

# Chemical substances: an industry takes responsibility and gets mobilised

*Companies using chemical substances, such as Procter & Gamble or Unilever, are getting ahead of the Commission's proposals by deciding to group themselves together. Thanks to the HERA project, they are becoming more efficient in testing chemical substances and increasing their transparency to the consumer. But aren't the requirements contained in the White Paper in danger of holding up this essential work being carried out by an industry that is feeling responsible?*

The downstream users of chemicals (known as "DUC") have always seen their main priority as responding to consumers who are becoming more and more demanding in terms of efficiency and safety. This ambition is perfectly consistent with the well-being these products offer to consumers. Each of those companies is well aware that its image depends on constant innovation as well as a high level of satisfaction and safety of its consumers. Moreover, much research has been carried out into the environmental impact of the use of these products. While being both a constraint and a driving force of innovation, the environment is now part of a researcher's day-to-day work.

## A longstanding and shared awareness

Faced with these requirements, each of the DUCs has taken specific action, although they have all been aiming at the same goal. By massively supporting research and development and creating research laboratories, their main objective is certainly to promote innovation, which gives them increased market share. But every new substance is tested and potential risks evaluated before it is launched on the market. For its part, the EC began to regulate chemical substances in 1967 when it decided to harmonise legislation in its six Member States concerning the classification, packaging and labelling of hazardous substances. From then on, the Commission has always put forward the necessity of harmonising all the regulations dealing with the use of the said hazardous substances and preparations (effective as of 1976, the 76/769 Directive bans the selling of substances containing too many risks to the consumer or environment).

This concern has been growing, especially with the development of an environmental policy since 1972. In this scope, the Commission has put sector-based action programmes in place. The fifth Action Programme (1992-2000) marked the beginning of a proactive policy since it called for the integration of the environmental dimension within all areas of the Commission's policies.

## The REACH system

By creating the REACH system (Registration, Evaluation and Authorisation of Chemicals), the European Commission wants to put in place a coherent system and put an end to the two risk assessment procedures which exist today, and make a distinction between "existing" and "new" substances (ie those on the market since 1981).

Although 2,700 "new" substances have already been tested, all "existing" substances must also be analysed. And these existing substances represent 99% of all chemical substances used (ie at least 30,000 substances).

As its name indicates, the REACH system consists of a three-step procedure:

**Registration:** industries wishing to produce or import substances must put forward a dossier containing all the information required by legislation. This data will then be put into an electronic database and will be checked from time to time by the relevant authorities.

**Evaluation:** the authorities examine the data provided by industry and give their opinion on the test programmes made

In February 2001, the publication of the White Paper on the "Strategy for a future chemical substances policy" represented a success. The Commission's first objective was to implement a single regulatory framework for a better protection of the environment and consumers through better communication from industries using or producing chemical substances.

For when it comes to chemical substances, the main obstacle is the lack of precise knowledge about a large number of them. A risk assessment procedure had already been put in place in 1981, which made testing of the hazards of all chemical substances discovered after 1981 (the so called "new" substances) compulsory. But this decision was not retroactive for "existing" substances. Hence the White Paper's call for the launch of the REACH

system: by 2012, all chemical substances will have to be tested and assessed.

The DUCs have played their part in expressing their concern about transparency. In 1999, two associations which grouped DUCs (detergents and cleaning materials) and chemical manufacturers decided to renounce the confidentiality of their formulas and share their risk assessment procedures for chemical substances they had been using for years. As Dr Véronique Scailteur, Associate Director Corporate External Relations Europe at Procter & Gamble, states, the launch of HERA (for Human and Environmental Risk Assessment) represents a great step forward. The aim of this operation is to deliver clear and dependable information to both consumers and regulatory authorities. Last but not least, HERA will allow the set up of a database on these classified products for legislating authorities, chiefly the European Union.

## A necessary and ambitious programme with many economic consequences

The DUCs agree in principle with the spirit of the White Paper.

In addition to the fact that it simplifies legislation, which is today much too complex to be effective, it follows the same concern about protecting the consumer and the environment. Moreover, it will oblige all companies to be particularly vigilant about the composition of products on the market. The DUCs also agree with the Commission on acknowledging science as the essential basis for any regulatory measure, which shows the same concern about being rational.

But there are still some uncertainties, mainly concerning technical matters. How do you determine whether a product is hazardous or not? The DUCs insist on the fact that some contributors to the White Paper are focusing on the pure collection of data concerning the impact of chemical substances without taking their actual level of exposure into account and fixing clear priorities. The DUCs consider the priority should be the elimination or the control of serious risk to health or the environment, rather than worrying about systematically assessing all substances on the market.

