

May 15, 2001

## **EU Committee Position Paper on the European Commission's White Paper on a Strategy for a Future Chemicals Policy**

The EU Committee welcomes the adoption by the European Commission of the White Paper on a Strategy for a Future Chemicals Policy, and the decision of the Commission to continue its dialogue with stakeholders on all questions related to the implementation, management and review of the White Paper.

The new Commission's strategy represents a fundamental regulatory development that will have a very **considerable impact** on numerous members of the EU Committee, whether chemical-producing companies or downstream users of chemicals, as well as, more generally, on a substantial part of the trade within the EU and between the EU and the US and other parts of the world. Therefore, it is crucial that the **dialogue** be continued at all levels so that the future EU chemicals policy indeed achieves the fundamental objectives that the Commission is rightly pursuing.

The aim of this position paper is to identify the main areas of the Commission's proposed strategy that are of **serious concern** to the members of the EU Committee and should give way to adjustments or clarifications, and to offer some practical **suggestions** to that effect. In doing so, the EU Committee focuses on those aspects of the debate where it can have a specific contribution, in view of the horizontal and transatlantic dimension of its membership.

IN SUMMARY, the EU Committee fully **supports the stated political objectives** of the reform and appreciates the efforts made by the Commission to find practical solutions to achieve these objectives. In the opinion of the EU Committee, however, the Commission's proposals for the implementation of these objectives are **not properly balanced** and will lead to substantial societal and economic drawbacks that are not justified, nor necessary, to achieve the desired objective. Indeed, while it is appropriate to emphasize the health and environment aspects of the reform, it is imperative that the other two pillars of *sustainable development*, the social and economic dimensions, be equally considered. The EU Committee believes that the White Paper excessively emphasises the former at the expense of the latter.

The EU Committee also *regrets* that the Commission chose to resolve the "existing chemicals issue" in isolation, instead of seeking to consult its trading partners to find an appropriate, international solution to what essentially is a global issue. The EU Committee therefore *suggests* that the Commission takes fuller account of the **international dimension** of this issue and further studies possible synergies with

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existing governmental and industry generated programme for the collection of data on existing chemicals.

Finally, the EU Committee *welcomes* the Commission's decision to associate the full chemical chain to the reform and *advocates* that the Commission further consult producers, importers and downstream users of chemicals to define means of ensuring the sharing of responsibilities and information on chemicals in a manner that is fair on all parties and respects at all stages the protection of confidential business information. The EU Committee looks forward to be associated to this dialogue on the **vertical dimension** of the reform.

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## THE FUNDAMENTAL OBJECTIVES OF THE REFORM

The EU Committee fully supports the fundamental political objectives of the proposed reform but considers that, in pursuing them, the Commission **failed to adopt a balanced approach** to achieve these objectives. Indeed, while the proposed strategy seems to properly address the objectives of the protection of human health and the environment, and increased transparency towards consumers, it fails to properly address the other objectives of the reform.

More specifically, it is the EU Committee's opinion that:

- ? The overall burden represented by the REACH system will not “enhance” but rather damage the competitiveness of the EU chemical industry, despite the noticeable progress made in raising the threshold for reporting chemicals at 1 ton as compared to the current notification scheme. Indeed, as further described below, the costs involved by the testing programme imposed on industry are not reasonable, nor proportionate. Also, the timetable set forth for its implementation is unrealistic.
- ? The Commission's approach is not “integrated with international efforts” but rather represent an isolated approach that may disrupt rather than enhance some ongoing international chemicals programmes. Indeed, if the Commission properly notes that “chemical safety is an international issue”, it has decided to move on by itself, without seeking the cooperation of its trading partners, and its attempt at convincing these partners to join a pre-defined scheme are not likely to succeed.
- ? The proposed REACH system will also cause a significant increase in animal testing that will certainly not be compensated by the Commission's proposed efforts towards promoting non-animal testing, however relevant and useful these efforts may be.
- ? Finally, the White Paper offers little, if anything, concerning another original objective of the reform, the streamlining and simplification of the chemicals legislation in place. Rather, unless important clarifications and modifications are made to the Commission's proposal, the implementation of the REACH system will be a source of confusion and conflicts, notably between producers and users of chemicals.

In terms of preventing the fragmentation of the internal market, another key objective of the reform, the EU Committee notes that none of the measures proposed in the White Paper would seem to affect the functioning of a single market of chemicals in the EU. However, no concrete measures are proposed to protect, maintain or enhance this essential dimension of the EU Chemical policy, such as measures designed at preventing the adoption of national registers or lists of dangerous substances.

