CEPI

ENV/152/03

THE DRAFT PROPOSAL FOR A NEW EU CHEMICALS LEGISLATION

COMMENTS FROM THE PULP AND PAPER INDUSTRY

July 2003

Introduction

CEPI represents the **pulp and paper industry from 19 European countries**:

- It is composed of about 900 companies and 1,250 mills and has a turnover of EUR 73 billion
- It employs about 251,000 people directly and the forest based industries cluster employs some 4 million people
- On average, the companies have 280 employees, with a wide distribution: a very large number of SMEs as well as some multinational companies with over 30,000 employees
- It produces some 91 million tonnes of paper and board and 39 million tonnes of pulp
- It exports over 12 million tonnes of its products and represents 28% of the world production
- The pulp and paper industry is highly dependant on recovered paper, about half of its fibre raw material are recycled fibres
- Next to virgin fibres, recycled fibres and water, chemical substances are an essential part of the papermaking process. The pulp and paper industry is an important downstream user of chemicals as well as an importer of chemicals
- It is producing substances as by-products of the pulp manufacturing and recovery processes.

CEPI supports the aim and the basic ideas of the draft proposal for regulation. If the system is successfully implemented, it should:

- Reduce impacts on human health and environment resulting from exposure to harmful substances;
- Enable downstream users to have information and knowledge about the chemicals they use in the manufacturing process and increase the overall transparency.

However, the system as it is proposed now, seems to involve heavy bureaucracy and covers a vast amount of substances, substances in preparations and in articles about which extensive information is required. CEPI is concerned that the proposed system will not function due to its magnitude. Hence it will bring no improvement compared to the current legislation on chemicals. We strongly feel that the focus should be on devising a workable system for the high volume substances of concern, selected e.g. by assessing their toxicity, persistence and bio-accumulation. At a later stage, once the system is operational and has proven its advantages, it could be extended to cover more substances. The more detailed comments given below also aim at simplifying the proposed system.

250 Avenue Louise Box 80 B-1050 Brussels Belgium
Tel +32 2 627 49 11 Fax +32 2 646 81 37 mail@cepi.org www.cepi.org www.paperonline.org
VAT BE 447 185 143 BBL 310 0943243 04

The pulp and paper industry has two main sources of raw materials: virgin fibres extracted from wood and recovered paper, both with cellulose fibres, a naturally occurring substance, as main ingredient. The pulp and paper industry is a major recycler, the recycling rate of paper and board was 51 % in 2001.
The pulp and paper industry will be mainly affected by the proposed regulation as a downstream user of substances, but also as an importer of chemicals and articles, and even as producer and recycler. The draft proposal is not entirely clear about whether our raw materials are included in the system or not. We understand that due its natural origin, wood pulp is excluded from REACH. Recovered paper should be excluded as well. It is difficult to trace the origin of the recycled fibres and impossible to register the substances in recovered paper. Furthermore, the substances used to produce paper and board before it was collected and recovered, will be subject to REACH. The industry would not be able to uphold the increase in the recycling rate if it has to register the substances in recovered paper or draft the extensive chemical safety reports as required under the Duty of care for the substances in recovered paper.

The pulp and paper industry agrees that “Duty of care” is a general principle that should be applied by all manufacturers and downstream users and should be part of the basics of the new European Chemicals Policy. However the detailed requirements as proposed in the draft text including the preparation of a chemical safety report are not workable and duplicate what will be required for registration. We feel that the development of the chemicals safety report should instead be connected to the registration procedure. In our opinion, the existing materials safety data sheets or similar systems provide enough information for a safe use of substances and preparations. In addition, the “Duty of care” provisions do not provide a “safe haven” for the producer or user. It is not clear at what point the risk management measures will be considered as sufficient.

CEPI fears that the requirement to register all substances contained in articles in volumes above 1 tonne if “during normal and foreseeable conditions of use and disposal the substance may be released so as to adversely affect human health and environment” will overload the system. This would de facto mean that the manufacturer of an article would have to look at all possible uses of paper and board products including the review of the use of inoffensive substances. Looking at the multitude of possible contacts of humans with paper products, this is clearly unworkable. CEPI therefore proposes to limit the consideration for the exposure of humans and environment to substances released from articles to dangerous substances. The possible release of substances during the re-use or disposal of articles, waste and workers’ health and safety related to the use of chemical agents at work should be excluded from the scope of the legislation, as these are already covered by separate Community legislation.

