September 2004

UNICE POSITION PAPER ON THE COMMISSION'S PROPOSAL OF 29 OCTOBER 2003 "FOR A REGULATION CONCERNING THE REGISTRATION, EVALUATION, AUTHORISATION AND RESTRICTION OF CHEMICALS (REACH), ESTABLISHING A EUROPEAN CHEMICALS AGENCY AND AMENDING DIRECTIVE 1999/45/EEC"

Summary

General: UNICE continues to support the political objectives of the proposed EU chemicals legislation, namely the protection of human health and the environment whilst ensuring the competitiveness of European industry. While UNICE acknowledges that a number of improvements on the internet consultation document were made in the Commission's proposal of 29 October 2003 we remain strongly concerned about key elements of the draft proposal. The proposed system is still unnecessarily complex and burdensome, with significant legal uncertainty. UNICE therefore believes that further modifications are required to ensure that the REACH system operates effectively and efficiently, and does not put European manufacturers, distributors and downstream users at a competitive disadvantage.

Competitiveness: The current proposal would place unduly onerous obligations on European industry, which competitors in other economic regions would not be subject to, thereby placing European industry and goods at a huge competitive disadvantage on the global market, and Europe at a competitive disadvantage as a place to do business. This would affect the whole dynamics of the industrial production and transportation arrangements in a way that may not necessarily contribute to sustainable development. The consequence will be that Europe will lose resources and important levers for contributing to sustainable development. UNICE is particularly concerned that the proposed regulation will lead to a considerable additional burden on industry, due to the very extensive data and testing requirements and the associated costs. This will not just mean an enormous increase in the costs of substances, preparations and many articles; it will also lead to delays in introducing innovative products to the market.

Further Work on Impact Assessment: A full impact assessment of the proposed REACH system on industry must be carried out in order to identify and amend the elements of the proposal which would prevent the implementation of an efficient and cost-effective system.
The workability of the proposed system must be assessed via pilot projects in order to ensure that potential bottlenecks and other problems are addressed in advance of the adoption of the proposal.

Scope, Overlap with other Regulations: In the interests of legal certainty and to avoid additional costs for industry, overlaps with other EU legislation must be avoided. Substances, articles and applications of substances which are already regulated in the EU or at international level should therefore not be covered under the proposed regulation. This applies for example to food and feed, drugs, medical products, construction materials, waste or explosives.
Existing data and risk evaluations collected under other regulatory or voluntary, national or international programmes (e.g. existing substances legislation, ICCA HPV, IUCLID, OECD initiatives, WHO) should be acceptable for submission under REACH in order to avoid the duplication of testing.

Union of Industrial and Employers' Confederations of Europe – Union des Confédérations de l'Industrie et des Employeurs d'Europe AISBL
Av. de Cortenbergh 168 - B-1000 Brussels -VAT BE 536.059.612 -Tel. +32(0)2 237.65.11 - Fax +32(0)2 231.14.45 - E-mail: main@unice.be -Website: //www.unice.org

Prioritisation According to Risk: The quantity-based principle should be replaced by a risk-oriented process, which is exposure-driven, thereby prioritising substances that are of greatest risk to human health and the environment. Exposure scenarios/categories should be used in order to prioritise substances that pose the greatest risk. Use categories should be broadly defined.
The data requirements must be aligned with the given risk. If no risk is associated with a substance, there must be an exit option in the process of data generation, testing, etc., regardless of the tonnage produced. Resources are scarce and should be focused on priority substances/uses in terms of risk; in the current proposal risk is not taken into account in an appropriate way.

Centralised Decision-Making, Agency: The enhanced role of the EU Chemicals Agency with respect to substance and dossier evaluation is to be welcomed. However, UNICE believes that this centralised evaluation role should be further strengthened in order to ensure harmonised market conditions. Therefore, the Agency should be entitled to manage the entire system to an extent which definitively provides for fast and slim administrative procedures and for one reliable decision in each single case.

