

Examples of impact of Court and BoA decisions on REACH and ECHA's processes

24 May 2017

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**First Category: Cases where
implementation is relatively
straight forward**

Changes to information published on ECHA's website

- Change of ECHA's legal notice indicating the legally binding decisions which ECHA publishes (C-625/11 P)
- Updating guidance documents as a result of Court judgments and BoA decisions:
 - Court and Board of Appeal decisions confirming ECHA's approach in relation to PBT/ vPvB assessment
 - Updating practical guides reflecting BoA's confirmation of ECHA's read across and weight of evidence approaches

Simple changes to ECHA's processes

- Change of ECHA's notification letters in dossier evaluation explicitly indicating by when registration updates will be considered (A-003-2012)
- Adapting ECHA's addressee policy in substance evaluation to registrants that are in the registration pipeline

More time consuming changes to ECHA's processes

- Implementing measures to ensure that registrants of the same substance are part of the same joint submission – IT systems needed to be adapted
- Changing guidance documents as a result of Court judgments:
 - Polymer guidance
 - Guidance on substances in articles

Process changes requiring MS cooperation

- BoA clarified requirements for all substance evaluation decisions. Normally compliance check should be first used to address data gaps in a registration (Case A-005-2014)
- Examples of impact:
 - Preparing and presenting assessment of the case to Member States and seeking agreement on approach to take
 - Change of decision formats and templates; training
 - Review and in some cases withdrawal of on-going substance evaluation cases
 - Review approach for future cases – still discussion among Member States whether data gaps can be addressed in SEV
 - Consequence: Less substance evaluation decisions taken

**Second Category: Cases where
implementation is complex**

Consensus building - Balancing of interests

- Topics that require the Agency to balance complex scientific and legal considerations, but also political choices of determining an appropriate level of protection for the society
- The European Commission and the Member States are intrinsically involved in adopting ECHA's positions

"Collective agreement within the Agency's Member State Committee on its draft decisions should provide the basis for an efficient system that respects the principle of subsidiarity, while maintaining the internal market" - Recital 67 REACH

- *"The BoA may exercise any power which lies within the competence of the Agency" - Article 93(3)*

Consensus building - Interpretation of REACH principles

- Certain topics depend on the eventual interpretation of the REACH Regulation by the General Court or the Court of Justice
- Usually questions that have implication beyond the application of a specific provision
- There are various instances where these questions are also pending before the General Court or the Court of Justice when the BoA takes a decision
- This overlap affects the implementation of the BoA decision

Example of SONC

- Decision A-019-2013 on statements of non compliance (SONC)
 - The question at stake involved political considerations for the Members States as to how long period is allowed for non-compliance before enforcement
 - In that context, ECHA initial position resulted from a consensus with Commission, competent national authorities and enforcement authorities
 - Since the BoA decision, there seem to be no consensus among the Commission and Member States as to the follow-up of decisions of ECHA
 - This question is also underlying another case pending before the General Court (T-283/15)

Example of intermediate uses of substances

- Decision A-010-2014 on intermediates
 - Question at stake involved political considerations for the Member States as to the scope of the derogation of intermediate uses, especially regarding Authorisation
 - In that context, the question had been debated amongst the ECHA, Commission, competent national authorities and enforcement authorities resulting in a consensus and a document clarifying the definition
 - Since the BoA decision, there is no consensus among the Commission and Member States as to the scope of the derogation of intermediate uses of substances
 - This question is also raised before the Court of Justice in another pending case (C-650/15 P)

Example of nanomaterials

- Decision A-011-2014 on nanomaterial forms of substances
 - Beside the scientific and legal considerations, the question at stake also relate to political choices of determining an appropriate level of protection for the society in a field of a developing technology
 - This question has been debated at length amongst the ECHA, Commission and competent national authorities
 - Discussions especially with Member States highlight concerns that the decision affect their political choices regarding nanomaterials
 - Difficulty to agree on the way forward

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