

■ The HERA structure

HERA is a large project, requiring an adequate working structure to ensure that the necessary knowledge and experience can be brought together as described in the following chart:



■ Who is involved?

The HERA project is sponsored by two industry associations, namely Cefic (with its relevant Sector Groups) and A.I.S.E.. The sponsoring companies produce the chemical ingredients on the one side, and formulate the finished products on the other. Hence, they are vital in providing the necessary hazard data on the ingredients, the consumer exposure scenarios for the products and the expertise to make the risk assessments. HERA is also forging close links with the sister associations of A.I.S.E. and Cefic in Japan and the USA.

Companies and associations involved in the HERA project have committed themselves to an efficient development of the project by agreeing to contribute to the methodology, helping to select the substances to be studied, providing the hazard and exposure information on human health and the environment, talking to stakeholders and ultimately, producing and publishing HERA risk assessments.

■ The HERA principles

- I HERA is committed to **partnership** between supplier and formulator companies and their representative groups.
- II HERA develops an **open dialogue with stakeholders** e.g. regulatory scientists and interested European organisations.
- III **Transparency** in all its activities is essential. This includes the risk assessment procedures, agreed data-sets, justification for data selection, reasons for overriding some standard elements of procedures such as those from the Technical Guidance Document for risk assessment of new and existing chemicals in Europe.
- IV **No preconceptions exist** of the outcome of the risk assessments. The results speak for themselves.
- V Above all, HERA is a solid commitment to a **science-based risk assessment** and to the use of a tiered ('step-sequence') approach to understanding the behaviour of chemicals during the use and disposal phase of household cleaning products.
- VI The HERA approach ensures the use of robust, available data thus avoiding **unnecessary animal testing**.

■ A preferred management tool

Risk assessment is the best tool to establish the need for risk management measures and to define them appropriately. So HERA risk assessments will naturally lead to risk management decisions being taken and implemented by companies; a guidance document to help this process is being elaborated.

For more information, including the latest news, methodology and risk assessments, visit the HERA website on: www.heraproject.com

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Human and Environmental Risk Assessment
on ingredients of household cleaning products

A preferred management tool

The HERA (Human and Environmental Risk Assessment) project is a European voluntary initiative, which was launched in 1999 by the following organisations:

A.I.S.E. (*International Association for Soaps, Detergents and Maintenance Products*), representing the formulators and manufacturers of such products, and **Cefic** (*European Chemical Industry Council*), representing the suppliers and manufacturers of the raw materials.

■ Why is there a need for HERA?

Until recently, the results of safety assessments carried out on ingredients remained confidential to the company that conducted them. In today's world, both the regulators and the general public rightly demand greater transparency of the information on the potential risks posed by the ingredients of products used in the home. There is now a call for data to be published so that the need for further information, if required, can be debated in public.

HERA brings together producers of chemicals and formulators of the finished product to provide such data and to place those in the public domain.

■ Objective of HERA

HERA provides a common risk assessment framework for the household cleaning products industry, and shows that this process can deliver validated safety information on the ingredients used in these products in an effective and transparent way.

This process is intended to support a risk-based approach to chemicals legislation in the European Union, and may serve as a pilot for the application of the same process in similarly structured sectors and / or other geographical areas.



A joint European initiative between



www.aise-net.org



www.cefic.org



The novelty of HERA is threefold: partnership, common methodology and transparency...

The concept of risk versus hazard:

- The “hazard” associated with a chemical is its intrinsic ability to cause adverse effects.
- The “risk” is the probability that such effects will occur in the various applications in which the chemical will be used and discharged (exposure scenarios).
For a chemical, a risk assessment takes into account both the hazards of that chemical and the exposure to it (both human and the environment).

■ The HERA targeted risk assessment concept

Industry firmly believes that hazard assessment is **NOT** sufficient to reach conclusions about the safety of chemicals. Only when the hazard is combined with exposure information is it possible to estimate the risk a chemical may pose in any particular exposure scenario.

HERA approaches risk from a specific viewpoint: it focuses on risks to consumers and the environment resulting solely from the use of these chemicals in household cleaning products when used by the consumer... hence the terminology **HERA assessments or targeted assessments**.

Risk assessments are conducted on chemicals used in household cleaning products (which is often the main application of these chemicals). The outcome of the HERA process is the delivery of risk assessment reports in a standard and practical format.

The HERA risk assessment concept uses common principles and a common language in order to aid communication with authorities and the general public. Publication of the procedures and the assessments allows for better transparency.

