HERA

Human and Environmental Risk Assessment
on Ingredients of Household Cleaning Products

# Five years ahead of REACH

## The HERA Reference Book

*A description of HERA from 1999 to 2005*

A·I·S·E

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

A European joint initiative between A.I.S.E. and Cefic

cefic

European Chemical Industry Council

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## Foreword

Over the last five years (1999 – 2005) the HERA project has experienced all the conceivable situations associated with chemical safety assessment, ranging from consortia formation to data sharing, data analysis, organisational issues, legal aspects, reporting of risk assessments, external consultations for technical or communication purposes, etc. During that period HERA has adapted its methodology and its organisation so as to be more effective and more responsive to the many challenges that such an ambitious initiative entailed. The HERA project will have completed in 2005 comprehensive risk assessments on more than 250 chemical substances, covering more than 90% of the total tonnage of chemicals used in detergent and household cleaning products in Europe.

Furthermore, HERA has developed some unique principles of working and of cooperation between industry partners (e.g. partnership between manufacturers and users, data sharing, risk assessment approach, one assessment per substance, open dialogue, transparency, etc) that, we believe, have lasting value and that could serve as a model of cooperation to other industry sectors of the chemical industry in the future.

Finally the HERA project has identified how critical a proper communication around chemical safety and risk is, both to the consumer and to stakeholders of this industry. It has revealed the shortcomings and futility of accumulating massive quantities of technical data on chemicals when no plan existed to translate and communicate appropriately the meaning of these data to consumers. As a result, HERA has pioneered a major effort around communication on chemical safety and risk, through workshops and novel and interactive tools (e.g. Clean House, Safe Home).

With the upcoming REACH legislation the HERA team felt it being important to share the key learning of this project, as it experimented and found solutions for many of the likely problems and situations that manufacturers and users of chemicals will face under the REACH registration process. Hence this booklet, which aim is to provide a quick reference and helpful hints on all aspects of chemical safety for manufacturers and users as well as for other groups or authorities concerned with this issue.

Thanks to the many people who have contributed to this success story,

Claude P Mancel Ph.D.
Chairman HERA Sponsors Committee

Prof. John F Solbé
Chairman HERA Operational Team

Dr. Christian Block
HERA Project Manager

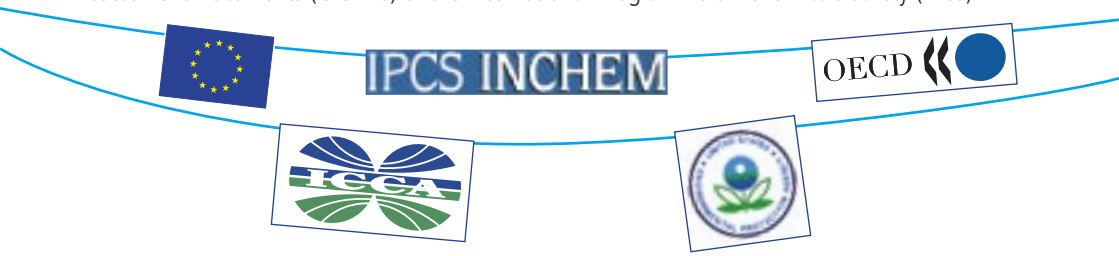
# 1. THE ORIGINS OF HERA

HERA (Human & Environmental Risk Assessment) was established as a joint A.I.S.E.[1] and Cefic[2] voluntary project, in September 1999. It complements other recent initiatives concerning the safety of chemicals.

## 1.1 General Introduction

Chemicals and their uses are part of our everyday modern lives, at work and in the home. Indeed, human beings have used natural chemicals and created artificial ones for thousands of years. The rate of development of chemistry has accelerated over the last two hundred years but only in the most recent times (since perhaps the 1930s) have concerns been raised about the effects of chemicals on people and the environment. Examples such as the reduction of song birds or hawks, caused by the low level but insidious presence of chemicals, gradually attracted the attention of the public, informed often by the media or by interest groups. Accidents in factories or at sea hit the headlines. Campaigns were started to improve awareness and promote action.

With the realisation that some chemicals may produce unwanted harmful effects, national and international efforts have been made by industry and regulators to ensure safe use of chemicals in all walks of life. The management of chemicals requires information on which to base decisions and several programmes have set out to provide harmonised, internationally agreed data sets and initial hazard assessments. (For a discussion of terms such as 'hazard' and 'risk' see Section 3.2.) In Europe the use of data to define the degree of harm inherent in chemicals (this definition is known as the 'classification' of chemicals) was set out in an important Directive in 1967 (European Council, 1967). Many studies of the effects of chemicals on humans and the environment had been made prior to this and continue to be made. The most recent global programmes on chemical data collection include the Screening Information Data Set (SIDS) programme (the 'High Production Volume Chemicals Programme') of the Organisation for Economic Co-operation and Development (OECD) the International Council of Chemical Associations (ICCA) High Production Volume Chemicals (HPVC) Programme, the US EPA Challenge Program on HPVC and the Concise International Chemical Assessment Documents (CICADs) of the International Programme on Chemicals Safety (IPCS).




**1.** Association Internationale de la Savonnerie, de la Détergence et des Produits d'Entretien (International Association for Soaps, Detergents & Maintenance Products)

**2.** European Chemical Industry Council

Laws have been passed to manage chemicals – for instance: although chemicals such as soap have been used for hundreds of years, their replacement by new surface-active agents that did not biodegrade rapidly, commonly resulted in foam on rivers. This resulted in the passing of special legislation in Europe (the 'Biodegradability Directives') to formalise testing to compare surface-active chemicals so that those with the lowest risk could be distinguished from others. In more recent times the realisation has grown that people should personally have access to information about safe and effective use of household cleaning chemicals in the same way that they could learn about the safe use of other materials used in the home.

The HERA project was designed to provide information to allow proper and scientifically sound judgements to be made on the safe and effective domestic use of cleaning chemicals. Several aspects needed to be covered by the HERA Project and this Reference Book describes these as well as the processes which were developed to produce the necessary assessments. The aspects include :

- *Hazard assessment,*
- *Evaluation of exposure,*
- *Risk assessment and*
- *Communication of information.*

*Hazard assessment* is a valuable process enabling substances[3] to be classified on the basis of their intrinsic properties but it does not, in itself, allow an estimation of risk to human health and the environment. *Exposure evaluation* identifies how (and to what extent) humans and the environment could come into contact with the chemical. *Risk assessment* requires that the intrinsic properties of a substance are assessed against the likely *exposure* of humans and of the environment in order to determine if a sufficient margin of safety is (or is not) likely in given circumstances. (For further discussion of these points see Section 3.2.)

Within the chemical industry there are two broad groups of companies (nowadays often referred to as 'Upstream' and 'Downstream') who are involved in most types of risk assessment. *Upstream* companies are producers (known as the Suppliers or the Manufacturers / Importers) of individual chemical ingredients. *Downstream* companies (the Formulators) transform the chemical ingredients to make products. Downstream companies are also known as 'Users' but this term should not be confused with the eventual users of a household cleaning product, the general public. In this booklet, Downstream User refers to the Formulator Company and not to the eventual users of the product. Upstream and Downstream companies were invited to become members of the HERA Team in September 1999, as explained below.

**3.** In HERA the term 'substance' is used in the sense defined by EC Council Directive 92/32/EC; Council Regulation (EC) 793/93.

## 1.2 HERA

The initial idea for the project known as HERA came from those downstream users of chemicals who were engaged in formulating and marketing Household Detergents and Cleaning Products in Europe. Leading companies serving this market, members of A.I.S.E. , wanted to ensure that risk assessment should continue to be regarded as the core tool for chemicals management. Individual companies in the consumer product industry had long used risk assessment as the basis for assuring the safety in use of their products and for their own risk management measures. The chemicals industry had never considered hazard assessment alone as sufficient for ensuring that products placed on the market are safe for human health and the environment. It was sensitive to the emergence of chemical management programmes around the world, often with the goal of bringing hazard data into the public domain. Since this could potentially occur without providing a proper perspective on exposure and hence risk, the public could be inadequately, even misleadingly, informed about the chemicals they use. *HERA has always emphasised the importance of good communication with the consumer* (See Section 7).

The largest companies in this Downstream Users group (who cover approximately 80% of the tonnage of Household Cleaning and Detergent Products sold in Europe) conceived the HERA project on behalf of their European Association and obtained the support of their main suppliers. Chemical suppliers participated either as individual companies or through their membership in their respective associations, most of which are Sector Groups of Cefic. This led to the establishment of the HERA project as an industry initiative in September 1999 as a partnership between A.I.S.E. and Cefic. (See Section 5.1 for a list of participants.)

This collaboration between Upstream and Downstream partners was not new to the industry. In the early 1990s a successful programme for the development of risk assessment techniques with their underlying science had been set up as 'ERASM'. Further details may be found in footnote 16 in Section 9. As HERA draws to a close, a similar joint piece of work is being developed in the 'Code of Conduct' of HERA partners; a code which is eminently suitable for transfer to any similar collaborative venture.

## 1.3 Legislative Developments

Recognition of the value of risk assessment in managing society's use of chemicals has certainly developed in recent years. In Europe, risk assessment legislation now addresses potential risks for both humans and the environment from chemicals which are notified as being first marketed after 18th September 1981 and from existing chemicals which may have been marketed before this date. Commission Directive 93/67/EEC (EC, 1993a) covers risk assessment of New Substances while Commission Regulation (EC) No. 1488/94 (EC, 1994), required under Council Regulation 793/93 (EC, 1993b), lays down the risk assessment principles for Existing Substances.

The process of risk assessment in the hands of regulatory authorities has shown itself to be complex and time-consuming. The European Union, in a statement on its chemical policy, called for the official risk assessment programme to be accelerated by 'targeting' those populations and environmental

compartments considered to be potentially at risk (European Council of Ministers, 1999). The REACH Proposal (see below) emerged from such concerns.

The Commission published a 'White Paper' on the Strategy for a future Chemicals Policy in Europe, in 2001, which sets out a basis for the development of chemicals management under the title Registration, Evaluation and Authorisation of CHemicals (REACH). Following extensive discussions a draft proposal was published, incorporating the principles and some of the processes of REACH.

REACH, like HERA, emphasises the importance of upstream producers and downstream users of a chemical working together and the use of risk assessment techniques to manage chemicals safely. The draft proposal of 29 October 2003 is the current working document of REACH. A Technical Guidance Document for REACH is now being prepared as part of the programme of REACH Implementation Projects (RIPs). Eventually, if adopted by the European Parliament and Council, the REACH principles and processes will form the main regulation for managing the use of general chemicals in the EU. Specific uses of chemicals (biocides, pesticides, cosmetics, detergent ingredients) may still be subject to different and specific Regulations and Directives.

The most relevant aspects of risk assessment will vary from substance to substance, depending on, *inter alia*, the properties of the substance, its annual marketed tonnage, intended place and pattern of use, the possibilities for misuse etc.

# 2. OBJECTIVES

The principal objectives of HERA are to:

- convince the authorities and other stakeholders of the importance of combining hazard and exposure information when assessing the safety and risk of chemicals;
- define a framework to report hazard, exposure and risk information which can be applied, if needed, to other geographic regions or types of chemical ('sectors');[4]
- develop one common risk assessment per substance or substance family, to avoid duplication and rework;
- run 'pilot tests' on selected substances used in household cleaning products to demonstrate the safe use of chemicals, even when they present some hazard;
- influence EU legislation on chemicals, towards a better, risk-based system;
- propagate classification and labelling based on likelihood of harm (risk) instead of hazard;
- improve the image of the industry, especially by forms of communication aligned to the needs of the various interested parties.

**4.** The nature of 'sectors' is described further in Section 5.1.

# 3. PRINCIPLES

## 3.1 Conduct

- HERA is committed to **partnership** between supplier and formulator companies and their representative groups.

- HERA can only succeed fully if it develops an **open dialogue** with stakeholders e.g. regulatory scientists and interested EU organisations.

- **Transparency** in all its activities is essential, including the risk assessment procedures and results, agreed data-sets, reasons for omitting data and reasons for over-riding some standard elements of procedures such as those from the Technical Guidance Document for risk assessment of new and existing chemicals in Europe.

- As a part of this, HERA is committed to finding ways in which data can be used intelligently to **avoid** or at least reduce to an absolute minimum the use of **vertebrate** animals in additional toxicity **testing**.

- **No preconceptions** are to exist of a successful outcome of the risk assessments. The results will be allowed to speak for themselves.

- Above all, HERA is a commitment to a **sound basis of knowledge** to achieve risk assessment and to the use of a **tiered** ('step-sequence') **approach** to understanding the behaviour of chemicals during the use, foreseeable misuse and disposal phases of household cleaning products.

## 3.2 Definitions of Exposure, Hazard, Risk and Safety

*Exposure*

We can distinguish different kinds of exposure. The first kind describes the part of the 'environment' which carries the chemical – air, water, soil. The second describes the form of the chemical – solid, liquid, gas. The third describes the period of exposure. Another concerns the mode of entry of the chemical into tissues – by inhalation, dermal contact, ingestion etc. (Such terms apply equally to non-human animals and more loosely to plants.)