0. General remarks

- The proposed process is very bureaucratic, the amount of information required for registration is vast and the additional resources and expertise that will be needed within the companies (producers and downstream users) to manage the REACH process are quite significant. The authorities (EU and member States) should make sure that there will be enough additional expertise e.g. for toxicology available within Europe.
- As a consequence, the price of substances for downstream users will go up, small suppliers to our industry might go out of business and specialised substances may be taken off the market (not registered) for economic reasons reducing the product

range. As a result, downstream users could be facing a monopoly position for the remaining suppliers/substances.

- It seems unlikely that small mills will have the resources to be able to comply with the downstream user requirements for REACH and the additional costs. As the PPI sells on an international market, we will not be able to pass on the costs to our customers and there will be difficult decisions for everyone about whether to try to comply, to rationalise the diversity of our products or simply relocate production.
- We have made a very rough estimate of the costs that REACH would entail for an average-size paper mill (see Annex) of 150 employees. It includes estimates for costs for additional expertise, training, research to replace substances that will be withdrawn from the market, additional work for the downstream user chemical safety report (CSR) and increased costs of the chemicals. The estimated total costs would amount to almost 6% of the annual turnover, which is close to the profit margin for some of the mills.
- Some definitions are missing from the text: "reasonable foreseeable use and conditions", "human health and environment are not adversely affected", “appropriate measures to reduce risks”. We feel this considerably increases the uncertainties for industry related to the impacts of the proposed policy.

1. Duty of care

- The pulp and paper industry supports the general principle of Duty of care, requiring industrial producers and users to make sure that, under reasonable foreseeable conditions, their use of substances do not adversely affect human health nor environment.
- However, we feel that the duty for both producers and users to undertake a chemical safety assessment (CSA) and chemical safety report (CSR) is too heavy a burden. They require the same information as is needed for registration of a substance, while the Duty of care will apply as of the entering into force of the regulation, even if a substance is not registered yet, or may even never be registered. The necessary information will not be available for all substances and downstream users will strongly depend on the information available from producers/suppliers in the initial stages of REACH. We doubt that we will get enough information, especially on preparations to be able to make correct risk assessments. Current experience from the Dutch pulp and paper industry ‘proeftuinproject’ in relation with SOMS, shows that this is the case today with sometimes incomplete or even missing safety data sheets.
- We therefore strongly feel that Duty of care should be limited to the general provisions and moved to the preamble of the regulation. The CSR and CSA should be linked to the registration.
- The chemicals safety requirements for substances that are not classified as dangerous should be drastically reduced to e.g. the format of the chemical safety data sheets, or an analogous system to the product information file under the cosmetics legislation that is kept available upon request from authorities; or the product safety declaration for food contact.

2. Chemical safety assessment and Chemical safety report

- We see difficulties for downstream users in handling the separate chemical safety reports for all the substances in preparations. The information flow is bound to be enormous if one thinks about the large number of substances in preparations.
- The chemicals safety assessments and chemical safety reports have to be written by experts and a high degree of expertise is needed to understand the chemicals safety reports from the suppliers. This expertise is lacking in the mills and is

currently not available in sufficient quantities in the general labour pool in the EU neither.

- Technical dossier, identity of substance, composition: there should be a "threshold"/selection criterion for impurities or additives to be included in the description of the substance. There must be a lower concentration limit for substances below which you do not have to take them into the consideration in the risk assessment. We feel that the system should be similar to the current situation, where suppliers are not obliged to give any information about substances below a certain concentration limit (as an impurity, additives or in preparations) depending on their hazard.
- Technical dossier, information on manufacture and use of substance, 3.6 waste quantities: not relevant for aim of this regulation, is already adequately covered by other community regulation.
- Technical dossier, guidance on safe use: disposal considerations should not be included here, again because it is not relevant for the aim of regulation.

3. Information flow

- The information flow up and down the supply chain is an essential element of REACH. Looking at the large number of separate substances, substances in preparations and in articles and the very complex structure of the supply chain, it will bring about an enormous passing to and fro of chemicals safety reports and other information, becoming especially difficult for actors at the end of a supply chain. CEPI feels that this process should be entirely simplified.

