E U R O P E A N E C O N O M I C A R E A

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O F T H E E F T A S T A T E S

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EFTA WORKING GROUP ON TECHNICAL BARRIERS TO TRADE

COMMENTS BY THE EEA EFTA STATES ON THE COMMISSION WHITE PAPER ON THE STRATEGY FOR A FUTURE CHEMICALS POLICY

I. EXECUTIVE SUMMARY

The EEA EFTA States welcome the Commission White Paper on the strategy for a future chemicals policy (COM (2001) 88). The new chemicals policy will have direct consequences for the EEA EFTA States, as they are part of the Internal Market. The EEA aspects have, therefore, to be taken into account when developing new legislation. The strategy is generally supported, but in the view of the EEA EFTA States, there are some points in the strategy that need to be further developed. Important points include whether registration will be a condition for the continued marketing of the *existing* substances and whether the authorisation scheme will be an important instrument in phasing out the substances of highest concern.

The EEA EFTA States are prepared to contribute actively to the future chemicals policy and to participate in the future work of a central entity, or expanded European Chemicals Bureau, as well as any planned network.

II GENERAL COMMENTS ON THE REACH SYSTEM

1. The EEA EFTA States support that the strategy draws up a chemicals policy based on the use of the precautionary principle and the substitution principle and agree with the different political objectives behind the proposal.

2. The EEA EFTA States support the proposal for a single system for both new and existing chemicals. The REACH[1] system provides a necessary framework for future chemicals management based on increased knowledge and on involvement and increased responsibility by industry. This is in line with the "polluter pays principle". The proposed chemicals policy should be sufficiently reflected in the Sixth Environment Action Programme "Our Future, Our Choice" for 2001-2010.

[1] Registration, Evaluation and Authorisation of Chemicals

3. Environmentally hazardous substances should be given even greater attention than already given in the White Paper. *The one-generation target*, as formulated in the OSPAR *Strategy for hazardous substances,* should be adopted in the strategy. This would also ensure better coherence with the newly adopted Water Framework Directive (Directive 2000/60/EC) where a similar target is included.

III REGISTRATION AND EVALUATION

4. The current state of insufficient knowledge is the fundamental challenge in the chemicals area. We therefore agree with the emphasis placed on tackling the lack of hazard data and the general lack of knowledge regarding risks to human health and to the environment. The proposed REACH-system will entail a great leap forward in generating knowledge regarding chemicals, their properties and their effects on man and the environment. This will enable the substitution of chemicals of high risk with alternatives that pose less of a risk.

5. A crucial factor will be the stepwise inclusion of the existing substances into the REACH-system. Industry will be obliged to supply the necessary registrations according to the deadlines set up in the strategy. In order to make the obligations firmer, the EEA EFTA States recommend that it should be made quite clear that such registration will be a condition for continued marketing of the substances after the deadlines.

6. There might be substances of concern below the *threshold of 1 ton* which are not subject to authorisation. It is necessary to develop proposals for how and when to include these substances in the overall system. The EEA EFTA States acknowledge that it is preferable to have a single system rather than two separate ones for *new* and *existing* substances. However, not placing a chemical on the market at all may be easier and less costly than withdrawing it from the market after it has been in circulation for a long time. Thus, considerations of a cost-benefit nature might be an argument for already now looking into whether some appropriate testing requirements might be considered for new substances below 1 ton. These requirements should be aimed at denying substances with severe CMR[2]-properties and VPVB[3]-properties access to the market.

7. *Harmonised classification and labelling* should be extended to environmentally hazardous substances, as well as CMR-properties. Sensitising properties are also an important hazard and should be included in the harmonised classification list.

8. The concern caused by *unintentionally produced hazardous substances*, such as PAH and dioxins, are inadequately covered in the strategy. There might also be a need to look further into how *imported manufactured products*, which contain hazardous substances, are dealt with in the strategy. The future chemicals policy should not give

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[2] Chemicals classified as carcinogenic, mutagenic or toxic to reproduction

[3] **V**ery **p**ersistent and **v**ery **b**io-accumulative.

incentives to get around Community legislation by producing products outside the European Economic Area.

9. It is necessary to clarify the role of the authorities in the EEA Member States and the relationship between producers/importers and the downstream users in generating exposure data.

10. In the *evaluation* part of REACH, the authorities will have an important role in validating the risk assessment carried out by industry. The authorities must have a central role to ensure confidence in a system based on assessment carried out by industry.

