EUROPEAN FREE TRADE ASSOCIATION
ASSOCIATION EUROPEENNE DE LIBRE-ECHANGE

Brussels, 26 April 2005
Ref. No.: 1054044

SUBCOMMITTEE I ON THE FREE MOVEMENT OF GOODS

EEA EFTA COMMENTS ON THE PROPOSAL FOR A REGULATION CONCERNING THE REGISTRATION, EVALUATION, AUTHORISATION AND RESTRICTION OF CHEMICALS (REACH), COM(2003) 644

FIVE POSSIBLE IMPROVEMENTS

GENERAL VIEW:

Within the framework of the European Economic Area (EEA), the EEA EFTA States have practically the same chemical legislation as the EU. Norway fully participates in the current expert groups in the chemicals area, and has taken its share of the workload. The EEA EFTA States stress the importance of direct involvement of the EEA EFTA States in the work of the new European Chemicals Agency, in accordance with the principles of the EEA Agreement. The proposed REACH legislation has provisions that are designed to accommodate co-operation with EEA EFTA States, and it is important that this is followed up in practice.

The EEA EFTA States support the need for a common regulatory system comprising "new" and "existing" chemicals including registration, evaluation and authorisation[1]. The new system (REACH) will give the chemicals industry a greater *burden of proof* to document the safety of chemicals and to demonstrate that they are used in a safe manner. A basic premise for improved chemicals management is the provision of basic information on chemical substances, and the REACH proposal addresses this challenge.

REACH will improve the protection of human health and the environment from the risks of chemicals. These benefits, mainly for consumers, workers, authorities and the environment, in all probability outweigh the costs.

[1] Norway supplied detailed views in the public Internet REACH consultation. These can be found on: http://europa.eu.int/comm/enterprise/reach/docs/consultation/public/public_gvnt_norway.pdf

However, in the light of limited resources, it is important to ensure that the system is tailored to address substances for which the greatest environmental and health benefits can be achieved. In this respect, the proposal can be improved, *increasing* the level of protection for health and environment and, *at the same time,* making the legislation simpler, more cost-effective, more workable and less bureaucratic. The EEA EFTA States believe that significant improvement can be achieved through the five specific changes described below.

I. INCREASED PRIORITISATION OF EFFORTS

REACH proposes a phase-in of existing substances according to tonnage and CMR characteristics only. This approach will not sufficiently focus efforts on the substances of high concern. The EEA EFTA States supports a more risk-based approach towards phasing in existing substances on the market, where the efforts are prioritised towards substances of the highest concern:

1. Current methods for identifying expected risks, including hazard screening methods (QSAR) and risk assessment models (ECETOC, EURAM), allow a sufficient possibility of a clear prioritization of substances for the registration of existing substances according to expected risk.

2. The substances of highest concern should in all cases be prioritised for early phase-in. These include identified PBT/vPvB[2] substances, CMR[3] substances or other substances of equal concern[4]. In addition, other substances that are classified as "dangerous for the environment"[5] should be registered at an early stage. This latter requirement could be based on the classification in Annex I, or industry's classifications.

3. For the 20.000 chemical substances that are circulated in smaller volumes[6], the proposed requirements do not provide sufficient basis for the industry to take responsibility for the safety of their products. As long as the efforts are prioritised towards substances of expected high concern through the application of risk assessment models, information on short-term toxicity and biodegradability should also be required for low volume chemicals.

4. Registration could for the time being be postponed for some groups of substances, examples are many naturally occurring substances, substances used purely for R&D and alloys not classified as CMR, sensitizers and/or dangerous for the environment. A more thorough examination of the *exemptions* (Annex II/III) for naturally occurring substances and "derivatives" needs to be made.

---

[2] PBT: Persistent, bioaccumulative and toxic substances/ vPvB: *very* persistent, *very* bioaccumulative substances
[3] CMR: Carcinogenic, mutagenic or toxic to reproduction, cat 1, 2.
[4] e.g. endocrine disruptors, some heavy metals
[5] N, R50-53
[6] 1-10 tonnes

These substances are relatively harmless and represent low risks, and should not overload the system. The exemptions seem to be rather randomly selected and non-exhaustive. Other substances like substances that are formed by simple hydrolysis of naturally occurring products like for example “protein hydrolysates” should be exempted as well.