Business Confidentiality: Confidential business information and intellectual property rights must be fully protected, since effective protection of intellectual property is the basis of the innovative strength and existence of many companies in the long term.

Consortia Formation, Competition: Consortia formation must be voluntary. While the principle of data-sharing is to be supported, a mandatory and inflexible approach to consortia formation may lead to breaches of EU competition law and intellectual property rights, and undermine investment in R&D.

Substances in Articles, WTO Compliance: Substances not intended to be released from articles should be exempt from the proposed notification procedure. This provision is unnecessary and unachievable since it is not possible to notify an unforeseen release in advance. It will also be extremely difficult to enforce with regard to imports, thus leading to the unequal treatment of articles produced in the EU and negatively affecting the entire EU economy. It is almost impossible to determine the individual substances and the respective quantities that would trigger a duty of notification. This provision must be completely revised.

Registration, Evaluation, Authorisation, Chemical Safety Report: The registration process is unnecessarily restrictive with regard to innovation, it is inflexible and it requires a fundamental review. Time delays in the introduction of new products must be avoided in all cases. Testing and data requirements should in turn be proportionate to the identified risk. The bureaucratic requirements in addition to the classification and labelling requirements are a superfluous burden. In principle, authorisations should be built on the registration and evaluation process and be issued in an abstract, general manner and only manufacturer-related in individual cases. It should not be possible to extend the area of application until experience with the explicitly named substances has been gained.

I. Introduction

1.1 UNICE supports the political objectives of the EU substances policy, namely the protection of human health and the environment and ensuring the competitiveness of European industry. UNICE also acknowledges industry's responsibility to ensure the safe handling of chemical substances, from manufacture to their use in processes and products, through to their disposal.

1.2 The extensive scope of the proposed Regulation on the Registration Evaluation and Authorisation of Chemicals, which aims to overhaul 40 pieces of existing legislation, means that all companies that handle substances or preparations commercially – including small and medium-sized companies – are affected by the proposed Regulation, since every physical product consists of substances. The proposed regulation thus directly or indirectly affects every product and every production process.

1.3 UNICE acknowledges that a number of improvements on the Internet consultation document were made in the Commission's proposal of 29 October 2003. However, UNICE remains concerned about key elements of the draft proposal. The proposed system is still unnecessarily complex and burdensome, with significant legal uncertainty. UNICE therefore believes that further modifications are required to ensure that the REACH system operates effectively and efficiently, and does not put European importers, manufacturers, distributors and downstream users at a competitive disadvantage.

II. Competitiveness

Withdrawal of Substances

II.1. Due to heavy bureaucratic burdens many substances, especially those manufactured in small volumes or linked with a relative low added value, might no longer be profitably produced in the EU or imported into the EU. These substances would no longer be available in the EU's internal market.
Admittedly, the testing requirements for substances with annual production quantities of 1 to 10 t/y have been reduced but along with this, the requirements for substances over 10 t/y have been increased with the result that many companies will be very reluctant to accept orders that would cause them to exceed this annual production or import volume. This is surely a result that has very little in common with the goals of a sustainable policy!

II.2. According to the last Mercer study, 10 to 30% of substances could disappear from the market. Downstream users that depend on these chemicals for their own production will be especially disadvantaged. They would either have to bear the costs of finding substitutes and re-formulating their products or, if no substitutes can be found, their activities might be under threat. Therefore the consequences of REACH might be particularly severe for downstream users.

Innovation

II.3. Compared with the existing system, the proposed requirements are less stringent for non-phase in (new) substances. Nevertheless REACH might cause long-term damage to innovative capabilities of the EU economy, as innovation also means using existing substances in a different way compared with their previous applications. The proposed provisions will make it very difficult to use existing substances in different ways as these new applications will first have to go extensively through the complex REACH system. Therefore the proposed REACH requirements might lead to less potential for innovation.

Substitution in the authorisation process

II.4. The Commission has added a new feature to the authorisation process; namely it is now possible for applicants to draw up a substitution plan in certain cases. This amendment represents a great barrier on the path to authorisation, because it anticipates the result of a search for a substitute.