In other words, the EU Committee regrets that, in focusing on bridging the “knowledge gap” on existing chemicals, the White Paper **does not propose an overall regulatory framework** that addresses the real issues and risks relative to the handling, use and disposal of chemicals. Adjustments should therefore be made to ensure a more balanced approach that would enable the chemicals industry to continue making its full contribution to social and economic progress in the EU.

## THE “REACH” SYSTEM

The essential part of the White Paper consists in a proposal to adopt a new chemicals control system based on the registration, evaluation and authorisation of chemicals, called the “REACH” system. This system is designed to apply both to “new” and “existing” substances and thereby respond, as regards the later, to the shortcomings of the current Regulation 793/93/EEC on the evaluation of existing chemical substances.

In general, the EU Committee shares the view of the Commission that the effectiveness of Regulation 793/93/EEC must be improved. Also, it can support the development of a new, coherent chemicals control system that would apply both to new and existing substances, provided that this system meets the fundamental objectives of the reforms both in terms of public health and environmental protection, but also of other important societal values, including industry’s innovation potential and competitiveness. As mentioned above, it is the view of the EU Committee that the proposed REACH is not properly balanced with respect to its own objectives. Also, several adjustments should be made to improve the practical workings of the new system.

On the positive side, the EU Committee certainly supports the fact that the REACH system will ease the development of “new” substances produced or imported in small quantities (below 1 tons) and by broadening the current exemptions for substances at the research and development stages. These measures will certainly help correcting the current situation that hampers innovation by the EU chemicals industry and prevents the introduction of safer chemicals on the EU market.

The EU Committee can also support the “registration” and “evaluation” phases of the REACH system. However, as further described below, it considers that the proposed “authorisation” process for substances of high concern will represent a disproportionate burden on industry and that the timetable for phasing existing substances in the REACH system is highly unrealistic. Also, it has great concerns over the practical administration of what is likely to become a (unmanageable) bureaucratic system.

## The Authorisation Process

The Commission essentially proposes to subject some chemical substances (CMR substances of category 1 and 2, POPs, and possibly other substances) to an authorisation process. In other words, it is only based on their hazardous properties, irrespective of their potential exposure to man or the environment, that these chemicals will be subject to what is the strictest possible regulatory regime, a pre-market approval. Also, the approval would be “use specific”, with the authorisation being

granted only if the specific use presents a “negligible risk” or, in the absence of safer substitute, if the risk is “acceptable”.

The EU Committee considers that this authorization system is disproportionate and should be withdrawn. An authorisation process is in itself a restriction that should not apply based only on hazard identification. Also, by reversing the burden of proof that a chemical must present “negligible” or “acceptable risks”, using the substitution principle, the Commission will allow risk management measures (including market prohibitions) to be taken in the absence of a proper risk assessment process. Furthermore, by subjecting all uses of all existing CMR substances to this process, even over time, it will place an impossible burden on Industry that may force out of the market chemicals that are essential to society for the sole reason that resources are likely to be devoted in priority to larger volume chemicals.

A more consistent approach would be to ensure that a proper risk analysis process is made following the “registration” and “evaluation” phases of the REACH system so that available resources are taken to deal with the chemicals of greatest concern based on the combination of their uses, exposure and potential hazardous properties, not just on hazard identification. To be efficient, the risk analysis process certainly can be based on industry being required to provide the necessary data to ensure the chemicals at stake can be properly managed. Also, the workings of the current Marketing and Use Directive 76/769/EEC can certainly be improved to accelerate the adoption of appropriate risk management measures, as the Commission itself suggests in the White Paper. If a proper risk analysis process is established based on real priorities, however, then there is no need to maintain the “authorisation” part of the REACH system.

### **The Phase-in of Existing Substances**

In terms of the review and evaluation of existing substances, and as noted in its position paper of September 2000, the EU Committee considers that it should be organised in a gradual way, starting with substances of higher concern, using practical and effective processes, and building upon industry’s sense of responsibility and international cooperation. By contrast, the Commission suggests that existing substances be phased in only based on their production or imported volume, starting with those with high volume (for which the requested data is the most stringent), irrespective of the risks involved.

