REACH ED Review

Report from the Commission to review if the scope of Article 60(3) should be extended to substances identified under Article 57(f) as having endocrine disrupting properties

Background

- *Article 138(7) of REACH asked the Commission to*

  'assess whether or not, taking into account latest developments in scientific know-ledge, to extend the scope of Article 60(3) to substances identified under Article 57(f) as having endocrine disrupting properties.'

- *In other words: Whether all endocrine disruptors (Eds) should only be authorised following the 'socio-economic route'*

Background

- *Results of the review were published in December 2016 as a Communication to the European Parliament, the Council and the European Economic and Social Committee (*COM(2016) 814 final)

- *Download link: http://eur-lex.europa.eu/legal-content/en/TXT/?uri=COM:2016:814:FIN*

Elements of the report

- *The report contains the following elements:*
  - **Context, i.e. basic questions like**
    - **What is an ED in the context of the review?**
    - **What is understood by "threshold" in the context of application for authorisation (AfAs)?**
  - **Considerations on what the science tells us on determining thresholds**
  - **Policy aspects for the routes for authorisation of EDs under REACH**
  - **Conclusions**

What is understood by "threshold" in the context of AfAs?

- *ECHA guidance documents discuss relevant thresholds (e.g. guidance doc. R.8 and R.10)*
- *For human health effects, DNELs can be considered as thresholds*
- *For effects to the environment, PNECs can be considered as thresholds*

What is understood by "threshold" in the context of AfAs?

- *For non-threshold substances (not possible to determine a DNEL or PNEC), an authorisation can only be granted if the socio-economic benefits outweigh the risk to human health or the environment and no suitable alternative substances or technologies are available (socio-economic route)*
- *Also the case if no or not sufficient data to demonstrate the existence of thresholds*

What is understood by "threshold" in the context of AfAs?

- *In order to facilitate the evaluation of ECHA's committees of applications for authorisation, the RAC has derived reference DNELs (effects with threshold) or dose-response functions (effects without threshold) for most CMR substances already included in Annex XIV*
- *Reference values are not legally binding but have been developed by RAC mainly to provide predictability on how it would like the applicants' risk assessment documented*

Science considerations on thresholds of ED-related effects

- *Question of thresholds is case-by-case assessment*
- *Report briefly discusses uncertainties surrounding the determination of thresholds, e.g. due to*
  - **Limitations of current testing methods**
  - **Non-monotonic dose response curves**
  - **Critical window of exposure**
- *Those issues are often discussed for EDs, but play also a role for other non-ED effects*
- *For details please see references in report*

Conclusions of the report

- *No need to amend REACH – it has all the tools needed*
- *As is the case for all substances subject to the authorisation requirement under REACH, it is the responsibility of the applicant to demonstrate that a threshold exists and to determine that threshold in accordance with Annex I to REACH*
- *It is up to the RAC to scrutinise the assessment*

Conclusions of the report

- *As for other substances, and in order to increase predictability and legal certainty to applicants, RAC may on a case by-case basis set reference DNELs, or reference dose-response curves.*
- *The 'adequate control route' applies for those substances for which a threshold exists and it can be determined. When this is not possible, only the socio-economic route can be used.*
- *Even though determining the threshold might be particularly difficult for EDs, it cannot be excluded that it will be possible.*