II.5. Moreover, substitution relies on the substitute being technically viable and available in the quantities required and at reasonable price. It is essential that substitutes present all characteristics of the substance that they replace, otherwise the performance of products may be reduced in certain aspects. This may not be acceptable for different important reasons such as safety and consumers may choose products from outside the EU which have been processed with substances no longer admitted in the EU.

Time to Market

II.6. For an ever increasing number of industrial sectors, the speed at which they can place products on the market is an essential differentiation factor if they are to remain competitive. The risk of delays in placing innovative products on the market inherent in some provisions of the REACH system will place these industrial sectors at a disadvantage. They have to position themselves on a global market and could be outstripped by international competitors which benefit from a shorter development lead time.

II.7. Users will be given the right to make their suppliers aware of a "use" not covered by their registration. It thus becomes an "identified use"; the supplier would have to supplement the registration documents, if necessary by requesting information from his (upstream) suppliers. This regulation is an inappropriate attempt to harmonise the interests of the downstream users and the manufacturers/importers: the user would have to disclose the intended use to the supplier, which could mean disclosing business or company secrets. In this case, the user would still have to hold back on usage of a substance until the registration documents have been supplemented. This can take some time, especially if the substance has already been used in several steps further down the supply chain. Or, as an alternative, if the manufacturer or supplier does not supplement the registration, the user could report information on the use of a substance himself, which is time-consuming and costly. The manufacturer is finally exposed to pressure to carry out tests for a use which he may not want to support. In addition, the duty of the downstream user to provide information relates to every single "use". But the definition of "use" is very narrow, particularly in the context of the definition of the "article". For instance, each time the processing form or the end product is changed, it must be examined whether this new use is still covered by the information from the upstream supplier.

II.8. Another factor is that uses of substances often have to be adapted flexibly and quickly to market requirements. According to the proposed system this will be possible only within the framework of the upstream supplier's statements. Otherwise, the user must report information on the use of a substance himself. This further restricts companies' flexibility. The need to coordinate changes in uses with suppliers can also endanger business and company secrets.

II.9. Moreover, registration is very time-consuming. It can be assumed that at least 4-6 months will be needed to complete the registration dossier for substances produced in quantities below 10 t/y. During this time the substance may not be produced. The possibility of using Robust Study Summaries available in Internet (article 23 (3)) helps only a little because the suitability of such a study for the registered uses has to be assessed for each individual case. The only way to solve this problem is that an incomplete registration dossier containing minimum data is also deemed to be adequate for starting production if the other required data are submitted within a specified period (so-called post-registration).

Business Confidentiality

II.10. With a view to protecting confidential business information, components in preparations should only be disclosed when this is essential for a risk assessment. Under the current REACH provisions certain data of potential economic interest remain unprotected. For instance, the safety data sheet for preparations must state the registration numbers of all the substances that are contained in a preparation in excess of the (very low) thresholds. This regulation comes very close to obliging companies to disclose their recipes. Here, the specifications for preparations classified as non-hazardous (Article 30: every registration number of every component) are even more stringent than for other preparations (Article 29 with Annex I b No. 3: essential components). These duties of disclosure could lead to expertise leaks. Therefore REACH should be amended to ensure that confidential business information be fully protected.

III. Further Work on Impact Assessment

III.1. The Commission's proposal is accompanied by an impact assessment that leaves many questions unanswered. For instance, indirect costs such as those caused by the negative consequences of REACH for competitive and innovative capabilities are dealt with only in a very superficial way, if at all. The effects on importers and their customers are not addressed, nor are the consequences on the inorganic sector as well as downstream users. Besides, the consequences for the national and EU administrations are not considered either. The social dimension is more or less ignored. On the whole, this impact assessment does not provide a full overview of possible broader effects on the economy. In that regard, a preliminary economic analysis of the Commission's proposal applying the methodology of the ADL study (www.bdi-online.de) shows that losses of up to 3.3% gross value added can be expected in Germany alone, with a loss of up to 1,230,000 jobs. According to the new MERCER study carried out at the request of UIC (Union des Industries Chimiques), the overall modelled impact of the REACH proposal could be as high as € 28 billion, or 1.6% of French GDP. The resulting loss of employment could reach 360,000 in the wider economy.