4. Registration procedure

- We welcome the intention of having 90% of all intended uses of a substance covered in the registration. We feel the registration is really an obligation for the manufacturer of the substance/preparation and should cover "nearly all" uses of a substance (including the registrants own). If a substance has a known use at the time of registration, it should be included.
- We propose to change the term 'intended use' into 'identified use'. If a downstream user informs a producer of a substance of a certain use, it is identified and should as such have to be included in the registration. There are actually no 'unintended' uses of substances, we would prefer to see 'supplementary' uses as terminology. To further improve the clarity of the text, we would suggest to delete "undesirable".
- It is not clear yet how the "intended" or identified uses will be characterised in the registration. We would welcome the possibility of using broad categories of "intended uses", e.g. "for use in paper production".
- We feel that if a substance is of no concern and is present in preparations in concentrations of less than 1%, it should not be subject to registration. If all substances would have to be registered, the system would not be workable due to the large number of preparations on the market and the large number of substances present in some preparations.
- It is not clear how different technical or purity grades of a substance will be handled. We feel that if they have similar properties, they should not be registered separately.
- The draft proposal foresees in the exemption from registration of substances for R&D purposes, however this seems focussed on long-term and large R&D projects. In the paper industry, trial runs are typically made from a few days to some months and with important amounts of chemicals (given that the annual production of the largest mills can exceed 500,000 tonnes of paper). In order to secure a high level of innovation, creativity and flexibility in paper making, we need to secure that R&D is not burdened by a too bureaucratic process, either for substances that have not been registered under REACH yet (point 9 f), or for substances where an innovative

(or unidentified or unintended use) is tested (point 33). Especially in R&D situations, the protection of confidential business information is crucial.

- The information requirements for registration (technical dossier), even for 1t substances are too detailed; this information is not needed for the large group of substances not classified as dangerous and should be very much simplified; Please see also comment under “Duty of care” on the safety data sheet or similar.
- There is no guarantee that the registration number is unique: the same substance might be registered twice by different producers/importers or might be registered under a different brand name. It should be the Agency’s role to rationalise the attribution of registration numbers.
- The list in Annex III with exemptions from the obligation to register is extracted from the current 93/793 Regulation on the evaluation and control of the risks of existing substances. As this regulation itself explicitly exempts all inorganic substances, there was no need to have inorganic substances on the original list. We feel that some inorganic substances should be exempt from registration and added to the list in annex III of the draft proposal. For instance, precipitated calcium carbonate should be exempt from registration because it is actually a very pure form of chalk, which is a mineral. Furthermore, ground calcium carbonate, the less purer form is commonly used as a food additive.
- Chemically extracted wood originating compounds should be exempt from registration by adding them to the list in Annex II. It would cover naturally occurring substances extracted from wood like lignin, mannose and xylose. It would also cover tall oil and sulphate turpentine which are either re-used as a fuel in the virgin pulp production process or from which e.g. rosins are extracted. Furthermore, they have similar properties as crude oil, and we feel it fully justified that they should be exempt as well.
- We understand that wood pulp is exempt from registration according to Annex III point 7, as cellulose fibres are mechanically or chemically extracted from wood during the pulping process, but do not undergo a chemical modification. In chemical pulping, the lignin is removed from the cellulose fibres without chemically modifying them. We would welcome confirmation of this point from the Commission.
- An importer of substances or preparations might run into considerable difficulties to register the substances or substances in a preparation. This was for instance shown for pigments imported from the east, where the EU NONS and SENSE projects identified a lack of information. We would welcome that the Commission should give consideration to these problems.

5. Polymers and
6. Intermediates

- We feel that polymers and intermediates should be excluded from the system. Monomers are subject to registration and are usually more reactive than polymers. There is no need to register intermediates as they will ultimately be transformed in substances that will be subject to registration. Both groups would add a considerable amount of substances to the scope of REACH. We would recommend to try to implement a workable system for REACH of which the scope can be enlarged afterwards.

7. Data requirements

8. Data sharing/consortia formation

- "Sharing and joint submission of information shall concern exclusively the intrinsic properties of substances". We feel that the information about intended (or registered

uses) should be shared as well, it would avoid having to duplicate the collection of this information and reduce the necessary input from the downstream users.

9. Procedures for downstream users

- A downstream user needs to evaluate the CSR of the supplier, to determine whether or not it sufficiently covers all downstream uses of a substance and evaluate the exposure scenarios. The expertise required to do this (a. o. expertise on toxicology) are not present in most mills, and hence will require additional human resources or outsourcing of duties which will not be sufficiently available in the EU labour pool.
- Too extensive requirements for downstream users would hamper innovation and development of safer alternatives because of the too large strain on resources.
- There is no platform for exchange of information where downstream users are involved. As there are numerous applications for substances, the downstream users will have to communicate the information about their uses of substances to the producers for inclusion in the registration procedure. The downstream user should have the opportunity to be actively involved in the registration, evaluation and registration procedure if he so wishes and to play a role in the consortia formation.

