

## **HERA AND THE RISK MANAGEMENT PROCESS**

**FD October 14, 2003**

### **Summary:**

HERA is not involved in Risk Management, but HERA contributes to the information that companies need to make Risk Management decisions.

### **1. Preamble**

For any type of risk, including risks possibly associated with chemicals and products made from chemicals, defining safety to human health and the environment requires

- an assessment of the defined or probable risk, comprising both hazard assessment and exposure analysis,
- management of the risk and
- communication to various audiences about the safety profile, the risk or absence thereof and any management measures.

Risk assessment is predictive and may lead to risk management. It uses scientific tools and knowledge to determine hazard profiles of chemicals and the likely exposure of people and the environment to chemicals. Risk management should flow primarily from risk assessment but may also arise from political or business policy, and, for companies, a business decision. This is because, within society, there are many perceptions of “risk”, its acceptability and its “necessity” in terms of the efficacy of chemicals to do a particular job. Furthermore, since each management decision is associated with an economic value, considerations like societal aspirations, social effects, costs, feasibility, and availability of resources, geographical circumstances etc. may also play a role in the final risk management decisions, in addition to the risk assessment.

### **2. The focus of HERA**

The first aim of the HERA initiative (Human and Environmental Risk Assessment) is to demonstrate that risk assessment, in addition to hazard identification, is essential to establish the safety in use of chemicals with broad exposure to the public and the environment. Risk assessment has been criticized in the past as either unnecessary or too slow and cumbersome. HERA sets out to prove that risk assessment is a feasible process, using chemicals in detergents and household cleaning products as an example.

Two consecutive HERA workshops in 2001 and 2002, and numerous dialogues with interested parties from Governments and NGO’s secured a broad consensus on the value of HERA as a model for risk assessment in practice and for suppliers-users partnerships. But many inquired how HERA handles risk management, which to date has not been made explicit.

### **3. Risk Management in the Detergent and Cleaning Product Sector**

Over the years, many tools have been used in the detergent and cleaning product sector by suppliers and by users, frequently acting in concert.

Risk Management options to reduce or eliminate exposure to chemicals have ranged from:

***a) Proactive measures early in the product development process on the choice of a substance:***

Substances or product prototypes where scientific evidence shows grounds for concern or is insufficient or inconclusive have been proactively eliminated as a precautionary measure long before widespread marketing occurred. The scientific evidence did not appear worth refining, possibly because of a need for additional animal studies.

In other cases, a series of chemicals may be compared to select the best one overall for safety and performance.

Such decisions are usually taken within individual companies without the knowledge of the outside world.

***b) Acting over time on the choice of a chemical for particular products; chemical specifications; raw material or product handling***

Actions include:

- manufacturing process improvements, which allow a reduction or elimination or avoidance of minor components of concern;
- modifying the physical presentation of the chemical to reduce exposure;
- improving the biodegradability profile of a class of ingredients;
- limiting the tonnage of a chemical to the applications offering the highest societal benefit;
- limiting chemicals to those applications where there is currently no alternative;
- voluntarily substituting or developing substitutes for substances where there are causes of possible concern.

***c) Acting on the communication regarding substances or finished products containing them***

For example

- providing clear instructions for use and for storage, training and education; e.g. discretionary additional guidance on safety data sheets;
- applying packaging constraints like child resistant closures.

Each of these cases is recognised to be more complex than portrayed here, and the assessment may have evolved as additional knowledge is generated. The examples are quoted merely to illustrate that companies have made risk management decisions.

The examples are not exhaustive but are illustrations of measures, which companies took in the past with the available knowledge at the time in the context of detergent and cleaning products. It is entirely conceivable that different decisions on the same substances might have been taken by the same suppliers and by other downstream sectors for other applications.

The majority of the examples above were not solely based on the scientific risk assessment but took additional factors into account such as public perception, reputation, regulatory complexity, costs and resources. Indeed in many cases, safety could be adequately demonstrated, yet a company or industry-group decision was taken to reduce, substitute etc..

Most of such issues were discussed and debated within the industry sectors, but decisions are invariably taken at company level.



Human and Environmental Risk Assessment  
on ingredients of household cleaning products

#### **4. The role of HERA in risk management**

The substances and families of substances chosen for HERA are *existing* chemicals. Many of them have been produced and marketed for use in detergent and cleaning products for decades, some of them in very high tonnages. As indicated above, on every one of these, an analysis of the need for risk management was already done in the past by each participating company individually, within their range of responsibility. In the majority of cases, the risk assessment showed that the substance was safe for human health and the environment in the application concerned, and thus the formulated product could be sold without explicit management measures. At other times, risk management measures were taken as described above.

HERA's aim is to help refine some of these historic decisions, question the need for others, or identify additional needs for measures not apparent earlier because the state of knowledge is continually advancing.

Indeed the HERA approach allows

- one common risk assessment of a substance by producers and by downstream users combining their knowledge and expert resources;
- a risk assessment methodology agreed upon by the HERA experts and acknowledged by the stakeholders consulted, providing more standardized and verifiable use of hazard and exposure information;
- risk assessment conclusions discussed openly between experts and published as drafts on the world-wide web, offering more possibilities for further dialogue;
- post verification for the detergent and cleaning product industry of the safety assessment conclusions and/or risk management measures already taken.

In conclusion, HERA does not provide Risk Management recommendation. However, if HERA assessment had suggested or would suggest a need for additional management measures, this will be highlighted so that each company evaluates its options and takes its own informed decisions.

Ultimately, Risk Management for products placed on the market is a matter for their manufacturers, and HERA accepts no liability for its Risk Assessments or for measures taken or not taken by manufacturers.