III.2. The effects for the new EU Member States that have little experience with comparable regulations could be especially serious. These effects have so far hardly been examined.

UNICE considers the currently initiated further work on impacts of REACH on the value chain, on innovation and the new Member States a valuable step with regard to an improvement of the Commission's previous impact assessment. UNICE is actively working with the EU Commission and other stakeholders to carry out these studies. However, to achieve the comprehensive impact assessment as required by the Council of Ministers further steps would have to be taken.

III.3. Moreover, it is absolutely necessary to test the technical and administrative feasibility of the main elements of REACH in companies and authorities by pilot projects, including possible alternatives. Also, within the industry, it is only possible to draw on limited experience. It would therefore be advisable to introduce the individual elements of the Commission's proposal in stages.

III.4. Finally, the results of the various impact assessment studies have to be evaluated and taken into account to improve the REACH system.

IV. Scope, Overlap with other Regulations

IV.1. Exclusion or exemptions should be given to substances and products already covered by existing EU legislation. This applies for instance to occupational health and safety law, waste law, transportation law, food and feed law, medical products, construction products law, etc. Therefore, UNICE proposes that substances and products in their entirety or in relation to a part of their lifecycle should not be within the scope of the proposed regulation if and to the extent that these aspects are already regulated in the EU. In this respect, it must be defined which provisions of the proposed REACH regulation do not apply because of already existing legislation. The inclusion of substances in articles under REACH provokes inconsistent and unduly burdensome overlaps and contradictions with other legislative acts, such as the EU Directive 2002/96 on the Waste Electrical and Electronic Equipment, the EU Directive 2002/95 on the Reduction of Hazardous Substances, and the EU Directive 2000/53 on end-of-life vehicles. These provisions must be explicitly described.

IV.2. A particularly striking example of double requirements within REACH is the classification and labelling inventory (Title X; Article 109 et seq.). The classifications and necessary information already exist for substances that are listed in Annex I of the Classification and Labelling Directive 67/548/EEC or for which a registration has been made. This is an unnecessary duplication of processes.

Waste

IV.3. The REACH proposal does not provide for a general exemption for waste, neither in the generally applicable provisions nor in the registration, data gathering and evaluation steps.
UNICE believes that the inclusion of waste in the REACH procedure is impractical and even counter-productive. Furthermore, waste is already regulated by a wide set of specific legislations and there should be no duplication of existing procedures applicable to waste management.

IV.4. Additionally, UNICE stresses that the inclusion in the proposal for regulation of secondary raw materials recovered from waste (which is no longer waste), in the scope of REACH could have a serious impact on recovery activities. The economic cost and the administrative burden for the recycler due to the inclusion of wastes and materials used as secondary raw material in the scope of REACH are not justifiable and certainly disproportionate. Neither the producer of the waste nor the possible user of the recovered materials will be inclined to use secondary raw materials if primary raw materials are more easily available for the same purpose. UNICE feels that waste management processes are adequately covered by European Community legislation and REACH would introduce unnecessary duplication.

IV.5. To ensure that the effort of national and European institutions and of industry to reduce the amounts of waste through recovery will not be counteracted by the REACH proposal, wastes and/or materials used as secondary raw material or as a source of energy in recovery operations should be completely exempt from the scope of REACH.