*Hazard*


The harmful properties of a chemical which are intrinsic (immutable) are known as 'hazards'. They include flammability, explosivity, toxicity to wildlife, toxicity to humans etc. The properties are inherent but they cannot be perceived or make themselves felt unless some thing or some organism is exposed to them under particular conditions. For example, petrol is flammable and may be explosive but it can neither burn nor explode in the

absence of oxygen and an ignition source. Rattlesnake venom is deadly poisonous but, obviously, there is no risk of death from the venom unless it has entered the body of the prey. Surface-active agents (soap, synthetic detergents) are inherently capable of killing goldfish, but only if a sufficient quantity is poured into the goldfish bowl. This last example is the same for any chemical – cyanide, oxygen, water: it is the dose which makes the poison, in other words the extent of exposure based on a combination of many things, but particularly the amount of chemical involved and the amount of time during which exposure occurs.

### *Risk*

For any chemical to cause actual harm, as explained above, exposure is required. A further consideration of risk concerns the vulnerability or sensitivity of the exposed organism. The young, the old, the pregnant and the sick, in the case of humans, and their equivalent states in other organisms eg embryo fish, seedling plants, may be particularly sensitive to chemical stressors.


Thus, for any chemical to present a risk, it must be sufficiently hazardous and occur with sufficient magnitude that there is a dangerous level of exposure for the system observed.

### *Safety*

'Safety', like risk, is a comparative term. We are comparatively safe if there is an absence of significant risk of harm but we (and the natural world) are never free from some level of risk, whether from natural or man-made causes, and are occasionally at far greater risk, whether willingly so (in the case of most forms of transport) or unwillingly (in the case of infectious disease or secondary exposure to tobacco smoke).

*In the natural world certain phenomena may represent enormous risks to life on earth. Meteorites occupy regions of the solar system close to the orbit of earth; the earth has a fluid core which is the root cause of movements of the tectonic plates. These facts mean that there is always a risk of impacts, earthquakes and volcanic eruptions. The frequency of such events may be rare but their consequences can be disastrous.*

In HERA, we concentrate on carefully defining (establishing the extent of) exposure to certain chemicals in certain situations and then combining this picture of exposure with the intrinsic properties of the chemicals to allow us to estimate risk. There are never certainties, just probabilities and HERA uses judgement to assign a probability of risk to each situation within its scope. (See Sections 4.1 and 4.2.)

# 4. SCOPE

HERA focuses on the risk assessment of ingredients used in household cleaning products in Europe. Such ingredients, or substances, are referred to here as 'HERA Substances'.

## 4.1 Criteria for Selecting Exposure Scenarios

HERA is a joint activity of Cefic and A.I.S.E in partnership. Member companies of A.I.S.E. use substances as ingredients in a range of formulated products. These final products[5] may be used in household cleaning (the cleaning of fabrics and hard surfaces around the home). The public may thus be exposed to such substances in the home. The environment may be exposed to them during manufacture and after the products which contained them have been used and disposed of, typically 'down the drain'.

### *Scenarios excluded*

HERA deliberately does not address human safety during the manufacture of the chemical. The assumption[6] is made that supplier companies will have sufficient safeguards and controls in place already for their workers and the environment to cover the manufacturing and distribution stages of HERA substances and that specific regulations exist that will cover these situations. Similarly the formulators have such systems in place in and around the factories where the ingredients are used to produce the formulated cleaning products and during distribution through the retail trade.

### *Scenarios included*

It is 'downstream' of these manufacturing and distribution processes (Figure 1) where HERA operates: in homes and afterwards, in those environmental compartments (eg sewage treatment plants, rivers, farmland and potentially the sea) which may receive the remains of the ingredients and their breakdown products.

Figure 1
The boundary of HERA assessments as originally conceived
Shaded areas to be within scope of HERA

| Area for attention | Manufacture of ingredient | Formulation of product | Use of product | Treatment & disposal of product |
|---|---|---|---|---|
| Human health | Occupational regulations | | household | food chain |
| Local environment | Local regulations | | yes | yes |
| Regional environment | Effectively within HERA (see text) | | yes | yes |

**5.** A full list of A.I.S.E product types may be found in the A.I.S.E Annual Reviews.

**6.** This is a 'working assumption'. It is recognised that it may be necessary to draw the boundary (Figure 1) to include local and regional areas for the manufacture of the ingredient and the products in which it is contained. This can be kept under review – to decide the optimum or most appropriate boundary on a case-by-case basis.

Once in the home and also after it has been used, HERA subjects[7] a substance to a thorough process of risk assessment. In the figure, the shaded area shows where HERA applies universally. The HERA methodology also calculates regional[8] environmental releases which include the contributions due to production and formulation.

## 4.2 Criteria for Selection of Substances

HERA interest in a substance may be generated for one or any combination of the following reasons. A set of explanatory notes follows the list.

I) High tonnage chemicals
This is especially relevant for an industry characterised by chemicals used in very large quantities in the home by consumers.

II) Main or sole use is in detergents and cleaning products
This ensures that the targeted risk assessment covers the majority of uses in a manner which is as convincing as possible.

III) Initially, at least one substance per important function, eg surfactants, builders, bleaches etc.
In this way HERA ensures as representative a sample as possible of substances used in our Industry and defines applicable exposure scenarios.

IV) Chemical selection covers a wide range of hazard profiles.
This allows HERA to cover a broad range of risk assessment situations and to demonstrate that HERA is committed to its principle of full transparency.

V) Chemicals on the EU Priority Lists are included.
Even if the chemical is of low tonnage this can be relevant from a risk assessment perspective - and it is especially important that HERA is seen to assess chemicals that other stakeholders see as problematic.

VI) Complementarity with other programmes
HERA set out to develop complementarity with eg the EU Existing Chemicals Programme, the ICCA HPV Initiative, the OECD HPV Chemicals Programme.
By this means HERA avoids duplication of effort and resources and covers the widest spectrum of substances.

VII) Prioritisation of substances that HERA suspects of potential issues
The intention is to point out the need for appropriate risk management decisions on these substances, *if risk assessment demonstrates such a need.*

**7.** Throughout this document the past, future and present tenses can be regarded as interchangeable when referring to HERA.

**8.** The term 'regional' is taken from the risk assessment scenarios described in the Technical Guidance Documents of the EU for new and existing substances. A region is defined as a notional area of 200 km x 200 km in which 20 million people live and use 20% of the European production of the chemical being assessed. This has consequences for risk assessment results, because it is making assumptions about the rate of use of chemicals by the population. An important early study by HERA examined the validity of these assumptions for HERA substances and provided realistic alternatives. An example of the outcome was published by Fox (2001).

**Notes on Section 4.2**

1. The order of listing criteria is not intended to indicate priority.
2. Not all substances meet all criteria.
3. Some substances previously used as ingredients by A.I.S.E companies have already undergone risk reduction measures, including substitution, on the basis of a risk assessment leading to health or environmental concerns; these have not been included in the HERA programme.
4. From the above it should be assumed that, without exception, all substances currently used by A.I.S.E companies are examined for their relevance as candidates for HERA assessment.

## 4.3 Limits of Responsibility of HERA in Risk Management

HERA has limited its scope to the production of risk assessments. The HERA Team is not a Company and does not have the legal status which would allow it (or impose on it) the ability or requirement to manage risks identified in its process. Instead it will deliver results and recommendations to the Sponsor Companies, who will have to manage the risks identified, as they see fit.

# 5. TEAMWORKING

## 5.1 Participating Companies and Sector Groups

Table 5.1 lists the Companies, Sector Groups[9] and Industry Associations which have contributed to HERA since its inception. Some Companies and the Associations have been participants in HERA from the start: others have joined and left depending on the work programme.

Participation in HERA takes a variety of forms. Most Companies and Sector Groups contribute financially. In addition most valuable contributions of the time and effort of personnel have been made. To a large extent, HERA has relied on this so-called 'sweat equity'. The work of the Task Forces, organising and advisory committees, and Substance Teams has been achieved in this voluntary manner.

## 5.2 Organisational Structure

The HERA Team has evolved over the 5½ years of its existence. The organisational structure described below is the final structure.

The Team consists of four types of sub-team: sponsoring and approving (5.2.1); managerial (5.2.2); substance-focused (5.2.3); expert (5.2.4 and 5.2.6). In addition HERA is advised by an External Advisory Panel (5.2.5 and 6.3). Figure 5.1 gives a general outline.

**9.** Companies may work together in Sector Groups which share a common use of chemistry or deliver chemicals for certain applications. Thus the Comité Européen des Agents de Surface et Intermédiaires Organiques (CESIO) is a group of companies who produce one family of chemicals, while the Association Internationale de la Savonnerie, de la Détergence et des Produits d'Entretien (A.I.S.E.) represents companies who put a range of chemicals to use within the area of cleaning products.

Figure 5.1 The Organisational Structure of HERA

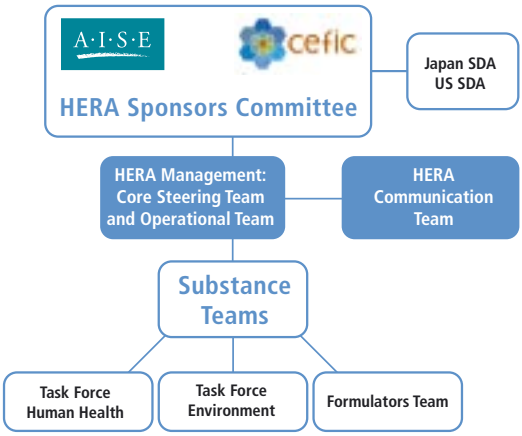



Table 5.1

| Group | Members |
|---|---|
| Upstream Manufacturing / Importing Companies | Aktivsauerstoff, Akzo-Nobel, Aragonesas Industrias Y Energia, Atofina, BASF, Bayer, Berlinka Perkemija, Boehme, Borax, BP, Caffaro, Ceca, Celanese, Chemische Fabrik Budenheim, Chemische Fabrik Wibarco, Ciba, Clariant, Cognis, Crompton, Degussa-Hüls, Delamine, Domo Caproleuna, Dow Corning, Dow Europe, Eka Chemicals, Ercros, Ertisa, Exxon, Exxon Mobile Chemicals Europe, Firmenich, FMC Foret, GE Bayer Silicon, Genencor, BK Giulini & Co., Givaudan, Huntsman, IFF, Industria Chimica Vera, Ineos, Ingessil, Industrias Quimicas Del Ebro, Kao, Kemira, Lyondell, Chemical Nederland, Novacap, Novozymes, Oxeno, Olefinchemie, Perstorp, Oxo, Petresa, Polimeri Europa, Prayon-Rupel, Quest, Rhodia, Rohm & Haas, Sasol, Shell Chemicals, Shin-Etsu Silicon, Silmaco, Sodes, Solutia, Solvay, Stepan, Thermphos International, Uniqema, Van Baerle AG, Van Baerle GmbH, Wacker Chemie, Warwick International, Woellner GmbH & Co., Zeoline, Zschimmer & Schwarz |
| Upstream Associations and Sector Groups[10] | ACA, AEPSAT, AMFEP, Amines Sector Group, UIC, ASSOBASE PITIO, CEEP, CEES, Cefic, CES, CESIO, DETIC, ECOSOL, EFFA, Eurochlor, Federchimica, GOSIP CIA, OSPA, Peroxygens, SGCI, TEGEWA, Zeodet |
| Downstream Manufacturing / Importing Companies | Colgate-Palmolive, Dalli-Group, Henkel, Luhns, McBride, Procter & Gamble, Reckitt-Benckiser, Unilever |
| Downstream Associations and Sector Groups | A.I.S.E., JSDA, US SDA, with contributions from certain European National Associations |

**10.** A glossary of abbreviations used in the Text Box may be found in Appendix B.

## 5.2.1 Sponsors Committee

The Sponsors Committee is made up of Company and Sector representatives who have executive roles and can thus commit resources. A summary of the role follows. The HERA Sponsors meet in committee from two to four times each year in order to

- define HERA policy and approve HERA strategy;
- represent individual companies, substance-oriented Sector Groups and the sponsoring organisations;
- provide human and financial resources and approve budgets;
- approve technical strategies and publication of results as proposed by the Core Steering and Operational Teams, whose role is described later;
- approve strategies to deliver transparency of the process by communicating with external stakeholders (European Commission / National Governments / NGOs and others) as proposed by the Communications Team;
- define policy for co-ordination with related industry initiatives outside Europe.

## 5.2.2 Core Steering and Operational Teams

HERA identified the need for two separate groups to manage the process. These are the Core Steering Team, a small group dealing with managerial, legal and other non-technical issues, and the Operational Team, whose role is essentially to facilitate the delivery of risk assessments. Their respective roles follow.

