

European Business Position

on the

“White Paper on the Strategy for a future Chemicals Policy”



September 2001

“White Paper on the Strategy for a future Chemicals Policy”

Eurochambres fully supports the objectives of the Commission for its future chemicals policy, that is to secure a high level of protection for human health and the environment whilst safeguarding the internal market and enhancing innovation and competitiveness in the EU chemical industry.

Eurochambres believes that the proposals outlined in the White Paper go some of the way to meet these objectives, but has concerns about the practicability of the proposed system and the impact on competitiveness.

Our major concern relates to the potential financial impact especially on smaller companies arising from the costs of generating the required data package plus any registration/review fees for existing substances charged by competent authorities. We would like to see specific data sharing provisions in order to minimise the burden in particular on SMEs. This measure will also help minimise the potential number of animal tests required.

We do not feel that there is, in general, lack of knowledge about chemical products at expert level, as there is various legislation in place to ensure data provision by producers and importers (e.g. the Directive on Dangerous Substances). In the past, when problems have arisen with certain products (e.g. benzidine dyes, asbestos), consequences usually had a long latency period and would not have necessarily been identified on beforehand. Today increased testing and awareness of structures with carcinogenic potential try to avoid these issues.

The European businesses consider that it must be the producers' and the downstream users' responsibility to supply detailed up to date information on chemical substances to all customers. Thus an immediate and effective means to withdraw a product from the market if necessary could be realised.

Given the lessons learnt from existing EU chemicals legislation, it is very important that any new chemicals legislation and associated processes introduced should be clearly defined (without any doubt about the interpretation) with agreed operational standards, pragmatic and adequately resourced both at Commission and Member State levels in order to guarantee fair competition. Measure taken must be proportional to the perceived risks.

REACH

Eurochambres believes the proposal for a single regime dealing with new and existing chemicals (REACH) is a good instrument to avoid current fragmentation and possible duplication. Thus, following the current notification of new substances (NONS) legislation, a manufacturer or importer has to notify a new chemical at the one tonne level with a



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"Base Set" package. If annual production or import of the notified chemicals reaches 10 t/a per single manufacturer or cumulative 500 tonnes per manufacturer, additional tests or studies in "level 1" have to be carried out within the time limit determined by the relevant national authority. A single regime for dealing with new and existing chemicals would mean that a manufacturer or importer of an existing chemical would need to expand the data set about intrinsic properties of the chemical as tonnage increases. This would ensure that equivalent data to those on new substances were available for existing chemicals.

We consider adequate information on hazards and risks of a chemical substance to be assessed throughout its life cycle as fundamental. A tiered testing programme incorporating exposure-triggered testing and waiving is a good way forward. It is essential that guidelines covering applicability of waiving and acceptability of available information should be clearly documented. Standards for testing requirements should be the same in all Member States. Testing required should be proportional to intended uses, exposure routes and potential risks.

We suggest that much greater emphasis should be placed on risk assessment and the proper controls arising from that risk assessment. For example isocyanates have been widely criticised for their sensitisation properties and the potential health problems they cause. Problems have occurred mainly, because recommended industry guidance has not been considered.

We believe that a requirement to conduct targeted risk assessments covering uses of a chemical should form part of the strategy so that there is concentration on what is important. A life-cycle risk assessment may be necessary in some cases. The scope of the analysis should be proportional to the issue.

Registration measures should also include downstream users so that information on all current uses of a particular chemical are available. Thus, the process of identifying areas of concern and decision making regarding targeted risk assessment could be improved.

Eurochambres supports the proposal for reduced testing requirements for new substances at lower volumes, since this will encourage innovation. We welcome the proposal that testing on substances produced/imported in quantities between 1 - 10 tonnes should generally be limited to in vitro methods. However, it is unlikely that companies will be able to utilise this provision due to the very small number of validated alternative test methods currently available.

The objective of the proposed authorisation procedures is to control the use of certain groups of chemicals with certain hazardous properties. This would generate resource implications, as Member States should authorise every single use of such chemicals, which would highly discourage innovation of new products.

A more effective approach would be to ensure that the existing system of controls on the marketing and use of substances is applied rapidly when required.



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Existing Chemicals

Eurochambres supports the overall concept of having a tiered, systematic process to review all existing substances by given deadlines which is based on risk assessment. We believe that the data required should be proportional to exposure routes and potential risks. Eurochambres also supports the transfer of responsibility for testing and initial risk assessment to the chemical industry.

The Commission White Paper quotes an estimated number of current existing chemicals of 30,000, which are not all available on the market. But the feasibility of any deadlines strongly depends on the number of chemicals to be tested, the number of studies required and availability for testing facilities. We believe the chemical industry should be given the opportunity to propose its own deadlines for data package-provision. Data packages should be proportional to exposure routes and potential risks.