The program recommends the testing, or at least the assessment, of a minimum of 30,000 substances over a period of 12 years. But within HERA's framework, which started in 1999, 16 categories of ingredients used in detergents are currently being analysed. This work will be spread over 2 years. Therefore, it is foreseen that classifying all the substances at stake will take a long time.

*Each of those companies is well aware that its image depends on constant innovation as well as a high level of safety of its consumers and the environment.*

In addition to this, another problem is the increasing number of laboratory animals needed (knowing that alternative methods to animal testing will be preferred), and above all the difficulty of finding the financial and human resources required (toxicology and eco-toxicology experts, specialised laboratories, etc.) within such a short time. Finally, the DUCs fear that competition law could be distorted by increasing safety requirements. Indeed, mobilising resources will definitely have a negative impact on the competitiveness of the companies concerned (especially SMEs), without forgetting that more restrictive measures could lead to some of these companies relocating their activities to

• WITH THE PARTICIPATION OF •



Procter & Gamble is looking to combine technical research and safety.



The White Paper's aim: to test chemical substances and evaluate their impact on the environment and public health.

This authorisation will take into account the economic and social effects of the use or withdrawal of these substances.

Finally, an accelerated procedure will be implemented for the specific use of substances where restrictive measures prove necessary. The White Paper aims at increasing the transparency of information concerning chemical substances, with the aim of managing risk to protect both the environment and the health of the consumer.

for each substance; these programmes are established by the industries themselves and validated by the relevant authority.

**Authorisation:** "For substances of very high concern, the authorities will have to give a specific permission" (White Paper 4.3).

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DOSSIER

other parts of the world where safety requirements are less strict. Hence the need to involve these other countries which either produce or use chemical substances.

In the same way, the implementation of the substitution principle has not only been approved but also already applied. Nonetheless, the DUCs would like a clear definition of this principle. For the time being, manufacturers are asking that it is not considered necessary to substitute an ingredient which has a property deemed unacceptable by some, when it can be proven that the risk it bears for day-to-day life is negligible. Is it logical, for example, to ban vitamin A or ethanol, which are both considered intrinsically toxic for reproduction, when their presence within many consumer goods (detergents, cosmetics, etc.) will never result in such consequences?

Moreover, the inherent risk of a substitution substance will need to be considered throughout its whole life cycle. A substitution that has been made too rapidly might well lead to bad decisions.

## A industry which feels responsible and is seeking collaboration

The DUCs have shown their concern for a better protection of the environment and the consumer. However, they are ready to admit their shortcomings in terms of communication and partnerships. As Charles Laroche (Vice-President Corporate relations & Public Affairs at Unilever Home and Personal Care - Europe) points out, scientists have not understood that "emotion is part of life", and that what is consistent from a scientific point of view needs to be explained to the general public and political decision-makers.

The most important thing is to avoid demonising chemical substances and any psychosis among consumers. Chemical substances are necessary for almost everything we use in our everyday life. Therefore, labelling of the word "hazardous" on each product containing a substance that has been classified as hazardous could well go against the transparency objective announced in the White Paper. Although the DUCs are ready to provide useful and useable information to the general public, they are also concerned about not overusing the concept of hazard. The consumer could well be inclined to lose his/her sense of vigilance and, after having used a product classified as "hazardous" many times with no problem, no longer be able to assess the scale of hazard of use.

Manufacturers do not wish to jeopardise the relationship of trust they have built with consumers; making the term "hazardous" systematic could discredit the whole industry which has always seen its main priority as improving the life of consumers.

As a consequence, the DUCs emphasise the necessity of distinguishing between risk and hazard. Providing that Directive

76/769 has already prevented certain hazardous substances from being sold, the White Paper would introduce even stricter measures which, according to manufacturers, are not justified. The fact that a chemical substance has hazardous properties does not automatically mean it must be removed from the market. It can often help production processes to take place in a safer and more ecological or economical way.

Hence the importance of a policy based on risk analysis and not simply the intrinsic hazardous

properties of certain substances. It is then a case of defining a regulation which would ban the use of those hazardous substances that have risks rather than one that would ban the use of all

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For Unilever, innovation should enable the reduction of the required quantities of detergents.

hazardous substances.

Finally, the DUCs are asking for the action taken within HERA project to be considered and conclusions drawn from it that would lead to a re-evaluation of the schedule proposed by the White Paper. They propose a cooperation with the European Commission to optimise the results of the ambitious programmes the two organisations have put in place.