### *Core Steering Team*

The Core Steering Team (evolved from an original Logistics Team, through a Technical Management Team) is formed from a smaller group than the Sponsors Committee of representative Companies, Sector Groups and A.I.S.E. / Cefic officers. Its role is to

*Claude Mancel - Chairman HERA Sponsors Committee and Chairman HERA Core Steering Team*

- propose HERA strategy to the Sponsors Committee;
- maintain awareness and find solutions to issues such as legal aspects of companies working together and sharing information;
- recommend budgets and other organisational aspects of the project;
- liaise on management issues, with observers from the Soap & Detergents Associations of the USA and Japan, when needed;
- send risk assessment reports to the Sponsors Committee to approve;

- agree with the Communications Group on external communication activities;
- prepare the agendas of all Sponsors Committee meetings, in liaison with the respective Chairs.

*Operational Team*

The Operational Team also developed from the original Management Team and has the following function:

*John Solbé - Chairman HERA Operational Team*

- take responsibility for the work structure, identify issues impeding progress, propose remedies and inform the Core Steering Team, seeking their advice as needed;
- facilitate and maintain awareness of the work of the Task Forces and Substance Teams as they liaise with Companies / Sector Groups; (the use of teleconferencing has particular value here);
- agree procedures;
- oversee preparation of reports by Substance Teams, advising as needed;
- establish, maintain and develop data management systems.

### 5.2.3 Substance-focused teams

*Substance Teams*

Substance Teams are responsible for drafting the risk assessment on the substance on which they are working. In general each Substance Team is led by a member of a supplier company. There are as many substance teams as there are substances to be assessed. Each HERA substance is assessed by a dedicated team composed of representatives of some or all of the Suppliers, Sector Groups and Formulators interested in the substance. There is often but not always a member of the Task Forces in the substance team. If this is the case then the Task Force (TF) member will have a responsibility both to the Substance Team (predominantly) and the TF. Once the risk assessment has been prepared then in the Human Health TF a named individual will be the lead reviewer. For the Environmental TF there was originally a multiple-reviewer process which evolved, due to resource constraints, to a process where a consultant takes the main review but there are still comments from various Environmental TF members. Since it is the Substance Team which agrees the data-sets to be used in the assessments, it is left to the Supplier, Sector Group and Formulator participants in the Substance Team to obtain approval from their management organisations to share their data in each case.

*Formulator Team*

The Formulator Team provides to the Substance Teams the various exposure scenarios on each Substance, because the assessment of risks of a chemical requires detailed knowledge of the amount used in the European market for the particular products being considered. The Formulator Team was established for this purpose within HERA. The Formulator Team consists of representatives of

*Hamish Will - Chairman HERA Formulator Team*

the detergent and household cleaning industry (A.I.S.E.) companies. It provides information on the particular chemicals used in A.I.S.E. products, especially on the tonnages used, the product categories in which the chemicals are used, the typical inclusion levels and the types of exposure which the public may experience during the use-phase of such products.

## 5.2.4 Task Forces

*Scientific Task Forces*

Two Task Forces (Environment and Human Health) were established from the start of HERA. They were responsible for developing the initial methodology for risk assessment. This was a major piece of work, even though the Task Forces could use as a basis the Technical Guidance Documents (TGD) of the EU for assessing risks from new and existing chemicals. In reality the TGD gave a useful outline but could be improved to make it more relevant to the HERA exposure scenarios.

*Carlos Rodriguez - Chairman HERA Human Health Task Force*

*Geoff Hodges - Chairman HERA Environmental Task Force*

To facilitate this process of method development real examples were needed and so it was decided to carry out individual risk assessments on three contrasting substances to provide relevant experience. The task took from November 1999 until approximately February 2001. Valued comments were received from other members of the HERA Team and from ECETOC[11].

The initial methodology, the principal subject of the Guidance Document in the public domain (see description of web-site in Section 7.1.2), was then be applied to other HERA substances and has been updated with further "lessons learned" as these arose from the additional substances. The Task Forces now provide an advisory resource to those undertaking the risk assessments, ie the Substance Teams. In effect, the Task Forces ensure that the science used in HERA is up to date and in line with HERA's technical methodology. To facilitate this advisory function, the Task Forces thoroughly review every risk assessment after it has been drafted by each Substance Team, so that every risk assessment published on the web has been reviewed by the two Task Forces.

### a) Human Health Task Force

One special output of the Human Health Task Force has been to define the exposure scenarios for people using cleaning products in the domestic environment. The details of this work are to be found in the HERA Guidance Document.

### b) Environmental Task Force

In a similar way, the Environmental Task Force spent some time developing new default data for risk assessments. The outcome has been referred to in the Footnote 8 above and may also be seen in the Guidance Document.

### 5.2.5 External Advisory Panel (EAP)

An External Advisory Panel (EAP) was created to provide external advice and criticism on the HERA risk assessments after they have gone through internal clearing and after publication. This panel is made of toxicologists and ecotoxicologists from Academia and has been selected based on their reputation in their respective fields. In the spirit of transparency, the comments of the EAP are also published alongside HERA risk assessments and can lead to amendments of the publications depending on substance. Although not a member of the HERA group, the EAP has proven important to bring an external and neutral view on the scientific work done by HERA. Through the EAP we gained unbiased criticism of our work, sound suggestions towards improving the science and increased acceptability of our results, thanks to this external check.

### 5.2.6 Communications Team

The purpose of HERA Communications Team is to help achieve transparency for the initiative and, by the process and the results, demonstrate that it is possible to use a form of targeted risk assessment, known as a HERA assessment as a fast, efficient and practical tool for chemicals risk management.

*Charles Laroche - Chairman HERA Communication Team*

The Communications Team was set up to facilitate this part of the project. In the most recent period, the Communications Team has focused on the needs to translate complex, scientific risk assessments into language comprehensible to the consumer. It has also identified the overall need, dictated by vast amount of information made public, to address the need to better communicate chemical risk to consumers and key stakeholders by building on the HERA work. As with other aspects of HERA, this will be pertinent to a new chemicals policy for Europe, especially as the REACH Proposal of October 2003 does not address the needs of the consumer for appropriate information on products containing chemicals.

HERA Communication Team uses web-sites, brochures and particularly workshops (See Section 7) to achieve its ends. In addition, all HERA Team members may have opportunities to present descriptions of HERA and its progress in a variety of conferences, meetings etc. The web-site **www.heraproject.com** includes copies of many of these presentations.

## 5.3 Forming Consortia

This subject is of increased relevance since the drafting of the proposed new Chemicals Policy for the EU. Consortia are one of the important means by which the very large number of existing chemicals may be assessed in a reasonable time-scale, leading to one common assessment per substance accepted by all participants, without duplicating effort and especially without performing unnecessary testing on vertebrate animals. This subject is dealt with in considerable detail among the Lessons Learned by HERA, to be found in Section 9: the sub-sections V, VII, X, XII, XIII, XIV, XVI and XVIII are of particular relevance.

## 5.4 Roles and Responsibilities

The complexity and size of HERA necessitates the definition of clear responsibilities and commitment for each of the main contributors at Company or Sector Group level. The same kind of considerations will be applicable to REACH.

These responsibilities are set out below for Suppliers, Formulators and the HERA Secretariat.

### 5.4.1 Suppliers, Leading Supplier Company, Sector Group

Bearing in mind the fact that in some cases the Downstream companies completed some or all of the following activities, the Suppliers of a HERA Substance were made responsible for

- establishing Substance Teams;
- defining the substance family where appropriate;
- defining the structure for collaboration (known as a 'Consortium' in REACH) and identification of stakeholder companies necessary for participation, contribution and approval of joint information and results (whether this is done via a lead company, Sector Group or some other consortium);
- gathering the hazard[12] data on the substance, including a request to Formulators or Formulator Team for any hazard data which may be in their possession; this was to be done in the context of legal obligations (eg the European Existing Substances Regulation) or voluntary Supplier Industry initiatives (eg the ICCA HPV Initiative) and will no doubt be under REACH in the future;
- assembling a data-set, which either included all data available, or, if all the data were not used (as can be the case when for example, there are several results for a single end-point or when there was some question over data-quality): an explanation for the choices made was required;
- utilising the Cefic Statistical Service where necessary (in cases, for example, where commercial confidentiality required this);
- discussing and completing the hazard data-set within the Substance Team;
- sending this hazard data-set to the Secretariat for input to the HERA database in parallel with the data depository requirements under legal obligations (eg the European Existing Substances Regulation) or voluntary Supplier Industry initiatives (eg the ICCA HPV Initiative);
- obtaining a European production volume of the substance, agreed with the appropriate Sector Group or other appropriate consortium;

**12** 'Hazard' in this case is taken to include all biological, chemical and physical data which may be required to describe the intrinsic properties of the substance relevant to risk assessment. (See also 3.2 above.)

- discussing and agreeing both the environmental and the human exposure data-sets based on production and importation information and those data provided by the Formulators or Formulator Team to the Substance Team;
- sending this agreed exposure data-set to the Secretariat for input to the HERA database;
- using the hazard and exposure data to prepare draft environmental and human health risk assessments and preparing a report following the format described in the Methodology Document;
- agreeing this assessment report with the Substance Team, sending it to the Core Steering Team, who send it to the Sponsors Committee for final approval;
- when all approvals have been received, sending the agreed assessment to the Secretariat for input to the HERA database.

### 5.4.2 Formulators

The Formulator Company or Companies were required to

- gather the human exposure data on the substance during use, choosing whether this was done through a Leading Company or some other consortium, such as, particularly, the Formulator Team, and including a request to Suppliers for any exposure data which may be in their possession;[13]
- send the data to Cefic Statistical Services who then assembled an integrated exposure data-set for the HERA Secretariat to input to the HERA database;[14]
- assemble, where necessary, an environmental exposure database utilising sales volumes and the percentages of the particular substance in A.I.S.E household cleaning products;
- discussing and agreeing both the environmental and the human exposure data-sets based on production and importation information and that provided by the Formulators or Formulator Team to the Substance Team; (Note – Formulators had primary responsibility for human exposure data.)
- agree the risk assessment report provided by the Suppliers with the Substance Team;
- send the draft risk assessment to the Task Forces for review.

**13** It was unlikely that Suppliers would have much of the human exposure data required, because HERA focused on the stages in the life of a chemical, ie use and disposal, downstream of the Suppliers' area of control and responsibility.

**14** Please note the difference between this stage and the equivalent for hazard data. Exposure data may be company specific and therefore confidential. It was therefore necessary for the HERA Data Manager to integrate all the exposure data. The integrated data-set would thus lose its specificity and would not therefore be commercially sensitive.

### 5.4.3 HERA Secretariat

The HERA Secretariat was based in Brussels. It consisted of a Project Manager and a Data and Communication Manager. Its role was:

*Christian Block - HERA Project Manager*

*Nadia Werkers - HERA Data and Communications Manager*

- to accommodate and manage the secretarial support and database for the HERA Team;
- to help co-ordinate the work of the HERA teams, in particular of the various Substance Teams: this was the most important role of the Project Manager;
- to help to collect information;
- to arrange meeting venues and the recording of proceedings;
- to bring to the attention of the HERA managerial and other teams any issues relevant to HERA which arose from the other activities of the A.I.S.E. and Cefic.

## 5.5 Cost-Sharing

HERA had to consider how the costs of preparing risk assessments should be shared. After discussion it was decided that the following principles should be applied. Substance Teams were free to agree whatever they deemed appropriate for their specific case.

In general the Suppliers had more hazard information on relevant chemicals than the Formulators. Suppliers and Formulators who were also producers of the chemicals should share the cost for the preparation of the risk assessment including the preparation of the underlying hazard data set.

Formulators were expected to contribute exposure information relevant to human health and environmental risks, and in the spirit of partnership, supply any hazard data they held.

Formulators were not expected to share financial costs of Substance Teams except in special cases. While Formulators bore a greater responsibility for safety assessment of chemical ingredients within their targeted end-use area, they were generally users of most HERA substances and so it was reasonable that they should bear a greater share of the generic operating costs of HERA.

Substance Teams were free to decide who prepared the risk assessment and the report/documentation. Three options were available. Preparation of risk assessments could be

I) a shared activity with experts from several member companies sharing the workload;

II) delivered by a member company of the Substance Team;

III) delegated to an external consultant to draft a proposal.

In the case of external consultants there was agreement that these costs should be shared by the Substance Team in a way that looked most appropriate to them

It was recommended that Substance Teams were explicit about their agreed cost-sharing arrangements and that they formalised the terms of such cost-sharing arrangements.

# 6. PROCEDURES

## 6.1 Data-Gathering and Maintenance of Commercial Confidentiality

### 6.1.1 Introduction

Companies participating in the HERA project and in consortia faced various confidentiality and competition law issues when they were being set up, or during their day-to-day operations. They were required to respect competition law. As a general rule, the establishment of HERA consortia, their internal agreements, structures, operating rules and the resulting HERA risk assessments remained under the full responsibility of the participating companies. Consortia formation is encouraged by the European Community draft legislation on chemicals (REACH). However, operational details of this legislation are still not described and must await the due process.