Increased prioritisation of efforts would allow for stricter deadlines to be set for high priority substances, this being balanced by more flexible deadlines for substances with a low priority, i.e. a delay could be allowed for the registration of these substances. The advantage of such prioritisation is that it does not imply an exemption or de-selection of substances. In time, all substances under the scope of REACH should be registered.

II. PURPOSES AND PRINCIPLES IN THE REGULATION

The main objectives of REACH, such as the protection of human health and the environment, and maintaining and enhancing the competitiveness of the chemicals industry, should be made explicit as the purpose of the REACH regulation in article 1. Ensuring the free circulation of such substances on the internal market will be a result of the legal basis of the Regulation (Art 95 of the EC treaty), and needs not to be stated as a specific purpose.

The REACH regulation should incorporate the concept of *duty of care*, even if this would be difficult to enforce directly. In Norway, a legal *duty of care* provision has been a part of Norwegian legislation for many years, and the experience is positive. Society expects producers to take responsibility for the safety of their products, and this should, of course, also be valid for producers and importers of chemicals. A legal *duty of care* is an important message to producers and importers to take the responsibility of their products, and should at the same time serve as a safety net. This is particularly important when prioritising efforts towards some areas, groups of substances etc, since the basic obligation of knowledge gathering and risk management should be valid for all chemicals and form a basis for industry's self regulation.

III. AUTHORISATION – A TOOL FOR ELIMINATING RELEASES OF THE SUBSTANCES OF HIGHEST CONCERN

It is of particular importance that REACH addresses the challenges from the substances of highest concern for human health and the environment; this will be a real test of the efficiency of the proposal. The authorisation scheme set up for the substances of highest concern must therefore be an effective tool in eliminating the unacceptable risks from releases and exposure of these substances. Where substitutes with less risk are readily available on commercial terms, authorisation should in general not be given. A more effective system can be achieved by setting targets, deadlines etc promoting such a system. In the current proposal this is lacking, neither the Agency nor the Commission have to meet specific deadlines. On the contrary, inclusion of substances under the scheme is legally made dependent on the Agency's capacity to handle them (Art. 55,3).

The current proposal could result in an overly bureaucratic and ineffective system, where the authorities have to elaborate detailed risk assessments in order to justify

possible denials of authorisations. This could have the unintended result that the authorisation scheme does not become an effective instrument of addressing the risks from the substances of highest concern.

IV. LINKS TO OTHER LEGISLATION

REACH will be the main instrument in identifying and managing chemicals risks. However, the REACH legislation must not overlap with legislation covering other purposes. Where such legislation does not sufficiently address the risks from chemicals, changes must be made that adapts this legislation to REACH.

Occupational health
REACH could be a valuable tool for ensuring better health and safety information of chemicals for the work place and has a potential for improving the working environment. We find it important that Chemical Safety Reports (CSR) made by the suppliers will be a complement to and a useful documentation for the employers that will make risk assessments on the work site after Directive 98/24/EC on chemical agents. High quality guidance documents will be necessary in this area.

However, it is unclear to what extent REACH in itself will fulfil the needs related to workers' protection. It is therefore important that the current regulations for chemicals at work be kept unchanged until experience with REACH would reveal possible overlapping of the existing regulatory systems. We emphasize the need to keep article 9 on prohibitions in the Directive 98/24/EC as it is at present. The scope of the obligation to compile and distribute data sheets should by no means be more limited than today. It has to be clarified how the REACH legislation captures occupational health impacts from intermediates.

Waste
The REACH legislation needs clarification with regard to recycled waste, as recycled substances should not need to be registered a second time unless a new, different substance is created through the process.

V. CLASSIFICATION AND LABELLING

Classification and labelling are important information instruments. It is well documented that classification and labelling of a substance with severe health and environmental hazards, effectively reduces the production and use of such substances. The classification contributes to important down-stream effects in other regulations such as the directive on hazardous waste, etc.

All chemical substances must therefore continue to be classified and labelled. Industry must have the main responsibility. However, harmonised classification and labelling will be of great value, and should cover the most serious hazard characteristics. Serious hazards such as "dangerous for the environment" and skin sensitisers should therefore be included in the system for harmonised classification together with CMRs and respiratory sensitisers.