10. Evaluation procedure

11. Authorisation procedure and
12. Restrictions procedure

- Authorisation and restriction should be based on scientific arguments. E.g. some water insoluble and hydrophobic substances, even though they degrade, are totally unjustified listed as a PBT under the current chemicals legislation or are in the process of being classified as such, without real proof of bio-accumulation. According to the draft proposal, these substances would be subject to authorisation. We strongly feel that the upcoming new regulation should provide the opportunity to straighten out the existing problems related to the hazard classification of substances.
- Restrictions: the information in the annexes is quite heavy and will be continuously amended. It will be difficult for downstream users to keep track of these changes, e.g. related to use in different articles. It should be the responsibility of the producer to inform users along the supply chain.

13. The Agency

- The role of the new Agency should be considerably strengthened and member states' responsibilities should be very much limited. A major piece of legislation like this, dealing with safety matters and influencing trade, could accommodate only one final authority to avoid discrepancies in implementation.
- The Agency should have a role in organising the formation of consortiums to make the process completely open and fair and to avoid multiple consortiums dealing with the same substance or to avoid that some producers could monopolise the market in a particular chemical.

14. Other

Substances in articles

- Registration of substances in articles by the producer should be based on application-specific risk assessment of the substances, instead of solely hazard identification of the substance and to registration of substances in articles by the importer if not already registered. In all other cases the substances have already been adequately covered by other provisions of the draft proposal.

- Exposure of consumers and/or environment to substances in articles should not be included in the scope except for dangerous substances. Substances in pulp and paper industry articles are typically used in volumes above 1 t. Investigating all the possible uses of the articles and possible exposures will overload the system and will not result in any benefit for man or environment.
- Currently in classification and labelling, the threshold for inclusion of carcinogenic substances in preparations is 0.1%. The draft regulation should not be stricter for substances in articles than the current Dangerous Preparations Directive. We feel that substances below 0.1% in articles should not be considered.
- The scope should not include exposure to substances from articles for workers' health and safety related to the use of chemicals in the production process, this is already separately covered by the legislation on protection of the health and safety of workers from the risks related to chemical agents at work.
- Substances naturally present in articles should not be covered (e.g. thinking of wood-based articles), only those that have intentionally been added are to be considered.
- The scope should not include substances in articles or materials intended for material recovery. This would be impossible to achieve for the use of recovered paper for instance. Furthermore, the substances used in the production of paper and board before it is recovered, will be subject to the new chemicals legislation.
- The disposal phase of articles should not be included in the scope, this is regulated by separate community legislation and there is no need to duplicate existing legislation. In general, waste should not be part of the draft proposal.

Other

- There is a need for a consistent approach to confidentiality that balances the need for information with the need to protect sensitive business information. A downstream user could e.g. have discovered an innovative use of a substance in its production process. Disclosure of this information would mean a commercial disadvantage and a loss of competitive advantages. Registration in terms of broad classes of "intended" or identified" uses would solve this problem.
- The REACH system should provide registrants the right to be heard before decisions on evaluation, authorisation and restrictions are taken and the right to appeal to an independent body against the decisions of the Central Agency and the Member States' competent authorities.
- The draft proposal does not mention "by-products". We would welcome clarification on how by-products relate to the definitions given for REACH.

Contact: Inneke Claes, + 32 2 627 49 23, i.claes@cepi.org

Annex

ESTIMATED COSTS OF REACH FOR FIRST FIVE YEARS FOR TYPICAL PAPER MILL

Issue	number	unit	each, Euros	multiplier	total, Euros
Full-time toxicologist or consultant	1 person	annual salary	75,000.00	5 years	375,000.00
Extra Administation staff	2 persons	annual salary	50,000.00	3 years	300,000.00
Computer systems & development	1 system	equipment	100,000.00	1	100,000.00
Work force training	150 people	1 man-day	400.00	3 day course	180,000.00
Inability to innovate/troubleshoot	2.5%	annual turnover	58,000,000.00	5 years	7,250,000.00
			Total, mill costs		**8,205,000.00**
Of 300 substances purchased (assume 10-100 tonnes/year band)					
withdrawn substances	60 substances	substitution and development	5,000.00	1	300,000.00
substances as supplier CSR	170 substances	DU risk analysis & CSR	100,000.00	20%	3,400,000.00
substances with some variation	60 substances	DU risk analysis & CSR	100,000.00	50%	3,000,000.00
substances outside supplier CSR	10 substances	DU risk analysis & CSR	100,000.00	100%	1,000,000.00
increased cost of chemicals	300 substances	incremental cost per year, each	500.00	5 years	750,000.00
participation in supplier CSR development	290 substances	1 man day	350.00	2 persons	203,000.00
			Total, chemicals costs		**8,653,000.00**
No Registration in first five years					
DU = Downstream User					
CSR = Chemical Safety Report					
			Grand total over 5 years - equivalent to 5.8% each year		**16,858,000.00 of turnover**

NS Barnwell, 30 June 2003