt but a restriction could be adopted.
- Imported resins where BPA is present only as an impurity would not be covered but a restriction could be adopted.
- Deadline for commenting is December 5, 2018.

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Select Other Open Consultations

- Recommendation for inclusion of 2-methoxyethanol and 2-ethoxyethanol on Annex XIV. Comments due December 5, 2018.
- Proposals for harmonized classification of various substances: https://echa.europa.eu/harmonised-classification-and-labelling-consultation
- Proposals for listing on the Candidate list: https://echa.europa.eu/substances-of-very-high-concern-identification
- Proposals for Restrictions: https://echa.europa.eu/restrictions-under-consideration

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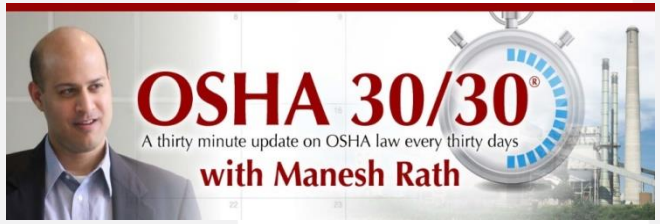

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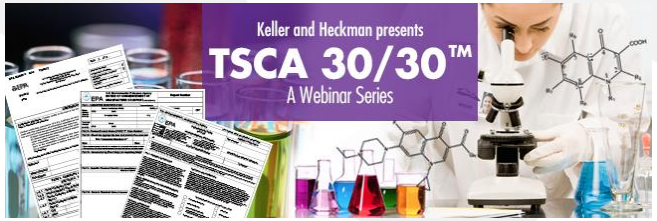

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THANK YOU

Next REACH 30/30 on December 12, 2018 at 1:35 pm EDT

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