In this context, HERA "Five years ahead of REACH" attempts to address a number of questions related to confidentiality, data ownership and data sharing as experienced when forming a HERA consortium. However, it cannot be exhaustive, nor is it a substitute for legal advice.

### 6.1.2 Data ownership, sharing and protection

HERA´s risk assessments are based on substance-specific and detailed information which belongs to individual companies. Consequently, the question of data ownership and protection was crucial for Companies co-operating within consortia, whether HERA or the ICCA/HPV initiative. It is even more critical when data are released into the public domain, making it difficult to prevent free-riding. The issue of data ownership will gain importance in the context of the upcoming REACH process, where a Registration dossier may require a so-called 'letter of access' to the original underlying studies.

Companies participating in a HERA consortium agreed to share and disclose data that could be considered as proprietary information. This may have included original study reports, study summaries, exposure information, etc.

HERA aimed at establishing dialogue with stakeholders and at transparency, including publication of risk assessments on the world-wide web. At the same time it strived to ensure that legal ownership of company data was not compromised by HERA activities while being compatible with the HERA principles. To achieve this several tools were used. For example, multi-company confidential disclosure agreements (CDA) have been developed in the course of the HERA project and pro-formas are available. HERA consortia were also free to agree any other options, including financial compensation agreements.

Rules of operation for each Substance Team had to be developed and documented. Consortia agreed on appropriate measures to deal with ownership of shared data. An inventory of what every party brought had to be developed.

To prevent companies from the misuse of a published HERA risk assessment the general recommendation was to limit any publication of data to descriptive summaries. By this means, original data remained solidly the property of the companies that generated them. The use of a standard disclaimer on the web reinforced original ownership of data. This proved wise, as recent legal analysis indicates that the publication of original study reports and robust summaries may compromise the data ownership of the company which has developed them. (A solution for REACH is under discussion within the Commission.)

It was agreed that access to original data or robust summaries should be permitted to the HERA External Advisory Panel (EAP) on demand and under CDA. Since this scientific body reviewed the HERA risk assessments for their scientific content, it needed access to original data when required. The details of confidentiality agreements were left to discussion between EAP members and companies owning the data.

### 6.1.3 Handling of confidential business information.

Particular care had to be taken with the management of confidential business information in the context of competition law. HERA consortia had to avoid being (or perceived as being) misused as a vehicle for exchanging such information. For the same reason, during the HERA process, the collection and consolidation of data concerning exposure and volume deserved special attention. These data needed to be compiled by an independent third party. This could be e.g. the Cefic Statistics Services, which were in an excellent position to provide guidance for any competition law issue that may arise along the process of data gathering. The HERA secretariat had experience too and could therefore be engaged in this process. However, care had to be taken because HERA staff were sometimes seconded by individual companies.

## 6.2 Science and Risk Assessment Methodology


Whether the risk assessment is to be carried out for human health or the environment, the procedure is essentially the same. This is set out as '35 Steps to a Risk Assessment' on the next page, and more detail is given in the following text. There is nothing unique about this general approach, except that it provides a convenient way to follow progress on the risk assessment process. HERA follows classical risk assessment techniques.

*General*

- The first step is to identify clearly the substance to be assessed. This may sound obvious, and it is, but it is not necessarily an easy process and great care is needed. Substances are known by many names and according to many systems. Generally the best approach is to use the Chemical Abstracts Service number (the 'CAS number')

which is uniquely allocated to each known substance. A substance may be a single entity, for example sodium chloride – common salt, but it may also be a tightly knit group of entities with a single name and CAS number, or even a more varied group, still having one CAS number. Occasionally the substance may have more, even tens of CAS numbers. This is the result of the substance being produced and marketed under a single name but arising from a series of chemical reactions (or biological ones) where the production process inevitably creates ranges of structures. For example, a common way in which many surfactants are sold is by a nominal 'chain-length', thus a $C_{12}$-------- has a chain of 12 carbon atoms along its length. In theory, a pure $C_{12}$ can be produced (maybe at great expense) but in reality, although most of what is bought and sold under that description may indeed be $C_{12}$, some may be $C_{10}$, some $C_{14}$ etc.

- Two more steps can follow before an assessment of risk begins – (a) the gathering of exposure data and (b) the gathering of hazard data. In fact, it is very important to begin the exposure assessment first, for two reasons. Firstly it may be found that after due assessment, exposure is not possible under normal conditions of use, or under reasonable conditions of misuse. If that is so, the assessment can be stopped immediately and much time and expense will be saved. No exposure equals no risk. Secondly, where exposure is found to have a chance of occurring, the type of exposure predicted will inform the toxicologists or ecotoxicologists the most important hazard data to examine. For example, if something is not volatile there is very little point in examining effects in the atmosphere. If something is totally consumed within the boundaries of the manufacturer by some process there is no point in examining its effects on the domestic user of the eventual product.

## 35 Steps to a Risk Assessment

| A. Initiation |
|---|
| 1. Check criteria for selecting substances for assessment |
| 2. Define reasons this substance prioritised for assessment |
| 3. Identify substance/s by individual or family name |
| 4. Identify lead company (usually a Supplier) |
| 5. Identify person in lead company who is able to resolve issues among team |
| 6. Name Substance Team leader to manage the technical delivery of assessment |
| 7. Identify sponsor companies, committed to completing assessment on time |
| 8. Obtain agreement to list substance/s on the HERA web-site (public commitment) |
| 9. Name executive contacts in each sponsor company able to commit resources |
| 10. Identify Environmental and Human Health experts; formulator lead person identified |
| 11. Identify lead persons for Environment and Human health risk assessments |
| 12. Define substance/s or family scope in chemical terms |
| 13. Sponsors agree how assessment will be generated (sweat equity and/or paid consultant), how they will manage cost sharing and confidentiality issues and commit to timeline |
| 14. Establish links with other consortia e.g HPV, ICCA and agree basis for collaboration, data exchange |
| 15. Quick screen, what tier assessment will be needed, how much data collection will be needed |

| B. Data collection |
|---|
| 16. List CAS N° produced and CAS N° used, from producers' Sector Group, and Formulators |
| 17. Calculate total production volume, grade of material, tonnage used in HERA sector |
| 18. Identify uses of products containing substance/s and proportion used in each product-type |
| 19. Define exposure of consumers to substance/s |
| 20. Collect hazard data. Validate and summarise data |
| **C. Assessment** |
| 21. Draft chapter on characterising substance |
| 22. Draft chapter on environmental risk assessment and write executive summary |
| 23. Draft chapter on human health risk assessment and write executive summary |
| 24. Review by Substance Team experts |
| 25. Review by Task Forces |
| 26. Repeat as needed step 21-25 |
| 27. Decide on further testing needs, when to be completed, how to be communicated |
| 28. Sign off by sponsor companies on assessment, executive summary and recommendations |
| **D. Completion and Publication** |
| 29. Sign off by HERA Sponsors Committee |
| 30. Post on the HERA web as 'First Edition' |
| 31. Review by External Advisory Panel |
| 32. Substance Team responds to questions raised |
| 33. Produce second edition; combine Human Health and Environment if developed separately |
| 34. Repeat release procedure steps 25 - 29 |
| 35. Publish on the HERA web as second, third etc edition |

*Human safety*

- Assessing exposure for humans involves the following questions.

  - Where is the substance to be used and in what form is the product containing it? Is it a tablet, a powder, a liquid etc? What is the concentration used in the product?

  - How could consumers come into potential contact with the product containing the substance? What are the recommended uses? Are other uses possible? (For example is it likely that the dish-washing liquid will be used to wash hands?) What would be the likely route of exposure? By penetration of skin, by inhalation, by swallowing? Is it also possible that people could become exposed to the substance by drinking water contaminated with it? (This is known as 'indirect exposure'.) And so on.

  - Next comes a step in which simple mathematical models calculate likely exposure. These models need to know 'habits and practices' – in other words how people really use the product, how often, by what means. Data are needed: if none are available there are safe numbers to use instead. These safe numbers are very cautious and are known as 'default values' because they are employed in default of real measurements. If such measured data exist they should be used.

- The last stage, from which the 'dose' can be determined, is to add up all the possible exposures to the substance from all the products which use it as an ingredient and to add together any 'indirect exposure' (see above). The word 'add' is important. The basic approach is to assume that all the different ways in which the substance could enter a human have the same potency, so the partial doses are not multiplied together, they are just added. After all, we are considering here a single substance.

- Now comes the calculation of 'dose'. "Dosis sola facit venemum" as Paracelsus (1493-1541) said: "It is the dose alone which makes the poison." The dose is the concentration of the substance in the body. It is important to calculate this as carefully as possible so that it can be compared with the next part of the risk assessment which defines the concentration which has no observable adverse effect. We now need to return to the second set of questions, which relate to hazard.

- There are various steps in hazard assessment for consumers which will be summarised now.

  - The first step is to collect toxicological data on the substance. These data may be a description of harmful levels, such as the dose which would be toxic to half a group of test subjects if taken orally. This 'oral median toxic dose' is just one example of what are known as 'end-points'. (Another end-point could be the highest concentration which, unequivocally, has no observable effect.) The descriptions will also include data on the physical and chemical properties of the substance such as its solubility in water and in fat, its melting point etc.

  - The second step is to look closely at the collected data and check them for quality and applicability. There are standard ways of doing this.

  - Thirdly, an important step is to check if there are any significant gaps in the data-set. If there are, these may need to be filled either by testing on animals (but this is now severely restricted, except with volunteer humans) or by calculations. It is also useful to see if some similar substances have the right kind of data and to make a careful 'bridging' between the known and the unknown.

  - Finally, the data are summarised with special attention to the end-points relevant to those areas where the exposure assessment has indicated the need for attention. From these, toxicologists derive the safe level for the substance in all its likely uses in household cleaning products.

- For the final stage, on the one hand we have the safe level derived from hazard data and on the other we have the dose expected to occur under the conditions of use. If the dose exceeds the safe level there is a risk: if it does not we have a margin of safety which can be described by a number. If that margin is large the exposure could be increased by almost that amount before there was any risk. On the web-site there are examples of the margins of safety found for HERA substances.

- All this work is then summarised into a statement of risk characterisation and the conclusions of the risk assessment.

*Environment*

- For assessing exposure leading to an environmental risk assessment there are some necessary differences from human health risk assessment.

  - The first step is to identify the tonnage of substance delivered from manufacture for incorporation in products. All the production information from all the manufacturers can be collected. The tonnage actually used for HERA use scenarios must then be collected from the Downstream Users. This second figure is estimated from the ranges of concentration reported in each product (remembering that many very similar products are made by the companies) and a total tonnage figure is derived.

  - Next, the rates of breakdown of the substance are examined. This breakdown could occur at the moment of use, ie in the washing machine for example, in the sewer *en route* to the wastewater treatment works (WWTW), in the WWTW itself (where the most powerful degradation processes exist in the form of the bacteria and other micro-organisms which are given optimal conditions for the process), or in the receiving environment – the rivers, the sea and agricultural land (where sewage sludge is used as a fertilizer and soil conditioner). Often there are measurements of degradation available but if not, there are models to simulate degradation.

  - The third stage is known as 'partitioning' and it involves working out from the properties of the original chemical and the properties of any breakdown products just whereabouts in the environment chemicals might go, and how the situation would look when all the movements (eg from water to atmosphere) had settled into a state of equilibrium. The EU has a computer program called EUSES which performs all the necessary calculations for detergent ingredients, so this program was incorporated in the HERA Guidance Document. The importance of understanding partitioning is three-fold: (a) to work out concentrations in each part of the environment (air, soil, water), (b) to see which types of animal, plant and micro-organisms might be exposed to the chemical and thus which hazard data might be appropriate and (c) to predict whether the chemical might return to form part of human exposure if food or water retained traces of the chemical following all the possible degradation processes.

  - The last piece of work, equivalent to estimating dose in humans, is to calculate the Predicted Environmental Concentrations (PEC) using the EUSES program above, modified to improve on some of the constants (where, otherwise, default values would have been used by the computer). In this case, the default values of interest include the density of population of humans and thus the intensity of use of a product in a large area of the environment known as a 'region', the connection to sewer and proper sewage treatment in the region and the most extreme use of a product compared with the average use. All these factors affect the PEC. It is at this point that the ecotoxicologists would have told the toxicologists of any chances of secondary exposure via the food chain and drinking water. Now, as with toxicology it is necessary to return to hazard assessment appropriate to the type of exposure predicted.

- The process of hazard assessment for the environment is exactly parallel to the human hazard assessment. The data are collected and validated. Any gaps in the data-set are evaluated and if they are of importance, work is put in hand to fill them by modelling or reading-across from other similar materials. In some cases additional testing is considered and may be performed to fill the data gaps. Finally the equivalent of a safe level is derived for each relevant environmental compartment. It is known as the Predicted No Effect Concentration (PNEC).

- So now we have the two elements for risk assessment in environmental compartments – the PEC and the PNEC. The risk characterisation stage involves comparing PEC and PNEC for each compartment. If PEC (the concentration in the environment) is greater than PNEC (the safe level) there is a risk of harm to that particular part of the environment: if PNEC is greater than PEC there is no risk of harm. Clearly, when the two figures are close together great care is needed before making the final risk assessment, and always, with the environment, there are uncertainties which must be handled carefully.

