

**Austrian Economic Chamber - Position Paper**  
**EU White Paper on “Future Chemicals Policy”**

**Summary**

The Austrian Economic Chamber 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.

The Austrian Economic Chamber 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: there is already sufficient legislation in place to ensure that this cannot happen, for example the Dangerous Substances and Preparations Directive. In the past where problems have arisen with certain products (eg benzidine dyes, asbestos), the consequences usually had a long latency period and would not have necessarily been identified. This is less likely to happen today because of increased testing and awareness of structures with carcinogenic potential.

Where State of the Art knowledge indicates problems or potential new hazards, then it must be the responsibility of the manufacturer and others involved in the supply chain to ensure that the up to date information is supplied to all customers and, where necessary, to have in place an immediate and effective means to withdraw that product from the market place if applicable.

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. Measure taken must be proportional to the perceived risks.

## **REACH**

The Austrian Economic Chamber believes the proposal for a single regime dealing with new and existing chemicals (REACH) is a good idea to avoid current fragmentation and possible duplication. Under 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 "Base Set" package. When annual production or import of the notified chemicals reaches 10 t/a per single manufacturer or cumulative 500 tonnes per manufacturer, there may be a need to carry out some or all of the additional tests or studies in Level 1 within the time limit determined by the Competent 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 are available for existing chemicals.

Adequate information to enable the hazards and risks of a chemical to be assessed throughout its life cycle is 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 with no grey areas. 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 health problems they cause. Statistically where problems have occurred it has been because the recommended industry guidance was not followed.

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 in the issue.

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

The Austrian Economic Chamber 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 that give rise to concern. There are resource implications - could Member States cope with authorising every single use of such chemicals even if they could ascertain what they all are? Equally important such a regime as is proposed would 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.

### **Existing Chemicals**

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

The Commission White Paper quotes an estimated number of current existing chemicals at 30,000 - is this a true picture? How many of these are actually placed on the market? Feasibility of any deadlines would depend on for example the number of chemicals to be tested, the number of studies required and availability for testing facilities. We believe 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.

Why not adopt a review regulation procedure similar to that for the Biocidal Products Directive, ie 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 downstream users identifying their usage (quantity per years, how used, typical level in product). The Commission can use these data to identify chemicals of concern and, in conjunction with industry, set realistic deadlines for data requirements provision. This will help the decision making process regarding testing programme important if there is a move to exposure-triggered testing.

Rather than the Commission setting up yet another existing chemicals review programme, the Austrian Economic Chamber would like to see the EU building on existing international review programmes such as the OECD programme and the ICCA HPV initiative, and encouraging downstream users (who have information on the uses, and the potential exposure to, specific chemicals) to actively participate in targeted risk assessments related to specific uses of a chemicals.

It would help companies if the Commission could publish a list of chemicals which have been through the Commission Classification Working Groups and not classified as dangerous - such a list should include reasons for non-classification.

### **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 (eg use of existing information, modifying testing requirements, maximising use of non-animal test methods). The White Paper also talks about promotion of non-animal testing ("testing requirements will be met as far as practicable through use of existing non-animal testing methods") - this would be difficult given the very small number of validated alternative test methods currently available.

### **Costs of Implementation/Resource Issues**

Costs of implementation ultimately fall on companies particularly with respect to existing chemicals - testing costs, data package generation and any industry charged levied by Member States to cover their administrative costs. We believe that the testing costs quoted in the White Paper are on the low side and may not take account of data package generation.

Other cost items to consider include:

- Staff costs for dedicated personnel to staff/manage project (rather than Technical Director or Production Director trying to fulfil function in addition to other duties such as Quality, SHE, etc);
- Cost of generating hazard data packages – up to € 100.000 for Base Set, up to € 300.000 for a full Level 1 test package and up to € 800.000 + for a full Level 2 package depending on tonnage;
- Competent Authority notification/assessment fees/charges.

Many companies, particularly smaller ones, could face resource/technical expertise issues when addressing the proposed strategy requirements. 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 contact 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 thus would have to buy in 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 - this could be a significant cost given that the length of time to undertake even a targeted risk assessment could be substantial.

The suggested programme would probably kill development of new products in Europe and severely reduce the role of traders. They would not in a lot of cases have the ability to fund the testing requirement to bring in products from for example Asia or the Far East.

The White Paper refers to an expanded ECB - how will this be funded? The costs could be significant (190 staff mentioned) - we note that the Commission has yet to carry out a feasibility study and cost/benefit analysis.

The Commission should ensure that risk management measures are applied rapidly when required and that Member States allocate adequate resources with the required expertise to carry out evaluation and enforcement.

The Commission has recognised several elements concerning the responsibilities of downstream users but says little or nothing about how they will be successfully managed (eg "the role of downstream users is the testing of chemicals needs to be further considered"). How will it ensure that downstream users are involved in the system and contribute their knowledge of the uses of and potential exposures to substances and, at the same time, protect commercially confidential information? We believe that specific data sharing provisions would help the process rather than just "encouraging companies to share data".

## **Enforcement**

The level of enforcement activities must be consistent across all Member States - there are resource implications if enforcement is to be effective. Any sanctions/penalties to deal with non-compliance must also be consistent across all Member States.

### **Import Products**

There must be a "level playing field" for chemicals (especially imported chemicals) as constituents of finished products ( eg toys, textiles). Substances used and placed on the EU market as constituents of such products should not be exempt from notification where such substances may be released during use and disposal in amounts which may impact on human health and/or the environment. Controls must be in place to ensure that finished products imported into 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**

If it is made too difficult to manufacture, blend or formulate products in the EU, or if national deviations are still possible in a significant way, then such industrial processes will be transferred outside Europe. Correspondingly, finished goods will then be imported into Europe, if they manage to take the hurdles of the new strategy. This would destroy the present basis of chemical manufacturing and innovation in Europe and could lead to large scale redundancies in one of Europe's prime industries as well as to a possible lack of product types needed in other industries.

Whilst welcoming the very real objectives of the White Paper, they must be taken in context with the proposed policy's potential effects on future economic investment or development within the EU plus the very serious socio-economic implications and potential environmental issues.