Also, considering the reporting requirements, the proposed timetable (2005, 2008 and 2012 for substances exceeding 1000, 100 and 1 tons, respectively) is unrealistic. It is based on assumptions in terms of number of chemicals involved, required testing and testing costs that are grossly underestimated. In the opinion of the EU Committee, the costs of the proposed system in terms of loss of competitiveness and other important societal values (e.g. animal testing) will be tremendous and are disproportionate to the objectives being pursued.

To speed up the process of data collection and reduce costs, the Commission should ensure that any data on chemicals be accepted, provided they are scientifically sound, notably those being generated under foreign governmental or industrial programmes, as further described below.

## **Practical Administration of the REACH System**

Also, the EU Committee is concerned over the practical administration of what is likely to become a (unmanageable) bureaucratic system, unless significant and appropriate clarifications/modifications are made. Whether in terms of financial and human resources, in terms of coordination of the respective roles of the Commission, the enlarged European Chemicals Bureau (ECB), and the Member States Competent Authorities, or in terms of means of sharing responsibilities between and among producers and downstream users of chemicals, the proposed REACH system raises more questions than it provides solutions.

In the view of the EU Committee, the Commission should rather select an approach that goes further in building on industry's responsibility (by requiring producers and importers to collect data and perform appropriate "targeted risk assessments" and take risk management measures under their own responsibility) and allowing authorities to further concentrate their efforts and resources in dealing with the more difficult and acute cases. In the Committee's view, the risk certainly exist that the authorities be swamped with data collection and assessment duties for substances that do not present particular concerns and that the whole system does not achieve any of the initial objectives of the well intended reform.

## **THE "INTERNATIONAL DIMENSION"**

As mentioned above, one of the Commission's declared objectives is to "integrate" its new chemicals policy with international efforts. The Commission indeed rightly notes that "chemical safety is an international issue" and that "no one country has yet been successful in overcoming the huge gap in knowledge of substances". In the EU Committee's view, however, the Commission is suggesting to do precisely the opposite, i.e. deal with the "burden of the past" by itself, without the active participation of its trading partners.

It is not disputed that a large proportion of the chemicals that are currently marketed in the EU are also marketed in the USA, Japan, Canada and other EU trading partners, with the same or similar concerns, so that the "burden of the past" is a global issue. Hence, as the EU Committee noted in its September 2000 position paper on the EU Chemicals Review, the Commission should actively seek to "share" this "burden" with its trading partners rather than work "in isolation". However, rather than seeking to organise the international cooperation that one could expect to "bridge the knowledge gap", the Commission merely suggests to "feed" the recommendations of the White Paper into the international programmes. The White Paper does not indicate that the Commission has or will discuss with its trading partners how to best approach this global issue; the Commission seem to only be ready to welcome those that would wish to join the agreed EU system.

Of course, the Commission proposes to "recognise non-EU test results", but a closer reading of its proposal shows that the Commission only offers to accept data generated under the International Chemicals Council Association (ICCA)/OECD's High

Production Volume (HPV) programmes that the EU has already recognised and encouraged. Since the data so generated will be based on globally harmonised testing methodology, it is hard to see how the Commission could not recognise it. However, this does not represent any move towards a new international cooperation in the area.

In view of the above, the EU Committee respectfully submits that the Commission should not try to impose its views and methods on its trading partners but should make genuine attempts at seeking a consolidated international solution to what essentially is an international issue. More specifically, the Commission should actively consider synergies with the recent initiatives taken by other Governments, including the United States and Canadian Governments (the Canadian project will affect 23.000 existing chemicals), and recent industry initiatives<sup>1</sup>.

In view of its international character, the EU Committee certainly remains available to discuss with the Commission services ways of enhancing international cooperation in this area, as described above. Indeed, integration of EU initiatives with on-going international efforts is clearly an aspect where industry/public authorities liaison is critical; international companies like those represented by the EU Committee can certainly play a role to assist in coordination efforts with existing programmes on the basis of their experience and knowledge, as demonstrated by their cooperation in the ICCA HPV programme.

#### THE “VERTICAL DIMENSION”

Another key element of the White Paper is that it extends the responsibility for the safety of chemicals along the manufacturing chain not only to manufacturers and importers of chemicals but also to downstream users. In that same vein, the White Paper suggests the sharing of information between producers and users and that both be obliged to provide exposure data. More specifically, the proposed system would require manufacturers and importers to submit to authorities information on the intended uses of their products, including estimated human and environmental exposure, and a preliminary risk assessment based thereon; downstream users would be required to carry out additional testing to complete the available data and risk assessments where their uses differ from those originally envisaged by the manufacturer/importer.