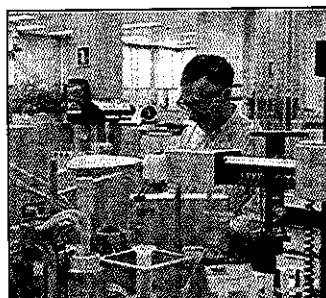
The DUCs, and in particular detergent and cleaning material manufacturers, wish to follow the White Paper recommendations which confirm the action they have already taken. But they have a firm opinion on the adjustments needed to enhance the feasibility of the programme. And they do wonder to what extent this White Paper will improve health and environmental issues.

Caroline HUPIN

## HERA: A pioneering project

The HERA (Human and Environmental Risk Assessment) project was set up in 1999 by two organisations: AISE, which groups manufacturers of detergents and cleaning products, and C.E.F.I.C., which represents suppliers and manufacturers of chemical substances. HERA constitutes a unique partnership in Europe.

This initiative aims at responding to an increasing demand for transparency from consumers and public authorities. Therefore the DUCs and producers of chemical substances decided to pool their knowledge and develop a unique methodology for establishing a collective list of tested products whose



Two organisations have grouped together to share their research.

At present, 115 chemical substances have been studied, that is to say 16 categories of substances. The results can be found on the Internet at <http://www.heraproject.com>.

HERA brings together teams of environmental and public health experts, as well as teams working on the chemical substances themselves. All these teams are headed by the management board, which is in permanent contact with public authorities and American and Japanese associations.

HERA wishes to push forward the notion of risk rather than hazard as the latter is nowadays preferred by certain legislation. It also wants to develop partnerships with authorities (chiefly the European Union) so that it can participate in research being carried out into the risks chemical

## IN BRIEF

By publishing the White Paper on chemical substances in February 2001, the European Commission decided to launch a wide reform of the practices concerning the use of these substances, their degree of dangerousness and their appreciation by European consumers.

In reality, the Commission's ambition is to clearly guarantee a better protection of consumers and ensure environmental issues are really taken into consideration. With this, the White Paper fits in well with the sustainable development objectives regularly reaffirmed by the European Union.

However, the measures foreseen by the Commission are perceived by the industries that use these chemical substances as particularly demanding, both in the application methods required and in their theoretical presuppositions.

The creation of the HERA project as of 1999 by these same industries illustrates precisely their willingness to pool their knowledge and means to carry out assessments themselves, even if this means they will have to ban the use and marketing of potentially dangerous substances.

Although the users of chemical substances approve of the objectives in the White Paper, they still have worries about how to reach them and would like their own efforts in that area to be taken into consideration. They also do not want their activity demonised, especially concerning the notion of "hazard", which would gradually replace the notion of "risk". All things considered, they would like to have a dialogue with European policy-makers about the immediate consequences of the White Paper, not only for Europeans, but also for the European companies concerned.

DEBATE

# True, but is Industry being really penalized ?

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The new chemicals policy aims at gathering information that will allow a better assessment of the risks linked to the use of chemical substances. Its implementation requires an evaluation process based on scientific grounds, regulations to frame risk, as well as greater transparency. Therefore, I would like all substances used in products to be listed and assessed according to the criteria proposed by the White Paper. The schedule foreseen for registration is good, even if it should not be handled too strictly. Legislation is now being prepared and we need clear and reliable information to draw it up. Once the Directive has been proposed, we shall ask the major sectors involved to express their views.

In this perspective, the DUCs will play a leading role as partners with public authorities and consumers. A project such as HERA indicates a real awareness and proactive attitude on the part of the companies, showing they can contribute to the drawing up and improvement of legislation.

Several substances do have so-called "hazardous" properties, and this is precisely why some industries use these substances as reactive raw material or intermediaries within several forms of synthesis.

Controlling the correct usage of chemical substances is more important than controlling their intrinsic properties. I do not advocate a complete ban or a substitution of certain chemical substances, since we could

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need them for production processes or for research. This is why the PPE distinguishes between the properties of chemical substances and their use, research and consumer goods.

Finally, the DUCs are now more involved than ever in risk assessment. Since these are mainly SMEs, we await the Commission's new proposals with great interest. If SMEs must guarantee the safety of their products, they must not be overburdened by the demands of the new legislation. We fully support SMEs, and this is one of the key points of the PPE's position on the chemicals policy proposed by the European Parliament.

\*White Paper Shadow Rapporteur within the PPE-DE

Thanks to the White Paper, we have been able to realise that many questions (and even concerns) exist amongst the general public and politicians, and that there is a real need for transparency and explanation. It puts forward this need to understand and know the dangerousness of chemical substances better according to their exposure and use. There is no sense in demonising these substances, but it is important to know how to use them by assessing the risks they could bring. The notion of "risk" preferred by manufacturers sounds like a good compromise: it is true

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that a product which contains chemical substances is not necessarily hazardous when used correctly. But here again, it is important that all consumers have clear and accessible information about these products.