VI. Centralised Decision-Making, Agency

VI.1. The Commission's proposal contains new provisions for evaluation and envisages two forms: "substance evaluation" to determine the need for further evaluation and "dossier evaluation" to examine the testing proposals for the registration of substances produced in excess of 100 t/y as well as the correctness and completeness of all other registrations ("compliance check"). UNICE welcomes the fact that the EU Chemicals Agency will now coordinate rolling programmes of the Member States for "substance evaluation" and develop risk-based criteria to prioritise the substances to be evaluated. Hence, the need for uniform and legally secure evaluations can be fulfilled, if not completely, then at least better than originally planned. However, this possibility of coordination does not apply to evaluations within the scope of "compliance checks". Therefore, UNICE believes that the evaluation procedure should be further simplified and be placed completely under the responsibility of the Agency. The evaluation procedure should also be strictly limited to substances produced in quantities exceeding 100 t/y

VI.2. The legal protection against orders and decisions of the EU Chemicals Agency has been considerably improved: a system of internal appeal proceedings has been established in the Agency and the European Courts can be appealed. UNICE welcomes this improvement, which takes up an important issue widely underlined in the internet consultation. However, a board of appeal needs to be established. The provisions concerning legal protection against the Commission's decisions have however not been changed and are still deficient. In particular, decisions and technical adaptation directives that the Commission can take in the comitology procedure can in fact not be appealed. This is an obvious gap in legal protection which has to be eliminated. A complete system has to be created that gives companies a right to a hearing, appeal and effective legal protection in the courts. The possibility for industry participation in these implementation processes of legislation must also be improved. In addition, there must be no imbalance between the company's legal protection possibilities on the one side and recognised environmental associations according to the Århus-Convention on the other side.

VI.3. The administrative procedures foreseen in REACH are very complex. The interplay between the EU Commission, the EU Chemicals Agency and national authorities is still prone to errors and unnecessarily bureaucratic despite the Agency being strengthened. This particularly applies to the evaluation and authorisation processes. UNICE proposes developing the EU Chemicals Agency into a central decision-making authority. Furthermore the industry's involvement in the Agency's committees should be extended.

VII. Business Confidentiality

VII.1. With a view to protecting confidential business information components in preparations should only be disclosed when this is essential for a risk assessment.
Under the current REACH provisions certain data of potential economic interests remain unprotected. For instance, the safety data sheet for preparations must state the registration numbers of all the substances that are contained in a preparation in excess of the (very low) thresholds. This regulation comes very close to obliging companies to disclose their recipes. Here, the specifications for preparations classified as non-hazardous (Article 30: every registration number of every component) are even more stringent than for other preparations (Article 29 with Annex I b No. 3: essential components). These duties of disclosure could lead to expertise leaks. Therefore REACH should be amended to ensure that confidential business information is fully protected.

IX. Substances in Articles, WTO-Compliance

IX.1. Articles as such are not covered by the registration obligation. Substances in imported articles have to be registered only if they have not yet been registered, if they are contained in quantities of more than 1 t/y in one type of article, if they fulfil the criteria for classification as "hazardous" or could be released under normal or reasonably foreseeable conditions of use. However, a notification (not registration) is required if the release is not an intended function of the article but is probable under normal or reasonably foreseeable conditions of use and if the released quantity could have a negative influence on health or the environment. In this way, the intention is to reduce the competitive advantage for imported products as compared with products manufactured in the EU.

IX.2. This provision will not have the desired effect, as it can still be expected that it will not have the intended effect in practice. Even the definition of a type of article (all cars of one brand? all cars of a certain type? all cars of a certain type with certain accessories? only parts of cars but not complete cars?) presents difficulties. Determination of the individual substances and the respective quantities that trigger a registration obligation is almost impossible. With regard to the safety and environmental compliance of articles, this regulation is superfluous because of the high density of product-related regulations that already exist. Therefore, UNICE demands that the provisions on substances in articles are completely revised.

IX.3. Another problem is the effects that the proposed policy will have on world trade. The inequality in the burden imposed upon manufactures inside and outside the EU will increase. In the present proposal there is a different treatment of the substances in articles that are produced in Europe and those articles that are produced outside Europe and afterwards imported. In the first case, all the substances that are necessary for the production of the article must have been registered (except for a few exemptions, for example substances produced in less then 1 t/y); in the second case the articles can be imported into Europe with a registration of only the dangerous substances that are likely to be released. Some of the substances that are used to produce an article in Europe may be the subject of an authorisation or may disappear from the European market when an authorisation is not given. This all means an economic disadvantage for the production of articles in Europe in comparison with the production outside Europe. In addition, elements of the proposed systems could represent technical barriers to trade that are incompatible with the specifications of the WTO. For example, when preparations are imported, all components above the relevant threshold must be registered.

