



Association Internationale de la Savonnerie, de la Détergence et des Produits d'Entretien  
International Association for Soaps, Detergents and Maintenance Products

## Notes on links between the ESC tool and REACH data – Update December 2014

The A.I.S.E. ESC tool was developed during the period 2008-2010 and made available to industry in July 2010. From the inception of ESC, it has been the working assumption and stated policy that key parameters used in the ESC Tool (PNEC<sup>1</sup><sub>aquatic</sub>, removal rate and tonnages) would ultimately be aligned with REACH data when those were published.

In November 2010, high tonnage substances were registered under REACH. As of April 2012, hazard data for most of these substances were available on the ECHA dissemination website. In May 2013, substances manufactured between 100 and 1000 tons per year were registered, and as of July 2014 most of these substances were available on the ECHA dissemination website. For each substance a PNEC<sub>aquatic</sub> is quoted, as well as the assessment factor used for its derivation. Removal rates in sewage treatment are not defined as such though there are environmental fate data (degradation rates etc) which are indicative of removal. Tonnages are not published, only tonnage bands, under ECHA's dissemination website.

Of all the entries in the ESC tool, around 240 were registered under REACH. Out of them, 150 were already updated from the 2010 registration deadline, having led to adaptation of 15 PNECs. Of these, around 60% are subject to a calculation in the ESC tool, and a third are automatically cleared because they are the subject of a published HERA risk assessment confirming the safety of the substance. The remainder are either exempt (e.g. low hazard, see ESC Tool Manual Annex A) or are not dealt with in ESC as individual substances.

- For those substances covered by HERA<sup>2</sup>, the current HERA PNEC was compared with the REACH PNEC specifically to establish whether this automatic clearance remains sound. In all cases it was found that either the HERA PNEC was lower than the ECHA PNEC or that any decrease in the ECHA PNEC would not have given a Risk Characterisation Ratio (RCR = PEC/PNEC) higher than 1.

**The HERA report conclusions have thus been confirmed to remain valid.**

- For substances not covered by HERA, A.I.S.E. considers that alignment of PNECs between the ESC Tool and ECHA dossiers should always be approached on a case-by-case basis,

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<sup>1</sup> PNEC<sub>aquatic</sub>: Predicted No Effect Concentration for the aquatic compartment

<sup>2</sup> <http://www.heraproject.com/> A voluntary industry programme to carry out Human and Environmental Risk Assessments on ingredients of household cleaning products. A unique European partnership established in 1999 between the makers of household cleaning products (A.I.S.E) and the chemical industry (Cefic) who supplies the raw materials.

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with a careful consideration of all the data. The following guidelines have thus been established :

- Where the REACH PNEC is higher (Less conservative) than the one already in the ESC tool, it is not a priority for modification. Except for ingredients giving a Projected Environmental Safety Ratio – PESR - ( $PESR = PEC/PNEC$ ) close to 1, alignment of these values can be considered at a later stage.
- Where the REACH PNEC is lower (More conservative) than the one already in the ESC tool:
  - When the REACH dossier is data rich and many studies are available, especially if they are recent and chronic studies (leading to a low Assessment Factor), it is a strong indication to rely on the PNEC and to adopt it. The ESC tool is then updated.
  - When a testing proposal is in the dossier, leading thus to a potential future modification of the PNEC, it was agreed that the REACH PNEC should not be adopted yet in the ESC (but only once final data are provided).

**As a result of this comparison exercise, a number of ESC PNECs have been revised to a more conservative value to align with ECHA data:**

- **In May 2012, it concerned 15 substances**
- **In December 2014, it concerns 8 substances.**

**When applying the ASP criteria to new products, as of 19 December 2014, Charter Members must use the latest version of the ESC tool.**

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