By creating the HERA project, industries using and producing chemical substances showed they had understood how much they were involved and that they have a responsibility to give information. In my opinion, the action they have taken is heading the right direction, even if there are still questions to be discussed, notably concerning the schedule given by the White Paper for the testing of the 30,000 existing substances. Indeed, this schedule seems unrealistic to me.

Nevertheless, manufacturers should keep in mind that the White Paper is not a Directive : it is a guideline. It deals with the main priorities of the debate with information heading up this list. We should all work together to improve the protection of the environment and consumer health and enhance transparency of chemical substances. In that respect, the environmental policy is a scientific challenge and the Johannesburg summit showed that it has become a concern shared by everyone.

With regard to the White Paper on chemical substances, my opinion is that it has a good understanding of the problem. But I still believe that the Commission should prioritise its objectives, that is to say select those substances that are hazardous instead of considering them all as potentially hazardous. Anyway, this process will take a long time and testing all 30,000 chemical substances could be unrealistic, especially over such a short period of time. Indeed, testing all chemicals does not appear necessary to me. The European Commission should rather collect existing knowledge and use the quick-scan procedure (which it has already used for other issues).

I think the White Paper and, generally speaking, the Commission, must not be for or against the industries concerned. The most important thing to keep in mind is of course the protection of the environment and public health. I do not fear any psychosis among consumers: but if a chemical substance proved to be potentially hazardous for its consumers, then the Commission should act immediately and without fear of industry discussions.

Once again, my only fear is that the White Paper might be over-ambitious, which could result in an overloaded agenda. Being

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ambitious (especially in this field) is good, but you have to be careful with the availability of existing resources (this problem appeared, for example, when the Commission tackled the pesticides issue).

Finally, I believe that the distinction between risk and hazard is not really the point. We should rather focus on the distinction between the uses that can be made of a certain product. If a product, particularly when widely consumed, proves to be dangerous then it must of course be labelled as "hazardous". Indeed, some substances might be hazardous only in certain conditions (for instance when combined with another substance), but not necessarily if used correctly.

Over the past 15 years I have noticed a change in the behaviour of the DUCs. But while some of them have indeed a more positive and constructive attitude, others are still driven solely by making profits. There is no doubt a growing sense of the manufacturers concerned taking responsibility, but I would like to see them getting more involved in this area, like what happened in Germany for instance. The HERA project seems to be a very good initiative to me and it must be

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considered as a major player in the political framework developed by the White Paper. The White Paper describes the current situation and takes stock of the provisions to be implemented in order to improve health and above all the environment, particularly on a long-term basis. Of course, the schedules given are ambitious, perhaps even impossible to fulfill. The upcoming legislation will have to lay down a method and top priorities: first, study the most hazardous substances and those that have a threatening longevity (the so-called POPs or Persistent Organic Polluters). This represents about 500 products, which is a really feasible number to assess.

Therefore, I think it is important to preserve the notion of "hazard" : risk assessing can only be considered as an instrument to inform the consumer. The consumer must be able to totally evaluate the products he buys.

Finally, regarding the most hazardous substances, both the DUCs and chemical substance manufacturers, as well as legislators, all share a great responsibility. Indeed, they must prevent production of the most hazardous of these substances being moved to the developing countries. We have the expertise and knowledge to limit as much as possible the negative effects of these products, we know how to control them, especially regarding their distribution, so we must make sure they do not fall into the wrong hands. Everyone must be responsible and consider this aspect of the problem to take the appropriate action.

DEBATE

# True, but is Industry being really penalized?

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The impact of the White Paper on enhancing the protection of the environment and public health will be very positive: when you examine current data,

*Knowing the intrinsic properties of every substance we use, as well as the whole range of usage we make of them, is fundamental for determining the level of risk. This is why the schedules stated in the White Paper must be met.*

you cannot help but realise that there are many substances about which nothing is known. Industries themselves are well aware of this, and they told us about this during a pilot meeting we had together. They complained about the lack of data they themselves had at their disposal. The HERA project – which follows the CEFIC initiative and the Long Range Initiative – shows that these industries are looking thoroughly into this issue.

Knowing the intrinsic properties of every substance we use, as well as the whole range of usage we make of them, is fundamental for determining the level of risk. This is why the schedules stated in the White Paper must be met. All the political players agree to them: the Council approved them, and I do not think that the Parliament has questioned them. Companies must then adapt themselves.