IX.4. Substances not intended to be released from articles should be exempted from the proposed notification procedure. It is simply not possible to notify an unforeseen release in advance. It will also be extremely difficult to enforce this provision with regard to imports, thus leading to the unequal treatment of articles produced in the EU and negatively affecting the entire EU economy. Moreover, it ~~is~~ is almost impossible to determine the individual substances and the respective quantities that would trigger a duty of registration. This provision must be completely revised. Besides that, in accordance with the General Product Safety Directive, it is not allowed to market articles which are not safe. Moreover, it is not defined which concentration affects human health or the environment.

X. Registration, Evaluation, Authorisation, CSR

Registration, General

X.1. The provisions concerning registration are a core element of REACH. The aim is to provide the authorities with certain data about substances that are manufactured or imported in quantities exceeding 1 t/y. UNICE believes that the scope of the registration process is too broad, the required data is too comprehensive and the documentation obligations associated with the registration are unnecessarily burdensome. This quantity-related requirement presents no major advancement for human health and environment. The required data must be submitted even if no risks are expected. Registration requirements should be simplified to a core set of data focused on environmental and human health end points.

X.2. The duty of registration also applies to substances that are manufactured or imported only as a component of a preparation. The cut-off limits of the Dangerous Preparations Directive apply only to the obligation to draw up a Chemical Safety Report (CSR), and not to the registration as such. But as an order of magnitude, there are over three million different preparations, many of them containing several dozen components. This makes the area of application of this regulation exceptionally broad. In addition, a special duty of registration is envisaged for certain intermediates.

X.3. On the whole, the process is unnecessarily innovation-restricting. The chapter in question must be fundamentally revised. The process should be structured flexibly. Time delays in the introduction of new products must be strictly avoided.

X.4. It should be stated that in the Commission's proposal numerous procedures build on the known procedures for registering new substances and handling existing substances, but do not take account of the experiences achieved with these regulations. Even within their previous, rather limited areas of application, these regulations concerning new and existing substances have demonstrated considerable weak points. Because of the low number of new substance authorisations, it cannot be denied that the EU procedure is too bureaucratic as compared with, say, Japan or the USA. The procedure for existing substances has also proved to be too complicated. Instead of eliminating these weaknesses, the Commission's proposal means in principle extending the scope of both procedures to all substances. Because of this, considerable doubts as to whether this system can function properly are in order.

Registration, Scope of Application (former II.4.5.1)

X.5. There is not enough experience available with the registration process; besides, more than 100,000 registration processes for substances can be expected. Therefore, the functionality of the process should be examined in pilot projects. According to estimates by Arthur D. Little and Fleischer et al., the costs for registering one single substance will still be in the range of € 20,000-40,000, in spite of the improvements made in the Commission's proposal. This figure does not include subsequent costs for updating the registration data or possible evaluation proceedings. One particular problem will be the sudden rise in the costs for substances produced in quantities of more than 10 t/y. For these substances, costs of € 200,000 and more will quickly be incurred. This leap will certainly prevent many small and medium-sized enterprises from expanding. Because of this, the data requirements for substances between 10 and 100 t/y should also be considerably reduced and tailored by relating them to exposure scenarios/categories.

X.6. A proper cut-off limit must be defined for substances in preparations. It must also be examined whether the registration of the components of preparations can be restricted to critical components. Otherwise, every single component of a preparation would have to be registered, no matter how small its share in the preparation. In the case of imports, every component of a preparation would have to be disclosed in order to determine if the annual tonnage threshold is exceeded. Therefore, the duties to provide information should relate to the preparation as such and not to its components.