- It is convenient to prepare a single document outlining the results of the risk assessments for both human health and the environment, but although this is desirable it is not essential and in many respects the two processes can work in isolation.

### 6.2.1 Internal review of risk assessments

The first part of Section 6.2 was concerned with the technique of assessing risks but HERA introduced an internal assessment and review process, whose detail can be inferred from Section 5. For clarity, this process is summarised below.

The Substance Team and Formulator Team worked together through the first 24 steps of the 35-step process for a given chemical. Every assessment was then passed to the Task Forces for internal scrutiny, checking for consistency with the HERA approach, appropriate science, sound selection of data and their interpretation and suitable formatting of the draft report. This constituted Step 25 and it may be seen from the above table in 6.2 that there was room for iteration between Task Forces and Substance Teams to refine the assessment if needed. Once a satisfactory stage had been reached, the draft could move to the Sponsors Committee and proceed from there as described in 6.3.2 (a) below.

## 6.3 Review Process – The External Advisory Panel

### 6.3.1 Introduction

This section describes the procedure by which a first edition risk assessment placed on the HERA web-site can be upgraded to a second edition risk assessment.

To place the text in context it may be helpful to review the concluding steps of a HERA risk assessment. These are shown in the Text Box 6.1. Of course there have been many preceding steps to prepare the risk assessment and reach this point. These steps have been summarised in Section 6.2 and may be found in the Guidance Document on the web-site.

### 6.3.2 The Process

a) The draft risk assessment (produced and owned by the Substance Team) was passed to the Project Manager and sent to the Sponsors Committee for their consent to the process of posting the risk assessment on the web-site. After a reasonable but short period (say, two weeks) for their opinion to be voiced, the risk assessment was posted on the web (or the document returned to the Substance Team for revision). The latter was a possibility but a remote one if the checks and balances afforded by the Task Forces (see above) and HERA Operational Team / Core Team had operated successfully.

b) The Project Manager arranged for the assessment to be published. It was now known as a 'first edition' and the public and External Advisory Panel (EAP) were invited, directly in the latter case, to review it. (Of course, the Panel Members may have had the opportunity to pick up the publication independently too.) In exceptional circumstances, a review could have been requested from some other named person or organisation either selected by the Substance Team (at its expense) or by the HERA Operational Team (at HERA expense).

Text Box 6.1

| |
|---|
| a) Sponsors' Committee consents to the process of posting the risk assessment on the public HERA website. |
| b) Post draft(s) on the public HERA website. |
| c) Review by External Advisory Panel, in exceptional cases by others either selected by the Substance Team (at its expense) or by the HERA Operational Team (at the expense of the central HERA funds). |
| d) Substance Team responds to questions raised. |
| e) Final risk assessment report produced. This should combine Human Health and Environmental assessments if they had been developed separately. |
| f) The approved procedure for releasing an assessment for publication should be repeated, with any further reviews or further work being undertaken if needed. |
| g) Risk assessment published on the public HERA website. |

c) Review by External Advisory Panel

The Chair of External Advisory Panel allocated one ecotoxicologist and one toxicologist (one to be the Lead Reviewer / Co-ordinator) to each substance, to undertake a thorough review in terms of all items relevant to delivery of a valid risk assessment 'fit for purpose'[15] such as data quality, justification of methods/data inclusion/data rejection and comprehensiveness, but not editorial matters (although they were encouraged to feel free to mention such matters if they wished). In addition, all Panel members would look at the consequent review, and the original risk assessment. The Panel had about three months to complete their entire review process on a substance. It was impracticable for the Substance Teams to receive several opinions of a given risk assessment: each substance was the subject of a single review, agreed within the External Advisory Panel.

**15** The need is for delivery of adequate risk assessments, accepted by the Regulator as adequate under existing or, at the time the assessment is published, foreseeable legislation, and not to seek perfection.

A process was established (as in (d) to (g) in the text box above, but not detailed here) of the structuring of the Panel reviews, communication through the HERA Secretariat with the Substance Teams and the means of responding to the comments of the Panel. If an assessment was subsequently revised, it was published and referred to as a 'second edition'.

## 6.4 Approval to Publish

In a multi-stakeholder process such as HERA, the approval of all industry participants had to be assured at each stage.

This section sets out the approval process which was used for two important cases: approval of communication and approval of a risk assessment.

### 6.4.1 Communication

All communications to an audience or readership outside the HERA Team beyond previously approved material had to be approved by the Core Steering Team and on a case-by-case basis by the Sponsors Committee. Such communications were typically prepared and co-ordinated by the Communications Team and included brochures, the web-sites, workshops and press releases.

### 6.4.2 Risk Assessments

There were four stages to consider in arriving at a risk assessment for a HERA substance. These stages and the responsible approving body were:

I) Selection of substance and confirmation of support and timeline for that substance: Sponsors Committee;

II) Approval of hazard data-set and exposure data-set: Substance Team;

III) Approval of draft risk assessment report: Substance Team, aided by Task Forces;

IV) Final approval of risk assessment report, following consultation in Core Steering Team and Sponsors Committee.

At all times it was the responsibility of the Operational Team to facilitate delivery of the risk assessments.

## 6.5 Citation of HERA Reports by Industry

### 6.5.1 Ideal situation

Ideally, the External Advisory Panel would review the draft and the HERA Team would respond to the Panel's comments and post a final version before it was used in public. This would have maximised the chance of ensuring that a HERA assessment was completely adopted by stakeholders and accepted as an objective and trustworthy approach.

### 6.5.2 Pragmatic way forward

As HERA progressed and an increasing number of assessments were posted on the web, we realised that use could be made of an assessment (or requested by authorities) as soon as it was in the public domain, ie while it was still awaiting review or being reviewed by the Panel, provided that certain safeguards and acknowledgements were adopted. A summary of these safeguards follows.

### 6.5.3 Safeguards

a) In utilising or referring to a HERA risk assessment report we agreed that we must communicate clearly that it was indeed the result of the work of the HERA Team.

b) The status of the given report was required. As soon as the report was posted on the web, and before the Panel had commented and the Substance Team responded, the report was a draft and had to be referred to as 'preliminary' or 'draft'. (Latterly, we have been using the term 'first edition'.) Once the review process and responses to it had been completed and a modified version was published the report could be referred to as 'final' ('second edition'). (Note that a HERA assessment is always available for further work as new information arises. Such new information might include new data on intrinsic properties or new data on exposure due to changes in use or tonnage.)

c) The HERA report was to be utilised or referred to in such a way that its own context within the intended form of citation was clear. For example, the reader should not be allowed to draw the conclusion that HERA had covered human exposure to a substance outside the HERA scope of domestic use.

d) The HERA Secretariat at A.I.S.E. was to be kept informed of any proposed citation and, following the presentation/publication, any consequent remarks by stakeholders. In this way HERA could help industry to maintain, improve and develop the HERA approach to the greater benefit of all those interested in its results.

# 7. COMMUNICATION

*If we are concerned that the European public should develop more confidence in 'chemicals' a special communication effort will be needed.*

*Risk assessments of chemicals need to be explained to consumers in the broader context of products. (Consumers are not interested in chemicals: they want to know if their products are safe to use and what precautions they need to take, if any, in using them.)*

*HERA and REACH will generate massive amounts of information to consumers with the aim to make consumers more comfortable with chemicals. If no serious effort is being put into communicating to consumers the correct risk assessment and safety-in-use of chemicals, this huge effort will be wasted and consumers won't feel more at ease with chemicals in the future than they were in the past.*

From the outset, it was realised that the major effort to be expended on developing procedures and delivering risk assessments in HERA would need a carefully constructed programme of communication to various stakeholders with the purpose to inform, disseminate and convince others about the scope and outcome of the HERA programme. Being diverse, the targets for communication of HERA required individual attention. Briefly, they were, with the objectives for each, as set out in Table 7.1.

Table 7.1

| Stakeholder Group | Objectives |
|---|---|
| **Academia** | The HERA science base relied heavily on work by ecotoxicologists and toxicologists over the preceding decades, as captured in the Technical Guidance Documents for the risk assessment of new and existing substances in Europe. Any fine-tuning of this guidance, to make it appropriate for the Detergents Sector, would benefit from the scrutiny of academics. Typically this was achieved by demonstrating various aspects of the work at scientific congresses around the world (in effect, the Northern Hemisphere). Fora such as the annual conferences of the Society of Environmental Toxicology & Chemistry (SETAC) in Europe and North America were used for this purpose. |
| **Government** | Acceptance of HERA risk assessments by regulatory authorities (either as stand-alone documents or as part of a larger picture such as REACH) was a target well worth aiming for. Usually a small number of members of the HERA Team visited individual Member States and the EU Directorates to explain the HERA process and receive comments on its direction and any stumbling blocks in the way of its success. Such issues could then be addressed by the Team. |

| | |
|---|---|
| **Non-Governmental Organisations** | Each NGO has its own agenda, whether this is the protection of consumers, care for the environment or the welfare of animals. HERA has many things to discuss with NGOs and has been received openly. It is not always possible to achieve agreement but an open and continuing dialogue is a valuable condition. |
| **Industry** | When HERA was first established, it was very much owned by the Suppliers and Formulators of the Detergents Industry. As time went on, the general applicability of the lessons being learned became apparent. It remains true that HERA had the advantage of being developed within an environment of close working among a wide variety of companies, but this is by no means unique to the Detergents Industry. It was certain that the rest of the chemical industry had to be made aware of HERA, so that they could share our learnings and follow our example, or not, as they wished. The development of REACH a few years after the inception of HERA has only added focus to this point. Industry gatherings, including SETAC (which is a tri-partite Society with membership drawn from academia, government and industry) have proved effective events to share ideas and gather opinions about HERA and its value. |
| **Media** | Interactions with the media have two advantages: HERA spreads its messages and the media inform HERA about the techniques available for communication in language appropriate to an intended readership. The media present the world to the public and it is vital to recognise their importance and to provide them with factual information. |
| **Public** | The public should be the ultimate beneficiaries of any successful policy on safety in use of chemicals. This applies equally to HERA substances, which have been used with confidence by consumers for decades, and to new substances or substances of known and required toxicity (such as pest control chemicals, anti-cancer drugs and many other pharmaceuticals). It is the opinion of the HERA Team that the new EU Policy will benefit greatly in its aims if it includes an intelligent approach to passing information down the supply chain to the ultimate user – the domestic consumer. |

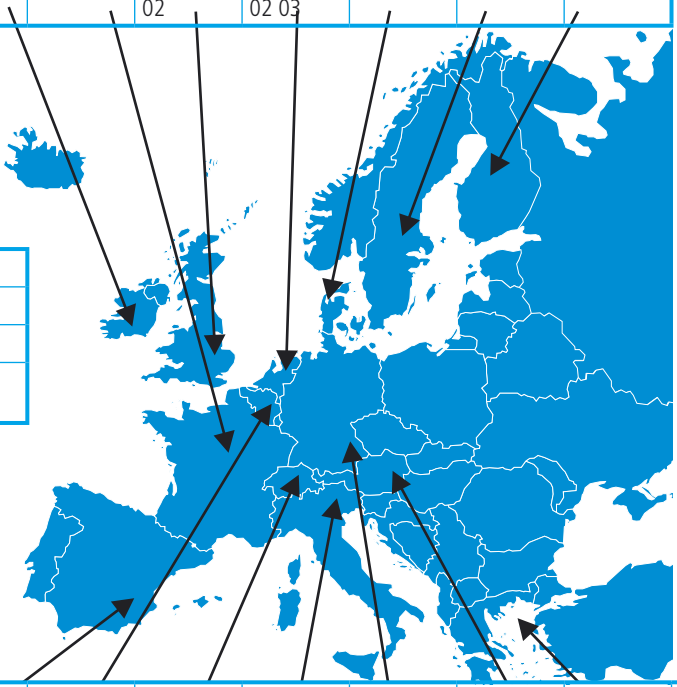
# 7.1 Stakeholder Contacts and Consultations

## 7.1.1 Presentations to Academia, Government, NGOs and Industry

Figure 7.1 Demonstrates the extent to which HERA has been described and discussed to various types of audience

Figure 7.1 Presentations of HERA to Stakeholders

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| GOV | 03 | 03 04 05 | 01 | | 02 | | |
| NGO | | | | | | | |
| IND | | 03 04 05 | 03 04 04 | 00 02 03 04 | | 03 | 02 |
| MIX | | | 02 | 02 03 | | | |



USA

| | |
|---|---|
| GOV | |
| NGO | |
| IND | |
| MIX | 01 02 04 |

CEE

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| GOV | | 00 02 02 | | 01 | 02 05 | 03 | | |
| NGO | | 02 03 | | | 02 | | | |
| IND | 01 02 03 | 00 01 03 04 05 | 02 04 | 01 03 05 | 03 03 04 05 | | | 03 |
| MIX | 03 05 | 01 02 03 03 04 | | | 03 | 02 | 03 05 | |

## 7.1.2 The HERA Web-Site

Perhaps the most important means by which the interested public could become informed of the objectives, programme and progress of HERA was the web-site: **www.heraproject.com**. This was established early in the project. The home page, illustrated below, points to sections on a general description, news & events, the risk assessments themselves, a library, relevant links and a means of contacting the HERA Team. (In addition there is another, restricted-access web-site and a regular Newsletter which contain information for the HERA Team and are not relevant for the public.)