IV AUTHORISATION SCHEME

11. *Authorisation should be the exception, not the rule*. A main focus of a chemical strategy is the minimisation, or elimination, of exposure to the most dangerous substances. Strict regulations should be used to phase out the use of the most dangerous substances. The EEA EFTA States acknowledge the intent behind the proposed authorisation system to be in line with such a policy. It is therefore important that the *identification of substances*, which will be subject to authorisation, is clearly linked to a general prohibition of marketing after the time limit unless a specific permission has been given. The relationship to the current regulation of substances in the "Limitations Directive" (Directive 76/769/EEC) needs to be clarified.

12. The authorisation scheme should focus on environmentally hazardous substances, as well as the most threatening substances for human health. The EEA EFTA States are therefore of the opinion that substances fulfilling *PBT*[4]*-criteria should be included* in such a scheme to a much greater extent than POPs[5]-like substances. Suitable methods for evaluating metals and inorganic metal compounds in such a scheme should also be developed.

13. *Endocrine disrupters* will only marginally be encompassed by the proposed authorisation scheme. Suspected endocrine disrupters do not systematically show CMR-properties and the proposed criteria for POPs-like substances will only allow a few such substances into the scheme. Special attention should therefore be given to developing better methods for assessing and managing risks connected to endocrine disrupting chemicals.

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4 Persistent, bio-accumulative and toxic chemicals

5 Persistent Organic Pollutants

V ACCELERATED RISK MANAGEMENT

14. *The accelerated risk management* of substances other than those included in the authorisation system is very important. It should be made clear that this is an independent possibility for strict regulation, and that the authorisation scheme is intended to handle only those substances with certain intrinsic properties that give rise to very high concern. Although more knowledge will be available as a result of the proposed system, uncertainty regarding risks will still be the norm. The use of the precautionary principle in risk management has to be strengthened.

VI TEST METHODS

15. Development of new in-vitro test methods is crucial, even if the predictive value of the in-vitro tests may be questioned for some hazards. This is particularly important because the data required for the registration of chemicals produced between 1 and 10 t is to be based on in-vitro tests. In addition, the number of in-vitro test methods for health hazards is currently limited, e.g. for reproductive toxicity and sensitising properties, no in-vitro test is available. The EEA EFTA States also recommend that the possibilities for increased use of models like QSAR[6] and "group entries" are elaborated.

VII ACCESS TO INFORMATION

16. The increased amount of knowledge regarding chemicals will be of far greater value if it can be communicated to the market in an understandable way. Everyone should have access to information on the risks to their own health, or the environment, when using hazardous substances. Information is essential to allow people to choose substances with less impact on health and the environment.

17. The EEA EFTA States therefore consider better access to information to be vital to the success of the future chemicals policy. It is necessary to have coherence between the chemicals policy and the integrated products policy (IPP). The easy access of information will also to a great degree ensure that it is in the interest of industry to supply reliable data on chemicals in their products.

VIII THE INTERIM PERIOD

18. Although implementing this strategy is very important, work should be carried out within the existing regulatory framework in the interim period, e.g. to identify PBT-substances, to do targeted risk assessments and to consider appropriate risk management measures. This should be done in accordance with the new strategy.

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[6] Quantitative Structure Activity Relationship

IX INVOLVEMENT OF THE EEA EFTA STATES

19. The new strategy concerns legislation which falls within the scope of the EEA Agreement. Therefore, the EEA aspects have to be taken into account in the development of new legislation. Furthermore, the participation of the EEA EFTA States in the work under the new legislation should be based on the general provisions of co-operation in the EEA Agreement.

20. The EEA EFTA States welcome the proposal to establish a central entity or expanded European Chemicals Bureau for the administration of the REACH system and the provisions of technical and scientific support. The EEA EFTA States found participation in other such agencies set up to assist the Commission in their work to be a very positive experience, eg. their involvement in the EMEA. The EEA EFTA States are prepared to contribute actively to the future chemicals policy and to participate in the future work of a central entity or expanded European Chemicals Bureau, as well as any planned network of the Member States and Candidate Countries Authorities.

X RESOURCES

21. In conclusion, the EEA EFTA States support the work to implement the REACH-system into an effective system for managing chemical risks in the EEA area. To enable this, it is necessary to increase the amount of *resources* allocated to chemicals management - in industry, in the central entity outlined in the White Paper, and in the authorities of the EEA Member States.

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