X.7. Metallic alloys should be defined as "special types of preparations" that need to be assessed on the basis of their own specific intrinsic properties as defined in the Technical Guidance Document on metals Risk Assessment

X.8. The exception for research and development should be further simplified. The pre-requisites for applying these exceptions are still very restrictive. For instance, the EU Chemicals Agency requires the quantity of a substance, a reason for the quantity, the customers and the research programme to be notified. No obvious justification can be seen for this. On the contrary - this regulation inhibits research and should therefore be completely removed without replacement. The exemption for research and development is still too narrow for many applications. Above all, the unnecessary waiting period of three weeks should be replaced by a "post-registration process".

X.9. According to Annex III natural substances such as natural gas, oil and coal are exempted from the obligation to register. Other natural substances, for instance minerals and ores, are only excluded in cases where they are not chemically modified and unless they are classified as dangerous. This imbalance leads to a competitive disadvantage for the metals industry which uses minerals, ores and concentrates as raw materials. Therefore minerals, ores and concentrates should be excluded as well. Potential risks of the use of these substances are already well managed under existing legislations.

Registration, Recognition of Existing Data and Risk Evaluations

X.10. The possibilities of using existing data for registration should be strongly improved. The industry has compiled a large amount of data in the past. The Commission's proposal is unnecessarily restrictive in this regard. The demands placed on the accuracy of data should be in proportion to the assessed risk: the less problematic a specific substance's properties, the lower the degree of required data accuracy can be, with no adverse effects on human health, occupational and environmental protection. For instance, all risk evaluations concluded according to the Regulation on the Evaluation and Control of

the Risks of Existing Substances 793/93/EEC must be expressly acknowledged as a registration according to REACH requirements.

Registration, Obligations of the Downstream Users (former II.4.5.2)

X.11. From the point of view of downstream users, using safety data sheets as the main means of communication in the supply chain is a welcome sign. However, the implementation of the proposed provision causes considerable burdens. Companies that handle substances or preparations must examine the safety data sheets drawn up by the upstream suppliers with regard to the exposure conditions described therein (e.g. workplace or wastewater concentrations) to attest that the specified uses are complied with and that the proposed protective measures can be implemented.

X.12. UNICE proposes simplifying these obligations to a great extent by introducing legally more secure, simpler and broader exposure scenarios/categories. Exposure information requests should be made in a uniform format to reduce the burden on downstream users. Use categories should be broadly defined. Appropriate transition periods must also be envisaged.

Registration, Polymers and Intermediates

X.13. The Commission's proposal no more contains a duty of registration for polymers. This exception, which corresponds to the recommendations of the white paper, is welcome. However, the duty is still subject to an examination provision which causes a considerable amount of uncertainty among manufacturers and users. The examination clause should therefore be removed.

X.14. The Commission's proposal envisages a staged duty of registration for isolated intermediates that are used "on site" or which are transported to other production locations under strictly controlled conditions. The restriction of these privileges to substances that are transported to a maximum of two production locations, which was still contained in the May 2003 consultation document , has been removed. The duty of registration for intermediates should be removed completely. The existing legislation is adequate for ensuring the objectives of REACH. The waiting obligation associated with the duty of registration leads to disproportional losses in flexibility. The duties of disclosure are also problematic because intermediates as intermediate stages of complex syntheses often represent business and company secrets. Finally, the definition should be more precise in order to include intermediates derived from natural resources processing.