The web-site is maintained by the HERA secretariat. A summary of the various features to be found on the web-site now follows.

## The HERA Web-Site

*Home Page*
This is illustrated above. It provides links to various aspects of HERA and also a means of gaining access to other information related generally to the work of HERA.

*HERA Initiative*
These pages introduce HERA and describe the need for the project and its objectives. Going deeper into this section one can find notes on how HERA is an example of targeted risk assessment, its perceived value to various stakeholders, the phasing of the work, the principles to which we work and the organisational structure and contributors to the project.

*News & Events*
The HERA team make many presentations of the work of the project. These are made available through this page.

*Risk Assessments*
This page contains a complete listing of all substances whose risk assessments have or will be published by HERA and a complete listing, with summary and full reports of all assessments now completed to at least 'first edition' stage. A whole series of links are provided, so that the reader can search for a CAS number, see to which CAS number a substance relates, follow the progress of an assessment and examine the methodology of a HERA risk assessment.

*Library*
The Library contains the methodology document, a two-page summary of the process of risk assessment, a basic 'core' slide presentation about the project, copies of the posters, leaflets, updates of leaflets and the proceedings of workshops. There is also a considerable library of HERA presentations going back to May 2000.

*Links*
This page presents the huge power of the world-wide web to link the reader with the work of international organisations such as the United Nations and the EU, the HERA sponsors themselves and some of the chemical industry associations and initiatives around the world of relevance for HERA, such as the OECD program on high production volume chemicals.

*Contact*
Finally there is a page which gives the reader the chance to send messages to HERA about its approach and results. The site has received many 'hits' but it is quite likely that many of these are from industry, seeking information about chemicals and progress as well as methodology.

### 7.1.3 Brochures

In addition to the web-site, it was considered useful to have a summary of HERA in the form of a 'calling card' or brochure. This has been revised three times to provide up-to-date information.


The current (third) edition of the brochure consists of a single sheet of six folded sides and a double-sided insert.

### 7.1.4 Workshops

Throughout the HERA Project Representatives from the European Commission, European Parliament, Member States, NGO's, Media, Academia and Industry were invited every year to debate topics of relevance to HERA and its goals. These 'Stakeholder Workshops' are described below.

*Speakers at a HERA workshop included from left to right: Panagiotis Daskaleros, European Commission; Frédérique Ries MEP; Charlotte de Roo, BEUC; John Baeckens, Keystone Network who all shared their views and perspectives on risk communication.*

*a) First Workshop 11 October 2001*

This first HERA Workshop was aimed at assessing the validity of the HERA project from a scientific perspective. A variety of experts were invited, including members of the External Advisory Panel. They gave general approval of the overall approach of the methodology. A number of very helpful suggestions for improvement were made for the Guidance Document, while recognising that it was a 'living document' – in other words a document open to developments. The Panel underlined the importance of the risk assessments needing to follow the specific points set out in the HERA Guidance Document.

*b) Second Workshop 11 July 2002*

The purpose of this workshop was to communicate HERA's progress and lessons learned and to exchange views about its relevance as a potential contribution to the future EU Chemicals Policy. While the First Workshop had a science focus, the second was more of a political check on the work.

Representatives of the European Commission, Parliament, Members States, Academia and NGOs provided constructive input to the discussion. The project was considered a very good voluntary industry initiative. Inger Schoerling, Member of the European Parliament stated that "Transparency in gathering and sharing data is what we have to do for the new chemicals policy so I think HERA is a very good start". She also raised the issue of the precautionary principle, insisting that it should be applied.

The Chairman of the HERA Steering Committee, Claude Mancel, confirmed that HERA would endeavour to address the various points made in the Workshop, including the issue of the precautionary principle.

*c) Third Workshop 26 November 2003*


The principle of transparency in the way HERA operates has always been strongly upheld, both for internal audiences and external stakeholders. Complementary to this, there was an increasing attention to the overall question of communicating risk and safety on chemicals by the different interests. It was in this spirit that the Third Stakeholder Workshop, entitled "Talking about chemicals with consumers; the language of risk communication" was organised. The objectives of the Third Workshop were to acquire an understanding of the expectations of stakeholders regarding risk communication to consumers and to review initiatives in the area. Given the difficulties in addressing the topic adequately, gaining advice on HERA's first attempt was crucial.

It was found very challenging to meet the different expectations – both on content and style – simultaneously, while providing useful and transparent information on risk assessments to the range of different audiences (from academia to politicians, trade, consumers etc…). A very clear message emerged from the Third Workshop: Risk Communication cannot be 'one-size-fits-all'. It must be fit for the purpose. Collaborative efforts among the many parties involved in risk communication to share the lessons learned, were considered critically important.

*e) Fourth Workshop 9 November 2004*


HERA has pioneered several approaches towards addressing the needs of the consumer for appropriate information on the safety in use of products. Aiming to build further understanding in how to talk about risk with the public, some questions were posed at the beginning of the Fourth Workshop, which was entitled "Talking about chemicals with consumers; confidence though communication?"

The questions were:

- What more have we learned about communicating with consumers to achieve confidence in chemicals?
- What tools work and how should they be used?
- What role has HERA to play in this?

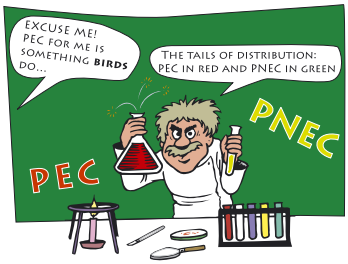
The conclusions may be summarised as follows:

- Communication needs to be acceptable. It needs to take into account the 'world of risk' that people inhabit in their everyday lives.

- Everyone at the workshop seemed to agree that zero risk did not exist. The question was: how should this be explained and what were the implications of 'acceptable' risk to the public? Precaution must be proportionate.

- The theme of no 'one-size-fits-all' raised in the Third Workshop was repeated. While different communication channels, methods and messages must be based on common information, it was clear that action was needed in terms of managing risk, as well as telling people about it. Consumers wanted to understand the issues, not the process.

## 7.2 Risk Communication: talking about chemicals with consumers




The communication approach developed by HERA has brought forward a few principles around risk communication which have to be kept in mind whenever addressing chemical safety and risk.

- The need for risk communication seems to be expanding. Consumers are more aware of risks and society is becoming more sensitive to risk liabilities: people want to know the risks that they face. Little has been done so far to address this need.

- We have to recognise that consumers want to buy products in the confidence that they are safe. The list of chemical ingredients is obviously important, but not necessarily a good way to communicate risk. Running a risk assessment without proper means of communication to the end-user is insufficient in today's world.

- Risk communication needs to be continuous. Mistrust is created if companies are perceived only to communicate or react in a crisis.

- Risk communication cannot be "one-size-fits-all". It must be fit for the purpose. Communication needs to be acceptable – it needs to take into account the world of risk that people inhabit in their everyday lives.

- It is important to 'rephrase' risk reduction actions and pre-emptive measures that are being taken all the time, drawing attention through 'silent risk communication'. For example, if a pack has a child-resistant closure, this is silently communicating a hazard which can become a risk.

- Because consumers are primarily interested in finished products, the wider supply chain should be involved in the debate.

- It is important for all industry partners to forge alliances elsewhere too. Industry needs intermediaries to convey a more credible message to the public.

## Clean House, Safe Home

*A pioneering interactive tool*

The HERA communication project is recognised as a useful tool to help policy-makers in responding - or even better - anticipating the questions and fears of consumers and NGO's about using chemicals in their daily products in the home.

Realistic risk communication is critical. In today's time-poor, information-rich society, people are overwhelmed by the huge amount of (sometimes even conflicting) information relating to health and environmental issues. Therefore, it is imperative for all sectors to avoid over-promising, but to provide sufficient information to help consumers make risk-based decisions and to strengthen their confidence in both the short and long-term. According to the Lisbon agenda, Europe should become the most competitive, knowledge-based economy by 2010. However, a lack of confidence in products and/or manufacturers threatens not only industry's, but also Europe's competitiveness.

Establishing the balance between risk and hazard is also of paramount importance. People's thoughts naturally turn to hazard but failure to understand the actual risk leaves them overly constrained and unprepared to manage risk safely. Information that is useful for consumers is much more likely to be achieved by a sense of balance: risk versus benefit and hazard versus risk.

Offering HERA's scientific risk assessment work to consumers in an easy and accessible way has been, and continues to be, strongly appreciated. HERA's first attempt to offer constructive input into the risk communication debate resulted in the development of plain language (Q&A) summaries on the outcome of its risk assessments. While exploring new ways to be transparent and deliver information about risk and safety, it became apparent that better communication to consumers starts from their reference point: their home and their daily products.

Consequently, HERA has developed an interactive web-based information tool 'Clean House, Safe Home' which aims to relay the scientific work of HERA risk assessments in such a way as to enable consumers to manage risk in their everyday cleaning activities.

'Clean House, Safe Home' displays cleaning products and detergents in the home environment. The visitor can discover animated hot spots and find information on all household cleaning products and their ingredients for each of the rooms covered (kitchen, bathroom and laundry room in a first stage, but ultimately all the rooms of the house). A 'Scientist Section' is also available and guides the visitor to HERA's plain language Q&A's and ultimately to the whole HERA website in case more detailed information is requested.

'Clean House, Safe Home' will become available to the public towards the end of 2005.

# 8. PROGRESS

## 8.1 Substances assessed 1999-2005

There were three overlapping phases in the HERA Project, each using its own range of substances. These are listed in Table 8.1, with general notes on the functions of the substances and their allocation to each phase of work. It may be seen that the three phases were intended for different purposes. Phase 1 was a 'trial phase', involving only three substances, to learn about the process and to give the Task Forces some examples to work on as they developed the HERA Technical Guidance. The three substances differed from each other: one was inorganic (a water softening agent: Zeolite A); of the other two one was a major tonnage chemical (a surfactant: Alkyl Sulphate) and the other a minor-volume but important ingredient (a fabric brightener: FWA-5). This range of types was needed to check out the general applicability of the Guidance Document.

Phase 2 extended over almost the whole range of functions to be found in products of the HERA type, but it only took selected examples.

The third and final phase was used to deepen our understanding of risk assessment of the whole diversity of chemicals used in HERA-type products and run risk assessments on the complete range of chemicals used in detergents and household products. The degree to which HERA has assessed the whole market sector is discussed in Section 8.2.

Table 8.1

| **Phase 1 – Developing the methodology** | |
|---|---|
| **Substance** | **Function and notes** |
| FWA-5 | Optical brightener |
| Alkyl sulphate family ($C_{12-18}$) | Anionic surfactant |
| Zeolite A | Water softening agent |
| **Phase 2 – Broadening the range of substances examined** | |
| Alcohol ethoxy sulphates | Anionic surfactant |
| Boric acid * | Formulation aid /. Stabiliser |
| Enzyme: protease | Biological cleaning agent |
| Fatty acid salts | Anionic surfactant / Soaps |
| Linear alkylbenzene sulphonates | Anionic surfactant |
| Phosphonates | A class of complexing agents and scale inhibitors |
| Polycyclic musk AHTN * | Perfume ingredients |
| Polycyclic musk HHCB * | |
| Secondary alkane sulphonate | Anionic surfactant |
| Sodium carbonate | Water softening and cleaning agent |
| Sodium perborate (mono and tetrahydrate)* | Bleaching agent |
| Sodium percarbonate | Bleaching agent |
| Sodium tri-polyphosphate | Water softening and cleaning agent |
| Tetra-acetyl ethylene diamine | Bleaching activator |

| Phase 3 – Deepening knowledge on each function | |
|---|---|
| Alkali silicates | Cleaning agent, corrosion inhibitor |
| Amine oxides | Nonionic surfactant |
| Citric acid salts | Complexing agent |
| Cocoamidopropylbetaine | Amphoteric surfactant |
| Cumene-, Toluene- and Xylene-sulphonates, | Formulation aids |
| Diethylenglygol n-butylether | Solvent |
| Enzymes: amylase, lipase and cellulose | Biological cleaning agents |
| Ester Quats | Cationic surfactants, fabric softeners |
| FWA-1 | Optical brighteners |
| Hydrgogen peroxide | Bleaching agent |
| Hydroxycitronellal | Fragrance ingredients |
| Isoeugenol | |
| Isopropyl Alcohol | Solvent |
| Monoethanolamine | Formulation aid |
| Propylenglygol n-butylether | Solvent |
| Sodium sulphate | Formulation aid |
| Zeolites P and X | Water softening agent |

*Chemicals which the EU regarded as a priority for assessment as existing substances.

