# Registration, evaluation, authorisation and restriction of chemicals (REACH); European Chemicals Agency

2003/0256(COD) - 20/12/2016 - Follow-up document

The Commission presented a report on the review provided for in Article 138(7) of the REACH Regulation to assess the need to extend the scope of Article 60(3) to the substances identified under Article 57(f), which have endocrine disrupting properties.

**Background**: the Commission should review how certain substances of very high concern, i.e. those with **endocrine disrupting properties**, should be treated as part of the REACH authorisation procedure.

Endocrine disrupting substances (EDs) can be identified as substances of very high concerns under REACH based on Article 57(f) provided that there is scientific evidence of probable serious effects to human health or the environment which give rise to an equivalent level of concern to carcinogenic, mutagenic or toxic to reproduction category 1A or 1B (CMR Cat. 1A/1B) and persistent, bioaccumulating and toxic or very persistent and very bioaccumulating.

For the purpose of this review, the Commission is going to apply the WHO International Programme on Chemical Safety definition of endocrine disruptor.

**Authorisation procedures**: for an authorisation to be granted, one of the following conditions must be fulfilled:

- the risks from the use of the substance are adequately controlled (‘Adequate Control Route’), or;
- it is shown that socio-economic benefits of continued use outweigh the risks to human health or the environment arising from the use of the substance and there are no suitable alternative substances or technologies (commonly referred to as ‘Socio-Economic Route’).

The REACH Regulation therefore provides for two authorisation procedures depending on the possibility to determine a threshold or not for a substance of very high concern (with the exception of persistent, bioaccumulative, toxic or very persistent and very bioaccumulative substances which are always subjected to the ‘Socio-Economic Route’).

**Existence or not of threshold for EDs**: in 2013, the ED’s expert advisory group on EDs concluded that most experts considered that thresholds of adversity are likely to exist for EDs but may be very low for individual EDs, depending on the mode of action, potency and toxicokinetics.

Several experts also expressed the view that, although thresholds may exist, it might be difficult to estimate with any confidence the biological thresholds of adversity based on currently available standard tests.

In addition, **several uncertainties surrounding the determination of thresholds** were highlighted in the debates between scientists. Some are specific to EDs, while most are common to all chemicals.

**Conclusions**: the report noted that Article 60(3)(a) of the REACH Regulation already lays down that for substances for which it is not possible to determine a threshold, the 'Adequate Control Route' for authorisation is not possible.

The information set out in the report showed that it is not appropriate to extend *a-priori* the scope of Article 60(3) to all substances identified under Article 57(f) as substances with endocrine disrupting properties which have an equivalent level of concern.

Consequently, **Article 60(3) of REACH will continue to be applicable to those EDs for which it is not possible to determine a threshold,** only the 'Socio-Economic Route' can be used when a threshold cannot be determined.

It remains the responsibility of applicants for authorisation to demonstrate that a threshold exists and to determine that threshold in accordance with Annex I to REACH. It is up to RAC to assess the validity of the assessment and ultimately decide on the possible existence or not of this threshold. Furthermore, as for other substances, the Risk Assessment Committee may on a case-by-case basis set reference Derived No Effect Levels (DNELs), or reference dose-response curves, which industry can use when applying for authorisation.

Given that regulatory stability is desirable, **the Commission will not propose a change to the legislation**.