



HERA

Human and Environmental Risk Assessment
on ingredients of household cleaning products

Partnership

Producers

and

Downstream users

of chemicals in household cleaning
products.

A European joint initiative between:

- **CEFIC** (European Chemical Industry Council), suppliers of the raw materials

and

- **AISE** (International Soap, Detergent and Maintenance Products Association), formulators and manufacturers.

The concept of Hazard & Risk

Associated with a chemical, ...

- Hazard = intrinsic ability to cause adverse effect
- Risk = probability that such effects will occur in the various applications
- ➔ Risk assessment : Takes into account BOTH the hazard of that chemical AND the exposure to it (both human and environment)

The HERA Targeted Risk Assessment Concept

- Focus on ingredients of household cleaning products and identify
 - potential environmental effects
 - potential effects on human health

→ hazard
- Focus on consumer phase
 - known and probable uses and discharges of detergent and cleaning products

→ exposure

Principles

- Partnership chemical/products manufacturers
- One common risk assessment for both industries
- Safety evaluation to be based on risk & hazard; tiered approach
- Open dialogue with stakeholders
- Transparency:
 - Data
 - Procedures
- No preconception of outcome of risk assessment
 - Risk management to be considered where needed
- Avoid new testing by using existing data

Objectives

- To demonstrate to Authorities with real examples that the HERA risk assessment concept:
 - Can provide relevant safety information and evaluation concerning ingredients used in household cleaning products
 - in an efficient, effective and transparent way
- To provide relevant information to Consumers about the safety of household cleaning products
- To contribute in a useful and practical way to a risk-based approach in EU chemicals legislation
- To serve as a pilot for possible application in other product sectors and/or geographical areas

Phase I

- Develop methodology for Hera risk assessments
- Objective: efficient, good & sound science
- Work on example substances
- Objective: establish feasibility with industry partners, Authorities and all interested parties

Phase II / Phase III

Apply to all relevant substances used in household cleaning products

■ Phase 1

- Scientific and regulatory stakeholder input
- Establish methodology and write guidance manual, using two substances as examples:
optical brightener FWA 5, zeolite A
- Evaluate and refine methodology on another 14 substances / families

■ Phase 2 & 3:

Use methodology on relevant household cleaning ingredients.

- Relation with other chemical initiatives:

A voluntary initiative complementary to other chemicals management programmes: ICCA, ACA, EU Existing Chemicals, and USA HPV

HERA and the EU "Strategy for a Future Chemicals Policy"

- Revision by the EU of the Chemicals Policy through its "White Paper", Feb 2001
- Common Points:
 - Industry takes responsibility for safety
 - Information/Collaboration between manufacturers and downstream-users
 - Risk-based approach
 - Grouping of substances
 - Responds to challenges on existing substances
 - International integration

Stakeholders dialogue

- Ensure regular review of the HERA process, especially at development phase on:
 - Methodology
 - Risk Assessments
- Stakeholders input received *via* workshops and *ad hoc* meetings with Academia, EU and national Authorities, NGO's: positive, encouraging outcome
- Share experience at EU but also at Global level

HERA in summary

- Collaboration: suppliers - formulators
- Safety : based on Hazard and Risk
- Concrete outcome: one common risk assessment
- Dialogue : scientific experts, Authorities and consumer / environmental organisations discussion forum
- Consumer safety : Hera will deliver relevant information accessible to the public
- Harmonisation:
 - Towards global concepts and methods
 - Use work done elsewhere