Registration, Exposure scenarios/categories

X.15. The introduction of exposure scenarios/categories is a suitable means of reducing the burdens associated with registration without having any adverse affects on human health, occupational and environmental protection. This proposal has been included in numerous statements submitted within the framework of the internet consultation, especially from associations representing the so-called "downstream users

X.16. Exposure scenarios/categories should be structured according to exposure path, exposure frequency and amount of exposure. They should be bindingly standardised to ensure uniformity and calculability of application for all those involved. In this way, data gathering as well as exposure determination and risk evaluation can be reduced to the question whether the conditions for safe handling within the scope of the specifications of the respective exposure category exist. Above all, this will make dealing with the

requirements of REACH much simpler for small and medium-sized companies. Protection of economically important information will be improved. Users of substances will not be dependent to an even greater extent on the expertise of their suppliers. Initial pilot projects of the German Federation of the Chemical Industry have shown that the administrative expenditure can be considerably reduced in this way and that protection of confidential information in the supply chain can be decisively improved. UNICE proposes that this process is tested in further pilot projects in order to identify a suitable procedure. With regard to the EU Chemicals Agency, standardised exposure scenarios/categories would also reduce expenditure for translations.

Chemical Safety Report

X.17. The provisions regarding information in the supply chain have been simplified. The Commission has thereby implemented an important result from the internet consultation. Now, an extensive Chemical Safety Report is required only for substances that are subject to the registration obligations when they are produced in quantities exceeding 10 t/y. Communication in the supply chain will be carried out using the established safety data sheet, which will be extended where necessary. The provisions concerning duties of documentation contained in the Annexes have been supplemented with an Annex for the creation of safety data sheets with special regulations for preparations. UNICE welcomes this supplement because it provides important information for this key communication tool within the supply chain.

X.18. However, it should be mentioned that the duties envisaged especially in Annexes I and XI concerning risk assessment and documentation of the risk assessments in a Chemical Safety Report (CSR) remain unnecessarily complex and voluminous. They are based extensively on the process according to the regulation on existing substances 793/93/EEC as specified in the Technical Guidance Documents (TGD). In the past, these processes have proven to have little practical use, only experts and specialists are able to implement them. CSRs now have to be drawn up only for substances produced in quantities exceeding 10 t/y, these quantities are however often found in small and medium-sized enterprises.

X.19. The expenditure associated with these provisions will be increased even further by the fact that no standardisation is envisaged in the CSR statements. In other words, different manufacturers of one and the same substance can describe permitted applications in different ways. Users are left in the dark as to which information applies to them. This can be an almost insoluble task when preparations with many components from different suppliers are being further processed.

Authorisation

X.20. The provisions concerning the authorisation process have, in some cases, become more severe through the Commission's proposal. This makes the use of highly critical substances, which in many cases is socially desirable or in fact indispensable, even more difficult. The authorisation procedure is designed to regulate the admissibility of every application of a substance that is subject to authorisation. An authorisation is addressed to manufacturers, importers or users. Unauthorised substances and unauthorised applications are banned. Downstream users must register every use of a substance that is subject to authorisation. In this way, factual pressure towards substituting these substances is supposed to be increased.

X.21. The scope of the authorisation procedure is unclear. In addition to carcinogenic, mutagenic and reproduction-toxic substances in Categories 1 and 2 as well as PBT and vPvB substances, in individual cases, substances with “similar grounds for worry” may

be subject to authorisation obligations; this especially applies to endocrine substances. In the internet consultation this point was often seen as very problematic. After all, the authorisation process is not needed in specific cases from the aspect of human health, occupational and environmental protection, for example when metals and alloys are introduced to the market in solid form. This is already accounted for in Annex VI (Nos. 8.3. and 9.3.) of the Classification and Labelling Directive 67/548/EEC. Therefore solid metals and alloys should be exempted from the authorisation process. From UNICE's point of view, the authorisation process is unnecessarily bureaucratic. The indeterminate scope leads to legal uncertainty.

X.22. The authorisation process should be built on the registration and evaluation process. UNICE also proposes that authorisations are issued only in an abstract, general manner (for example via positive lists of approved substances and applications) and only in individual cases manufacturer-related. In this way, the bureaucratic expense could be considerably reduced and the innovation restricting effect of the authorisation process could be lessened. Besides, applications should be described in such a manner that product innovations still remain possible. The scope should be defined in a clear and legally certain manner. Duties of notification for downstream users should be abolished. The existing provisions for handling these highly critical substances are precise and strict enough to minimise hazards to human health and the environment.