■ What is the value of HERA?

To business:

Industry believes that it is essential to provide information about the potential risks posed by chemicals, and not just hazards, in order to provide its customers and consumers with a balanced perspective and reassurance that industry is behaving responsibly. With this common framework, it will be possible to gather and communicate this information consistently.

By bringing together the main data holders (supplier companies) and experts in the products and how they are used (formulator companies), industry expects to speed up the process and deepen the general understanding of the scientific basis of risk assessments.

To regulators:

Under current legislation, companies that carry out assessments on their products often use individual standards. HERA differs because it provides a common industry response to a society which increasingly demands **that industry be more transparent** in sharing its data and decision-making processes. With a speedy and efficient delivery of information, HERA should also contribute to the refinement of a risk-based approach for chemicals legislation in Europe (see paragraph aside on HERA and the EU “Strategy for a Future Chemicals Policy”), and possibly other regions of the world.

To the general public:

Data are being made available to the public by various means, the internet being an important one (through www.heraproject.com). It is also planned to communicate the outcome of the risk assessments in an accessible and understandable way to the general public. Ultimately, the companies formulating and manufacturing household cleaning products are invited to take into account the HERA risk assessments in their risk management for their future developments.

■ HERA and the EU ‘Strategy for a Future Chemicals Policy’

The HERA project was developed a few months before EU Institutions announced the revision of the Chemicals Policy through a ‘White Paper’, which was presented in February 2001.

A.I.S.E. and Cefic believe that HERA is compatible with the aspirations of this proposal given the following key common elements:

- Industry takes responsibility for the safe use of chemicals;
- Information and collaboration between manufacturers and downstream-users;
- Risk-based approach (hazard and exposure);
- Grouping of substances;
- Responds to challenges on existing substances;
- International integration.

■ How does HERA relate to other initiatives?

The need for HERA was triggered by the reviews of chemical management policy in the EU and elsewhere such as the USA. It is the view of industry and academia that hazard data should not be considered in isolation, but in a risk perspective by the addition of exposure data. HERA complements the commitment of the global chemical industry (ICCA-International Council of Chemicals Associations) to collect intrinsic properties and generate initial

hazard assessments on 1,000 high production volume (HPV) chemicals by the end of the year 2004 and the OECD HPV Chemicals Programme (see www.heraproject.com/links.cfm for more information about both programmes).

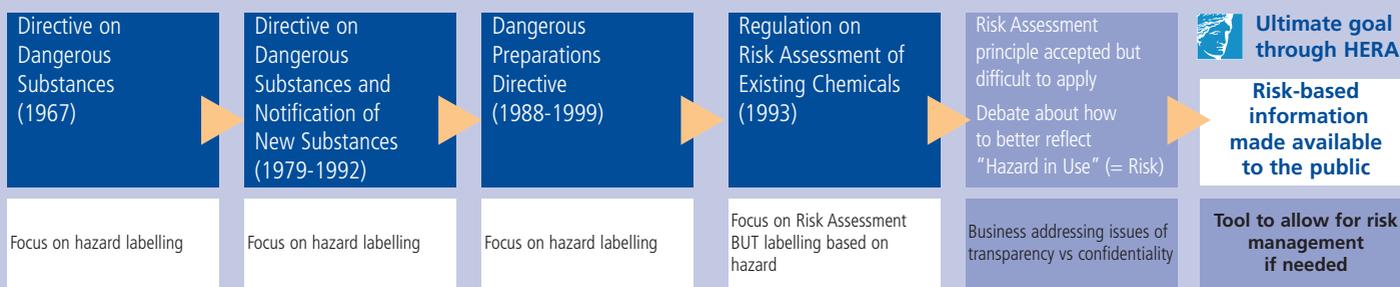
■ In dialogue with all interested parties...

HERA operates transparently. The first priorities have been to gain consensus on the procedures within the supplier and formulator companies sponsoring the project, and to complete the assessments on three pilot chemicals. Further to internal industry peer review, the methodology, first results and various stages of the project were discussed with experts in science – regulators and academia – as well as representatives of consumer and other non-governmental organisations.

HERA has now moved to a stage where risk assessments are being produced on the basis of the methodology thus established, i.e. in a dialogue with interested parties.

How the management of chemicals and products safety has evolved in EU society...

■ Progress of legislation



■ Evolution of the concept of labelling

Operating framework: companies fully responsible acting as per legislation and individual company standards

Common voluntary industry response