European businesses consider a review regulation procedure as appropriate, which is similar to that of the Biocidal Products Directive. According to this directive, manufacturers/importers of chemicals have to identify existing chemicals (chemical name, CAS number, current production/import quantity, hazard classification, intended uses) which is supplemented by information of downstream users (quantity per years, how used, typical level in product). The European Commission should use these data to identify chemicals of concern and, in co-operation with industry, set up realistic deadlines for data requirements provision. This could help improve the decision-making process regarding testing programmes.

We suggest to base legislative acts on existing international review programmes (e.g. the OECD programme and the ICCA HPV initiative), rather than setting up other programmes. This should encourage downstream users - having information on the uses and the potential exposure to specific chemicals - to actively participate in risk assessments related to specific uses of a chemical substance.

Moreover, we request from the European Commission to publish a list of chemicals, which have been classified as not dangerous by the Commission classification working groups.

Implications for animal testing

We believe the proposals in the White Paper would lead to a significant increase in animal testing particularly if downstream users are required to carry out additional tests. The Commission does identify ways of keeping animal testing to a minimum (e.g. use of existing information, modifying testing requirements, maximising use of non-animal test methods). The White Paper also promotes non-animal testing ("testing requirements will be met as far as practicable through use of existing non-animal testing methods") obviously not considering the very small number of validated alternative test methods currently available.



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Costs of Implementation/Resource Issues

Costs of implementation will finally lead to substantial burden for companies particularly concerning existing chemicals (testing costs, data package generation etc.). We believe that the testing costs quoted in the White Paper were too low and may not take in account data package generation.

Other cost items to consider include:

- Expert costs (unless technical directors or production directors try to manage additional duties such as quality, safety, health and environment management)
- Cost of generating hazard data packages – approx. € 110.000 to € 130.000 for “Base Set” plus approx. € 375.000 for a full “Level 1” test package and approx. € 750.000+ for a full “Level 2” package depending on tonnage;
- Costs charged by competent authority (e.g. notification, assessment, fees)

Many companies, particularly SMEs, would be affected negatively by issues of resources and technical expertise if the proposed strategy requirements were put in action. As in the hazard assessment process, resources will be needed to identify data requirements, ascertain what data are currently available and generate data to fill gaps (arranging testing etc) including interpretation of test results, companies may also face potential difficulty in getting contract research testing slots.

Risk assessments require great effort in terms of staff resources and time plus a high level of scientific and technical expertise. Many companies particularly smaller ones do not have dedicated in-house toxicology/ecotoxicology/regulatory affairs support. That means, that they would have to acquire special expert support to carry out risk assessments. It may also be difficult for chemical manufacturers to obtain exposure and usage data from users because of commercial confidentiality concerns.

We estimate the cost of expert support to carry out risk assessments at around € 750+ per day, which could be significant costs given the time for risk assessments.

The suggested programme would probably jeopardise development of new products in Europe and severely reduce the role of traders, as they would in a lot of cases not have the possibility to fund the testing requirement in order to import products from e.g. Asia or the Far East.

The White Paper refers to an expanded Environmental Chemicals Bureau, but its finance is still unclear. However, costs seem to be quite substantial (190 staff mentioned). We therefore suggest to the European Commission to carry out a feasibility study and cost/benefit analysis on beforehand.

The Commission should also ensure that risk management measures were applied rapidly when required and that Member States allocate adequate resources with the required expertise to carry out evaluation and transfer into national law.



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Even, the European Commission has mentioned several responsibilities of downstream users (e.g. "the role of downstream users is the testing of chemicals needs to be further considered"), their integration in the system and the contribution of their know-how is not specified. We believe that specific data sharing regulations could help improve the process rather than just encouraging companies to share data.

Realisation-Transfer in national law

In order to guarantee fair competition within the common market, realisation of the new directive must be consistent across all Member States, as well as any sanctions/penalties for not correct or too late transfer into national law.

Import products

There must be a "level playing field" for chemicals (especially imported chemicals) as constituents of finished products (e.g. toys, textiles). Substances with potential impact on human health and/or environment imported to the EU as constituents of products must not be exempt from notification. Controls must be in place to ensure that finished products imported to the EU do not contain untested and unregistered substances. This should ensure that EU manufacturers remain competitive with finished products from outside the EU.

Closing Remarks

Eurochambres fears that industrial processes could be transferred to third countries if EU legislation generated competitive disadvantages to manufacturing, blending or formulating products in the EU. As a consequence, finished goods would be imported to the EU, which would destroy the present basis of chemical manufacturing and innovation in Europe and could lead to large scale job losses in one of Europe's prime industries as well as to a possible lack of product types needed in other industries.

Whilst welcoming the general objectives of the White Paper on the Strategy for a future Chemicals Policy, Eurochambres strongly requests to consider the potential impact of the proposed directive on future economic investment, development, the very serious socio-economic implications and environmental issues in the EU.

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