The same is true for the labelling of products containing hazardous substances: the White Paper only repeats the requirements provided by the Directive on hazardous preparations, nothing more nor less. It must be noted that complete transparency of product composition benefits everyone: the consumer will be able to make his/her choice with full knowledge of the facts and increased confidence in the products to be used. And the image of DUCs will improve.

As for the economic consequences of the White Paper, no study has yet been able to clearly state what the effects of the upcoming legislative decisions would be. I can understand why the DUCs feel worried about it, but they should adopt a more open-minded attitude rather than contest without a solid argument. These industries must become aware of their responsibility, and I hope these constraints will move them to look for new substances and develop their Research and Development departments.

As published by the Commission, the White Paper is the result of a compromise: on the one hand, industry is required to increase its transparency and take responsibility. But on the other hand, the testing process is being simplified, which is not a positive point in my opinion.

To be more explicit, let me remind you that the current system does not make any systematic testing obligatory for "existing" substances. When dealing with "new" substances (ie those discovered after 1981), their systematic testing requires a very precise procedure with a level of investigation higher when production is increased.

Thanks to the REACH system, tests have been extended to all substances. But on the other hand, the level of requirement for information data has been lowered, given that the thresholds needed actually correspond to the quantity of tonnage registered. Thus, for many molecules, the testing dossiers will be simpler. But this is a double-edged sword for companies since when information on a given substance is lacking, safety factors will be applied according to the hazards and risk evaluation might end up being stricter than necessary.

*But it must be stressed that the studies on chemical substances have been put to one side for a long time now and we must find a way to make up for lost time (...)* Two complementary solutions are possible: supporting the training of new researchers and experts and developing partnerships.

But on the whole, the White Paper programme is positive in terms of environmental protection and public health, since tests are now comprehensive. And these tests now represent a priority for public authorities and manufacturers.

In creating the HERA project, the DUCs have shown their full comprehension of the problem: pressure from legislation has led them to get organised and stay one step ahead of the White Paper. Of course, they are worried about the deadlines assigned, since it is no secret that this programme is very demanding. But it must be stressed that the studies on chemical substances

have been put to one side for a long time now and we must find a way to make up for lost time. It is clear that the industry will increasingly need more toxicologists, although some companies have been reducing this type of activity over the past few years. Two complementary solutions are possible: supporting the training of new researchers and experts within higher education and developing partnerships with French and foreign laboratories.

As a matter of fact, nothing prevents companies from outsourcing this testing process, which would allow this already

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well organised expertise sector to develop. By the way, it must be emphasised that the quality of testing is controlled by a "quality assurance" system called the GLP (which stands for Good Laboratory Practises). This label certifies that the laboratory supplies a system of reference, traceability and reports, whose competency has been approved by public authorities. Laboratories given this certification are regularly audited and they guarantee a high level of service.

To come back to the White Paper, I reckon it is important to put forward the notion of "hazard" of a given chemical substance. It is often more suitable than the notion of "risk", which involves exposure: when a consumer handles a hazardous product, he must be aware of this. The end-user should be informed so that he/she can be more vigilant whenever necessary. Anyway, this requirement concerns imported products too, so that there will be no distortion of trade between European companies and the rest of the world.

Those who fear a decrease in competitiveness of European industries are perhaps right in the short term, but I think the situation will reverse long term: firstly, because environmental constraints will spread throughout the world and be imposed on everyone. Secondly, because such a legislative framework will stimulate innovation and allow the creation of environmentally-friendly substances with greater added value.

IN BRIEF

Although the objectives announced by the European Commission in its White Paper on chemicals seem to be unanimously accepted by European policy-makers because they aim at better protecting the environment and the consumer, the methods it recommends for implementing this ambitious programme are being hotly debated.

Opinions obviously differ depending on whether you pay more attention to companies or the average consumer.

No one denies that the measures laid down to companies by the White Paper are particularly demanding, indeed unrealistic to some people, especially in terms of their schedule. The whole debate is based on the question of company responsibility; in this perspective, an initiative such as HERA is welcome, provided that it shows how DUCs have really taken environmental and health factors into consideration.

Even if company concerns are understood, the positive impact of the White Paper seems to justify such measures. In fact, in addition to the tangible consequences (on the environment and the health of consumers), there will also be positive effects in terms of image and competitiveness.

Finally, the extension of the "hazard" notion is not a bad thing for, once again, we cannot afford to neglect the end consumer of these products.

It is again company ethics which are at stake here through the currently very popular notion of "making responsible", which is closely linked with sustainable development and the precautionary principle. Nonetheless, whether or not it is a current trend, Europe seems to have clearly decided to consider consumer protection as an absolute priority. Whatever the cost.