

THE RISK ASSESSMENT PROCESS UNDER HERA

The following actions are placed in chronological order:

1. Selection of the Substances

Substances are selected in accordance with one or more of the following criteria:

- usage in household detergents and cleaning products (in most cases main usage);
- high tonnage;
- typical representative of a functional class;
- suitable model substance;
- of concern to the EU Authorities.

The Hera phases 1, 2 and 3 cover 33 substances, making up more than 90% of the tonnage of household cleaning product ingredients and more than 250 CAS numbers.

2. Formation of the Assessment Team

A voluntary consortium is formed which should comprise of as many producer (ingredient manufacturers) and downstream user companies (detergent manufacturers). A lead company is identified and the companies commit to support the exercise. Producers will often participate via their substance oriented CEFIC sector group. These companies nominate experts (human and eco-toxicologists) to a (family of) **Substance Team**.

For example, for the substance group alkyl sulphates: CESIO (European Surfactant Producers), Shell chemicals (J. Heath, R. Toy, G. Veenstra), Cognis (H. Messinger); Unilever (G. Hodges, K. Fox, Ph. Carthew), Procter & Gamble (G. Boeje, C Rodriguez), Henkel (J. Steber),

For the substance group zeolite A: Zeodet (Association of Detergent Zeolite Producers), Henkel (J. Steber, N. Fedtke)

Whilst companies may take the lead in the assessment of these chemicals, it is important to note that the outcome is definitely a HERA assessment, namely a joint A.I.S.E /CEFIC one common to both industries which all agree to.

3. Data Collection

The HERA Data Manager collates all crucial information (production, volume, usage) in compliance with the competition laws. A **Formulators Team** representing the involved detergent manufacturers is created to monitor and ensure adequate data collection for the Substance Team.

The manufacturers and downstream users in the **Substance Team** gather all relevant hazard and exposure data on the substance that is to be examined. The exposure data is then stored in an ACCESS database and the hazard data in IUCLID.

4. Risk Assessment

The collected data are then reviewed and examined by the **Substance Team** for scientific consistency and completeness. Nominated eco-toxicologists and toxicologists use the collected data to carry out a risk assessment on Environmental and Human Health aspects respectively. The risk assessment is performed in accordance with the [HERA Guidance Methodology](#) which outlines the methodology of the HERA project and largely follows the Technical Guidance Document of the EU.

The resulting report is then reviewed by the Human Health Task Force and Environmental Experts Task Force. These groups in turn, evaluate the scientific consistency and ensure that the HERA Guidance Document was adhered to. When necessary, the report will be amended by the Substance team according to the comments from the Task Forces.

5. External Review Process

Transparency being a key principle of HERA, an External Advisory Panel was set up to review the work made in HERA. Further to the review of the methodology document, the External Advisory Panel's role is to examine the draft HERA assessments and provide comments to the HERA team. External consultation may also be organised through a wider group (Workshops).

The External Advisory Panel (chairman Professor J. Bridges, Surrey, U.K.) is composed of independent specialists from universities, responsible authorities, European Commission and NGO (environment, consumer, animal protection) representatives. These specialists are appointed according to the substances to be reviewed.

The External Review Process is also making draft risk assessments available on the HERA website (<http://www.heraproject.com>) thus inviting comments from a broad audience.

6. Final Publication of the Report

The Substance Team then considers the input received from these external specialists (via the external panel and the Internet website) and further compiles a final version, which is then published on the HERA website.

7. Translation of the Risk Assessment into public friendly language

A key outcome of the HERA consultation with stakeholders was the recommendation to make the conclusions of the Risk Assessment Reports understandable to consumers and other non-experts. Soon we will be able to deliver a "public-friendly" translation of these Risk Assessments and make them available via our public website at www.heraproject.com (in addition to the full risk assessment reports).