In general, the EU Committee supports the need to coordinate the collection of information from both producers and users of chemicals to properly assess the safety of chemicals, as used, and therefore supports the general philosophy of the White Paper in this respect. However, beyond the principles, the proposed system raises very serious issues that should be addressed or clarified to ensure that the new system is properly balanced and receives the trust of the manufacturing chain.

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<sup>1</sup> We refer in particular to the Health and Environment Risk Assessment initiative (HERA), a AISE-CEFIC project on risk assessment of chemicals in detergent products, and the Alliance for Chemical Awareness (ACA) project, a US industry initiative that proposes methodologies/tools to perform preliminary risk assessment on the whole life-cycle of chemicals, building from the US HPV program.

In terms of process, while the producers/importers would be subject to registering their own exposure data under the REACH system, the White Paper does not discuss which authorities, at what levels, and in what circumstances should be empowered to require additional data from downstream users, nor how the newly generated information will be processed or shared with producers and/or among downstream users. As noted by the Commission, any system should ensure to avoid the duplication of animal testing but also the protection of property rights and the introduction of exposure-triggered testing on both producers and users will certainly accentuate the need to find a balanced solution to these fundamental issues. The White Paper briefly mentions that companies will be encouraged to share the testing data they generate against a fair and equitable contribution, but falls short of making any suggestions as to how this can be achieved and how this can properly take account of property rights protection needs.

In the view of the EU Committee, it is essential that the Commission recognise at the outset the importance of protecting property rights and more generally of protecting any confidential business information (CBI). The system used in the USA for 20 years that allows companies to withhold CBI, including the specific chemical identity of a hazardous chemical, except in cases of emergency health-related situations, could serve as a useful model for that purpose.

In view of its broad membership, the EU Committee is particularly sensitive to a proper resolution of the “vertical dimension” of the future EU chemicals policy and is eager to participate in the necessary dialogue between stakeholders on the issue and in the elaboration of appropriate solutions. More specifically, the EU Committee suggests that the Commission further consults producers, importers and downstream users of chemicals to define means of ensuring the sharing of information on chemicals in a manner that is fair on all parties and respect the protection of CBI. To that end, “case studies” could be made using selected chemicals for which the information (including exposure information) is available so as to identify practical options and determine suitable processes. The EU Committee is certainly ready to fully contribute to these efforts.

## **OTHER CONCERNS**

In addition to the above, and without seeking to be exhaustive, below are additional issues raised by the White Paper that seriously concern the EU Committee and should be revisited:

- ? The Precautionary Principle: The reference to the precautionary principle made in the White Paper in relation to accelerated risk management measures is not consistent with the Commission’s Communication on the precautionary principle of February 2000 nor with the international agreements binding upon the Community. This should be corrected.
- ? “Finished Articles”: The EU Committee is very concerned about the continued intention of the Commission to impose reporting obligations on substances placed on the market as constituents of products (the so-called “finished

articles”). Either these substances can indeed be released during handling, use or disposal and they should be subject to the REACH system as any other chemicals substance, or they do not present these risks and their current

exemption from the chemicals control requirements should be maintained as in the rest of the world. Any other system would be simply unworkable and will surely cause a trade war between the Community and its trading partners. In our view, the “competitiveness” argument used by the Commission to justify its position on this issue is misleading. Indeed, it is not the “finished articles” exemption but the REACH system itself that will hamper industry’s competitiveness. Also, the Commission should rely on Industry to judge whether this measure is necessary to safeguard its competitiveness.

- ? The Substitution Principle: The EU Committee would also suggest that the Commission clarifies its intention with regards to the use of the “substitution principle”. In its view, this principle should not be an “objective” of the reform but a means of achieving other objectives in controlled circumstances. Also, its use in connection with the REACH system should be integrated in the full risk analysis process, rather than used only in connection with inherent properties, and should take full account of socio-economic benefits and the functionality of the alternative chemicals.

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The EU Committee of the American Chamber of Commerce is the key organization in Europe representing the views of 141 European companies of American parentage. Member companies of the EU Committee belong to a broad range of European business sectors, and represent 3 million jobs and 3 billion dollars of investment in the European economy. All EU Committee position papers can be found at [www.eucommittee.be](http://www.eucommittee.be).

A summary of this Position Paper is also available (copy attached hereto). It highlights the key messages of the EU Committee on the Commission’s White Paper for a Future Chemicals Policy.

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