## 8.2 Coverage of the Product Sector

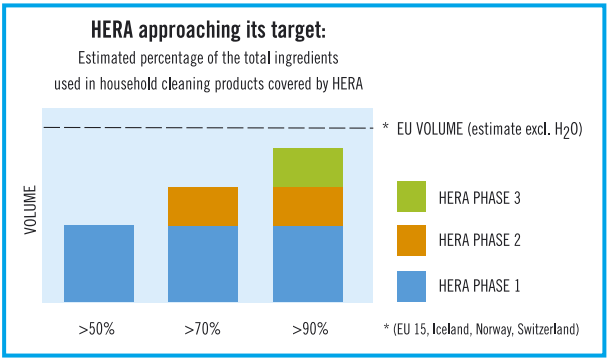
The HERA project was charged by the A.I.S.E. leading companies to assess the risks of all the chemicals in household cleaning products by the end of 2004.

The HERA team responded to this and established a process, based upon carrying out risk assessment of chemicals according to functionality and relevance. Thus all the major functionalities have been addressed, from surfactants, through builders, complexing agents and scale inhibitors, bleaching agents, fabric softeners, solvents and formulation aids to perfume ingredients etc.

Rules were established for the substances whose risk was to be assessed, taking into account competition law. Compatibility with this required that neither proprietary ingredients nor substances where less than three formulator companies used the substance could be assessed.

The programme has been very successful in that all the major functional chemicals will have been assessed.

Analysis by the HERA team indicates that when all the risk assessments have been published, HERA will have examined >90% of the chemicals used across all categories of household products.



## 8.3 Summarised Results of the Risk Assessments

Full summaries and complete texts of all the risk assessments, including uses and tonnages, done under HERA can be found on the HERA web-site at **www.heraproject.com**.

Appendix A provides a note on the special subject of polymers.

# 9. LESSONS LEARNED

The process of undertaking risk assessment, the comments received in the various fora where HERA has been presented and the feed-back from the web-site and the HERA External Advisory Panel, have all contributed to our experience. The following section describes some of the more important lessons learned to date. It is suggested that the value of these lessons lies in their potential universal relevance: an issue uncovered in HERA may be of equal importance to any other type of chemical and chemical use, and to the regulators who are trying to administer the new EU Chemicals Policy.

*Summary*

I) Risk assessment is feasible, it can be a relatively fast process if targeted, i.e. focused on a specific target area but there is no such thing as a quick and easy approach to the assessment of chemicals.

II) The concept of ONE risk assessment per substance has been successfully applied by HERA from the start. All companies producing or using a substance under HERA agreed to the publication of ONE common risk assessment per substance.

III) Environmental risk is generally easier to assess than Human Health risks. This is partly because the system for environmental risk assessment does not call for as much judgement as the human health equivalent. The latter is typically concerned with the protection of the individual, whereas in the environment the target for protection is much wider – the population or even an entire ecosystem.

IV) The household cleaning product sector has unique features that others might not have. The approach to supplier/user collaboration and the depth of risk assessment required in the HERA Project result from the particular features of this supply chain. Aspects now recognised as significant include

1) chemicals are used in high volume;
2) there is a relatively short supply chain between chemical suppliers and downstream users;
3) the chemicals are present in every home and with exposure to large numbers of consumers;
4) the chemicals are discharged down-the-drain after use with the potential for wide dispersion in the environment. Alternative approaches may be more appropriate where these features are not present.

V) There is a need for commitment at the highest levels of Companies involved. In larger companies, support from the head of the Business Unit concerned may also be critical. Expert resources are finite and are being solicited to support many other programmes, both legally obligatory and voluntary. They will need the commitment of their management to engage in supporting HERA.

VI) Communication priorities may differ. Downstream user companies, which sell directly to the general public, are very conscious of the vital importance of risk assessment for consumer health and environment and wish to communicate relevant information proactively to insure public confidence. Chemical producers are equally concerned about the safe use of their chemicals by consumers; however, their natural focus is on ensuring safety during the production and distribution phases and on communicating safety information to their direct customers. These differences need to be ironed out when dealing with external stakeholders, as involvement and consultation with these partners is key in order to ensure transparency of the project.

VII) There is a need for a *modus operandi* to organise collaboration of producers and downstream users. It does not happen by chance. Rules must be established and legislation (eg competition law) be observed. In this market area there had been a substantial history of collaboration between suppliers and downstream users and between some of their associations, particularly on environmental aspects. These relationships, both organisational and individual, have helped initiate and progress the project.

VIII) Setting up, from the onset, contact points knowledgeable about the needs and the project in every company (suppliers AND downstream users) has been critical to the realisation of the project.

IX) Organising flexible teams but with a few core individuals providing continuity is also of great help in such a lengthy project.

X) The budgetary burden must be acceptable, ie relatively light, knowing that some members will contribute more financially and some will contribute more in human resources or data. Funding contributions via existing supplier Sector Groups using existing budget processes has been helpful and broadens ownership of the project and its results. For perspective, direct funding per company or Sector Group has been in the range of 12,000 - 15,000 €/yr. This excludes indirect support in personnel and sweat equity or outside consultant work on risk assessments.

XI) Common exposure scenarios are feasible. This means that once an exposure scenario has been defined for one use, any product used for that purpose can be dissected to define its ingredients and these ingredients can utilise the common scenario defined. This makes the risk assessment of a new substance easier to do if another substance used for the same purpose has already been studied.

XII) The producers of household detergent and cleaning chemicals (in contradiction to the implication for Downstream Users in the original White Paper on REACH) do have up-to-date data to contribute on both hazard and exposure for ingredients, and they also have data on finished products (preparations) which may be of use in certain aspects of risk assessment,

such as particular issues concerning risks to Human Health. HERA is clearly showing that the best way to truly asses the safety of any chemical is by full co-operation between Suppliers and Users of this chemical.

XIII) Legitimate barriers to co-operation arise not only from concerns re competition law, but also from the financial and competitive value of proprietary data. This will be a continuous barrier to full co-operation until the "vagueness" of the REACH text around this point is lifted. Several scenarios were developed to cope with the competition law while progressing on the reports. Sorting out the potential legal issues within a consortium is critical for progress and for properly working the best form of co-operation within a consortium.

XIV) It takes time, effort and encouragement from a substance or user group co-ordinator to get all relevant information (hazard data, use information, tonnage, chemical identity etc) from potential contributors. Simply sending out a survey is normally not sufficient. This is not ill will. Each company is organised differently and data management and retrieval systems vary. It is a lot easier for some to respond than others. In some cases getting a response requires changing organisation or priorities, not just getting the request to the top of an overloaded in-tray.

XV) Active communication among the players, both within Companies and Associations and towards the outside is paramount. A variety of media are needed: the web, newsletters, workshops, conferences, posters etc. It cannot be taken for granted that everybody "knows". Internal communication (within Companies) is far more critical than first imagined. Three years after starting the project, we realised that visibility and awareness of the HERA project within industry needed to be further strengthened. The communications efforts were directed partly to this end. In any project of this type, in order not to forget the lessons learned, a record must be kept and regularly reviewed of what worked and what did not, new solutions etc.

XVI) Skilled technical resources in industry are not unlimited. The collection, assessment and use of hazard and exposure data require specific skills. There may be a need for highly experienced staff to make the necessary robust judgements. The validation of existing data and the deliberate setting aside of poor quality data needs skilful justification steps and rigorous documentation.

XVII) *Hazard data generation:* Unlike the HPV programmes, it was not the intention for HERA to fill gaps in standard data sets. However, the discipline of developing a standardized risk assessment and exposing it to scrutiny, both internally within the project and externally, was expected to provide valuable insight into where an assessment was weak. There has already been an example in HERA where a risk assessment could be completed with an acceptable outcome, but where suppliers working through their Sector Group elected independently to fund generation of additional data to enable refinement of the risk assessment. The web-site describes some such findings.

XVIII) *Upstream/downstream collaboration:* There is considerable and potentially unique experience among Suppliers and among Downstream Users in this market sector of working together in their respective associations. There is also some experience of upstream/downstream collaboration on specific projects e.g. the environmental risk assessment activities of ERASM[16] (a description is provided by Steber, 2000), but such collaboration is generally less extensive and

less institutionalised. Among the difficulties encountered in supplier/user collaboration have been unexpected mismatches in estimates of usage volume developed by suppliers and users. Resolving these can consume much time and effort. Leadership was needed in the Substance Team to recognise when such issues had been sufficiently resolved from a risk assessment perspective and it was acceptable to move on, or excessive delay could result. Secondly, there was (and will be under REACH) a need to coordinate requests for data on different substances before they are sent to Downstream Users. It was found to be very helpful if requests for data could be sent out in standard format and for a number of chemicals together on a campaign basis. End users can manage their response much better if they know what the overall plan is, when to expect the request and when it must be completed.

XIX) *An open mind on means of working:* There was no value in constraining Substance Teams to deliver their risk assessments by a single approach. A variety of tactics evolved naturally. These included an individual working on a draft; the Substance Team working collectively as a group; the group delegating to a consultant firm to deliver what was needed. Each method no doubt had its merits and disadvantages – the value of a democratic approach, the cost of a consultant, the speed of a one-man-band and so on.

XX) *The value of an external advisory panel:* HERA benefited from the close scrutiny of its External Advisory Panel. Most of the scientists in the HERA project had not worked in government departments and were not from academia. These environments bring their own attitudes to subjects such as risk assessment, divorced from any economic concerns about the long-term viability of a chemical for domestic use. Thus we gained unbiased criticism of our work and sound suggestions towards improving the science and increasing the acceptability of our results. The Panel showed itself to be flexible, dealing with a naturally erratic delivery of work for assessment. Dialogue was open and constructive, and the Panel was able to contribute in particular to the first HERA Workshop.

XXI) *Collaboration with other programmes:* There are both benefits and disadvantages where data on particular chemicals or families are also being collected and assessed in parallel initiatives, for example the ICCA HPV Initiative. Collaboration can result in efficiencies, more complete data sets and higher quality assessments where it results in common family definitions, mutual use of data compilations from one programme in the other, and access to a wider pool of studies. But achieving this is a challenge and has resulted in slower progress and rework in some cases through not engaging all contributing parties from the beginning, and where the programmes are moving with different timelines. In some cases other programmes have slowed down HERA progress, at times considerably, by having no firm deadline to reporting their work, and preventing HERA to develop a parallel activity on the same substance.

*In summary, HERA has been 'learning by doing' and this has proved a very valuable experience.*

**16** ERASM is the Detergent Industry (Suppliers and Downstream Users) Environmental Risk Assessment of Surfactants Management group. It was created in 1991 by the two relevant associations A.I.S.E. (Association Internationale de la Savonnerie, de la Détergence et des Produits d'Entretien) and CESIO Comité Européen des Agents de Surface et Intermédiaires Organiques. It initiates and co-ordinates joint industry activities for improving and enlarging the basis for and knowledge about the risk assessment of detergent-based surfactants in environmental compartments.

# 10. HERA and REACH

## 10.1 The Alignment of HERA and REACH

Although HERA has a limited remit, in other words to develop risk assessments for a particular range of chemicals and not to proceed to manage those risks, it has preceded and co-existed with the drafting and discussions of REACH, whose principal chemicals management tool is also based on risk assessment. HERA and REACH are closely aligned, because good approaches to risk assessment are inevitably unified. To demonstrate where the results of HERA, including its lessons learned, can have immediate application in REACH, the following diagram (Figure 10.1) shows the contributions available.

There are other players, omitted from this diagram, namely the Agency set up by the Commission in Helsinki to administer REACH, the Member States and the European Commission. All of these have activities in certain parts of the process.

The diagram shows the Industry's points of action ("By whom?") and the main headings for the REACH Process ("What?"). The information in the right-hand column indicates where HERA's work can contribute, and indeed must contribute (with the possible exception of the last item) if REACH Consortia are to acquire all the information they are going to need from the Detergents Sector (and others for that matter, where HERA substances are used for other purposes). A summary of HERA's contribution follows, using the terms familiar to the REACH process.

Figure 10.1 HERA within REACH

| By whom? ▶ / What? ▼ | Manufacturers/ Importers | Downstream Users | |
|---|---|---|---|
| Pre-registration ▼ | active | * | HERA helps to identify chemicals in use. HERA helps to ensure that animal test data are identified and that any data gaps are clearly defined. |
| Registration ▼ Dossier Evaluation ▼ | active | active or passive | HERA provides intrinsic properties, exposure estimates and risk assessments within its target scenarios. |
| Substance Evaluation | passive | passive | HERA identifies appropriate areas for risk management and allows defensive stances to be developed. |
| Authorisation | | passive | It is inconceivable that ingredients in household detergents will undergo Authorisation under REACH |
| Restrictions | | | HERA helps to manage discussions with the evaluating Member State |

*On a strictly voluntary basis DUs may make available information on vertebrate animal studies that they possess and which they are prepared to share with the members of a "Substance Information Exchange Forum (SIEF)".

### *Pre-registration*

In this stage all Manufacturers or Importers (Suppliers) who wish to supply a chemical in the EU (unless that chemical is already covered under other legislation e.g. pesticides) must complete and submit to the Agency an extensive form known as Pre-Registration. One objective of this is to make sure that in subsequent activities animal testing is minimised. It is also a source of information for registrants (manufacturers/importers) who wish to form a voluntary consortium for the registration of a substance, and for Downstream Users who wish to actively inform manufacturers/importers of "identified uses". Above some very low tonnage level it is recommended for the Downstream User to do this if confidentiality reasons permit. Otherwise the Downstream User will have to register the undisclosed use himself or subsequent use of that chemical for a purpose not disclosed will be illegal.

*HERA has defined the uses of a wide range of chemicals in household cleaning. Each of these pieces of information will have value in Pre-Registration.*

### *Registration*

In the Registration stage a great deal of work must be done by the Suppliers, who must submit a full package of information to the Agency on every applicable chemical they supply. The Downstream users would be expected to add their own data on intrinsic properties of the chemical (they often generate their own data if they have the resource) and in particular to describe the exposure conditions of humans and the environment to the chemical in their specific use or uses. In this way the two aspects of a risk assessment are assembled, as already described in Section 6.2.

*HERA has completed exactly these steps within its chosen use scenarios and has delivered the risk assessment using classical techniques as used in the EU.*

### *Evaluation*

Evaluation in REACH means two things: a) the evaluation of the paperwork (the 'dossier') to check for quality and content and to comment on the testing proposal, partly and importantly to prevent unnecessary animal testing and b) evaluation of the substance, giving the authorities the mechanism by which they can require industry to provide more information. The latter can become the starting point for a proposal by the evaluating Member State for restrictions of marketing and use.

*HERA has employed its External Advisory Panel to scrutinise its methods and assessments and has used the risk assessment process itself to highlight any requirements for additional data.*

*HERA helps to manage discussions with the evaluating Member States.*

### *Authorisation*

Where a substance is of very high concern (perhaps it is carcinogenic, mutagenic, a reproductive toxicant or very persistent combined with a great capacity to accumulate in food chains) it may still be important to use it for some special purposes where the risk can be strictly controlled. This needs a special assessment process which is termed Authorisation.

*The kinds of substance used in domestic laundry and cleaning are unlikely to attract an authorisation procedure so HERA does not have anything special to offer here, except to ensure that when an issue is raised about a chemical the data on which any concern is based must be of sufficient quality to justify the concern.*

*In addition*

We should add however, that where REACH currently stops short – by not providing the EU public with clear communication on chemicals. HERA has gone before and tried to work out ways of talking to the consumer in a constructive and helpful manner to enable safety in use of domestic products. Clean House, Safe Home is one such example.

## 10.2 The Future 'Beyond HERA'

In one respect the HERA project will come to a natural end when all the substances it set out to address have been assessed and the results published. However, HERA has turned out to be much more than a vehicle for publishing risk assessments: it has acted as a prototype of many of the issues now being considered by REACH – thus the title of this booklet Five years ahead of REACH. This title should not be taken to imply that there is some kind of race going on. HERA simply started first and encountered many of the real issues for which a workable REACH will have to find solutions. Meanwhile, the HERA experience has been offered to the chemical industry in a spirit of openness so that the procedures developed may be considered and possibly a great deal of time and money saved.

The particular items 'on offer' are a Code of Conduct, the risk assessment methodology, the experience of forming consortia and systems for effective communication to the people who matter, those who will pay for any new European legislation – the public. HERA, through such activity as this booklet, aims at helping the rest of the industry to be more effective in dealing with chemical safety, and brings proven tools to that effect. It also has the ambition to help set a "Code of Conduct" to incite suppliers and users of chemicals to work together to establish better ethics around chemicals safety. Finally it will continue to pioneer communication of safety and risk through such initiatives as "Clean House, Safe Home" and a reflection on proper communication tools on chemical risk.

### The Value of HERA

To business:
HERA has brought together experts and is providing reassurance that industry is behaving responsibly;

To regulators:
HERA has provided a common industry response and is contributing to the successful implementation of REACH;

To the general public:
HERA has communicated the outcome of risk assessments in an accessible and understandable format and the public will benefit from the use of such assessments by companies in the development of new and better products.

# APPENDIX A: POLYMERS

Polymers are a group of chemicals which are currently not subject to registration under the Commission's REACH proposal because they have very complex structures and also because they are judged to represent less concern than 'regular' chemicals. However, these substances are commonly used in detergents and household cleaning products.

Despite the vast technical challenge they represent, and for the sake of completeness, HERA has undertaken the programme below on Polymers.

## 1) Polymers: Background and Definition

A polymer is simply a large, sometimes very large molecule built up by repetitive bonding together of many smaller molecules, called monomers. Nature makes wide use of biological polymers (e.g. cellulose, proteins, and nucleic acids). Although most synthetic polymers are chemically much simpler than biopolymers, there is an immense diversity in the structures and properties of those.

Polymers are defined by OECD and this definition is used within the EU for regulatory purposes. HERA, therefore, uses this in its definition. The OECD definition was developed to describe synthetic polymers, rather than to provide a sound scientific umbrella-definition. For example, this definition does not include a molecular weight threshold, and a distribution over a range of molecular weights is an obligatory attribute. As a result, some biopolymers with high molecular weight (e.g. enzymes such as protease) are NOT polymers according to this OECD definition.

Polymers are increasingly being used in household detergents, providing multiple benefits ranging from basic performance such as auxiliary building to specific role for colour/fibre or surface care. They have been a driving factor in the development of new detergent formulations meeting changing consumer habits and needs.

Typical examples of Polymers used in Detergents and other cleaning products are Polycarboxylates (co- and homopolymers of Maleic Acid and Acrylic Acid), Polydimethylsiloxane. Alcohol Ethoxylates, one of the largest surfactants group in household detergents, are also polymers according to this definition.

## 2) Polymers under REACH

Currently, Polymers are "exempted" from REACH for reasons of workability and to focus resource on substances of more concern". However, the Commission is committed to consider Polymers at a later stage.

Article 14 of the current REACH draft says: "Before any proposal for introducing certain Polymers into the requirement to register is made, the Commission shall prepare a report looking at the risks of Polymers in comparison with others substances and whether, considering the balance between protecting human health and environment and ensuring competitiveness and innovation on the other, certain types of Polymers should be registered."

## 3) HERA's position on Polymers

A risk assessment for (a category of) polymers is very difficult to conduct, since characterisation is complex.

This is particularly true of Polymers used in Household products which are very complex mixtures of chain length, structures, feedstock, monomeric origins, etc, and are often molecules made of several different Polymers adding further to the complexity. Furthermore, there is no agreed or uniform methodology for these assessments. One of the crucial issues for such a risk assessment is the rationale for grouping, and the identification of representative species. Nevertheless and consistent with its transparency principle, HERA is pioneering in this difficult field, using new approaches, to see if these difficulties can be overcome and if a risk assessment is still feasible. But, understandably, this effort will require more time than for a conventional substance. This will be illustrated in more detail for Alcohol Ethoxylates (AE), a major category of surfactants being widely used in household detergents.

### *a) Substance identification and grouping*

Detergent-relevant AE are derived from linear primary alcohols in the range of C9 to C18. As marketed, such alcohols usually contain a distribution of alkyl chain lengths, including mixtures of entirely linear alkyl chains, and mixtures of linear and mono (methyl) branched alkyl chains (either in 2-position, or along the C-chain), though still with a linear backbone. The feedstock comprises alcohols from vegetable or animal sources via oleochemical processes, alcohols derived from the ethylene via Ziegler chemistry, or those derived from higher olefins via oxo-chemistry including the Fischer-Tropsch route. A more detailed analysis indicates that quite a large number of different C-Chains is present in the C9-C18 category; an "optimistic guess" for this purpose would be 20.

Ethoxylation of these base alcohols (i.e. the reaction with ethylene oxide) produces mixtures of homologues alcohol polyethyleneglycol ethers (Alcohol Ethoxylates=AE). The resulting material has a broad homologue distribution with a substantial content of still un-reacted alcohol. A typical AE with an average ethoxylation-degree of 7*EO units comprises compounds between 0*EO (the free alcohol) up to 20*EO or even higher.

### *b) Pilot Trial*

A risk assessment of Alcohol Ethoxylates has been carried out previously in the Netherlands by NVZ[1] in co-operation with RIVM[2] and VROM[3]; However it was recognised that there were a number of methodological issue that required to be tackled in order to arrive at a more robust methodology to deal with multi-component substances.

HERA has pioneered ways for dealing with multi-component substances. In its environmental risk assessments for example, it has proposed either the "toxic units" approach (used in the risk assessment of Alkyl Sulphates), or the "weighted average structure" approach (used in the risk assessment of LAS).

Based on the experience in the assessment of complex mixtures, HERA has decided to run a pilot trial for polymers, starting with Alcohol Ethoxylates (AE). A feasibility study is underway, looking into the possibilities to develop a workable methodology, using scientifically sound and sustainable ways under the HERA umbrella. First results are currently scheduled to be available during the second half of 2005.

### *c) Conclusion*

At present, it is still uncertain whether HERA´s methodology can be extended to Alcohol Ethoxylates or other polymers being used in household detergents. This will be depending on the outcome of the feasibility study described above.

**1.** Nederlandse Vereniging voor Zeepfabrikanten
**2.** Rijksinstituut voor Volkgezondheid en Milieu
**3.** Miniterie voor ruimte, wonen, milieu en rijksgebouwen

# APPENDIX B: GLOSSARY

| | |
|---|---|
| **ACA** | Alliance of Chemical Awareness |
| **AEPSAT** | Asociación Española de Productores de Sustancias para Aplicaciones Tensioactivas |
| **A.I.S.E.** | International Association for Soaps, Detergents and Maintenance Products |
| **AMFEP** | Association of Manufacturers and Formulators of Enzyme Products |
| **ASSOBASE PITIO** | Federazione Nazionale dell Industria Chimica (I) |
| **CAS** | Chemical Abstract Service Number (see Section 6.2) |
| **CDA** | Confidential Disclosure Agreement (see Section 6.1.2) |
| **CEEP** | Centre Européen d'Etudes des Polyphosphates |
| **CEES** | Centre Européen d'Etude des Silicates |
| **Cefic** | The European Chemicals Industry Council |
| **CES** | Centre Européen des Silicones |
| **CESIO** | Comité Européen des Agents de Surface et de leurs Intermédiaires Organiques |
| **CICAD** | Concise International Chemical Assessment Documents |
| **DETIC** | Association Belgo-Luxembourgeoise des producteurs et des distributeurs de savons, cosmétiques, détergents, produits d'entretien, d'hygiène et de toilette, colles et produits connexes |
| **EAP** | External Advisory Panel |
| **ECETOC** | European Centre for Ecotoxicology and Toxicology of Chemicals |
| **ECOSOL** | European Centre of Studies of LAB/LAS |
| **EFFA** | European Flavour & Fragrance Association |
| **ERASM** | Environmental Risk Assessment of Surfactants Management group (see footnote 16) |
| **EUSES** | European Uniform System for the Evaluation of Substances (see Section 6.2) |
| **GOSIP CIA** | Group for Inorganic Surfactants and Intermediate Products (UK) |
| **HERA** | Human and Environmental Risk Assessment |
| **HPVC** | High Production Volume Chemicals |

| | |
|---|---|
| **ICCA** | International Council of Chemical Associations |
| **IPCS** | International Programme on Chemicals Safety |
| **JSDA** | Japanese Soap & Detergents Association |
| **NGO** | Non-Governmental Organisation |
| **NOAEL** | No Observed Adverse Effect Level |
| **NVZ** | Nederlandse Vereniging voor Zeepfabrikanten (NL) |
| **OECD** | Organisation for Economic Co-operation and Development |
| **OSPA** | Oxygenated Solvent Producers Association |
| **PEC** | Predicted Environmental Concentration |
| **PNEC** | Predicted No Effect Concentration |
| **REACH** | Registration, Evaluation and Authorisation of Chemicals |
| **RIP** | REACH Implementation Project |
| **RIVM** | Rijksinstituut voor Volkgezondheid en Milieu (NL) |
| **SETAC** | Society of Environmental Toxicology and Chemistry |
| **SGCI** | Schweizerische Gesellschaft für Chemische Industrie |
| **SIDS** | Safety Information Data Sheet |
| **TEGEWA** | Home of Tendering Generating Watching |
| **TGD** | Technical Guidance Document |
| **UIC** | Union des Industries Chimiques (F) |
| **US SDA** | United States Soap & Detergents Association |
| **VROM** | Miniterie voor ruimte, wonen, milieu en rijksgebouwen (NL) |
| **WWTW** | Wast Water Treatment Works |
| **ZEODET** | Association of Detergent Zeolite Producers |

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HERA

Human and Environmental Risk Assessment
on Ingredients of Household Cleaning Products

Square Marie-Louise 49
B-1000 Brussels
Tel. +32 2 230 83 71
Fax. +32 2 230 82 88
e-mail : main@heraproject.com
www.heraproject.com

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