

Background paper: Commentary on the EU Commission's White Paper on Chemicals Policy

On 13 February 2001, the European Commission presented a strategy on a future Community Policy for Chemicals. This so-called White Paper on Chemicals Policy is currently being introduced in EU councils of ministers and at various stakeholder forums for discussion with industry, environmental associations and other involved parties. Such a meeting is taking place in Germany on 15 March 2001 in Frankfurt/Main upon invitation of the Federal Environment Ministry. It will then proceed to the EU's political process. Further information on the White Paper is available on the Internet at: <http://www.europa.eu.int/comm/environment/chemicals/whitepaper/htm>.

We are surrounded by chemical substances in virtually all reaches of our lives. In order to protect mankind and the environment from the potentially hazardous impacts of these substances, an assessment of the risk of these chemicals takes place and is then reduced if necessary. This is the goal of preventive environmental and health policy.

Testing, evaluation, and classification of chemical substances has largely been harmonized within the EU. A difference is made between new substances and so-called existing substances, which are substances that entered the European common market before 18 September 1981. Over 100,000 existing substances make up 99% of the substances currently on the market.

If new substances are to be introduced to the market, they must be registered by industry with the appropriate authorities. Registration of new substances in Germany has been regulated and is mandatory upwards of a yearly production amount in excess of ten kilograms. Based on the information submitted with the registration application, chemical substances are assessed by various authorities for their potential risks for mankind and the environment. The Federal Environmental Agency assesses the environmental hazard of substances.

The White Paper submitted by the EU Commission is the provisional result of political and expert discussions within the EU Commission on a new strategy for chemicals policy. Its goals are to provide more protection to mankind and the environment from the potential risks of chemical substances, to shed more light on the complex evaluation process, to make the evaluation of new and existing substances uniform, to place more responsibility on the chemicals industry, and to guarantee a more expedient and efficient evaluation of existing substances. This latter area especially reveals serious gaps in data, backlogs in evaluation, and management deficits. Compared to new substances, the test requirements for existing substances are extremely minimal, and only a very low proportion have been tested to date. The risk assessment process is slow and resource-intensive.

The following pages are a compilation of some commentary by the Federal Environmental Agency on the EU White Paper on Chemicals Policy.

1. General assessment

The strategy presented by the EU Commission is a remarkable and long overdue step towards future-oriented and conclusive risk management of all industrial chemicals. Chemicals management to date is in dire need of reform. The new approach for assessing chemicals is the so-called REACH system—**Registration, Evaluation, Authorization of Chemicals**. This procedure stipulates that, in future, industry must submit data and provisional assessments on all substances with an annual production/import volume of 1-100 tons in the registration procedure. A distinction between existing and new substances will no longer be made. Spot checks only will be carried out to verify this. For substances exceeding a production volume of 100 tons, submission of additional data and provisional assessments to authorities is mandatory. Substances with particularly hazardous properties, especially if they are carcinogenic, mutagenic or toxic to reproduction, will only be authorized for limited exceptional uses.

The REACH system opens up a realistic perspective for eliminating the considerable data gaps, backlogs in evaluation, and management deficits in existing substances. In general, it is positive that the distinction made between existing and new substances in assessment and registration is to be discontinued. After all, the new strategy is more flexible than the previous procedure, and it increases the responsibility of industry in preventive chemicals policy.

However, some questions remain unanswered and some areas are rife for improvement as concerns achieving the goal of providing more protection of mankind and the environment from the potential risks of chemical substances. As an example, the progress made in the assessment of existing substances may not be compromised by retrograde steps in the assessment of new substances, namely by setting higher threshold production volumes that would require submission of data for evaluation. The continued discussion process must formulate what exactly the responsibility of industry is. From an environmental protection perspective, it would be erroneous to exclude or insufficiently consider certain substance characteristics in the evaluation process.

2. Comments on individual key elements

At long last an authorization system for particularly hazardous substances

The introduction of an authorization system for particularly hazardous substances has been the Federal Environmental Agency's long-standing recommendation for effective and efficient chemicals management. The introduction of this fundamentally new instrument for industrial chemicals as the "authorization" phase of the REACH system represents a considerable step forward, since the authorization procedure will now be bound to a deadline and a reversal of the responsibility of proof from authorities to industry. This means that manufacturers must prove the harmlessness of their substances for specific uses, and only then will substances be authorized. All other uses of substances in the "authorization" phase are thereby inadmissible a priori. This key element of the chemicals strategy for

the future promotes the conscious responsibility and active involvement of the chemical industry, such as its self-designated motto of "Responsible Care" proclaims on its flags.

No exclusion of persistence and bioaccumulation as particularly hazardous substance characteristics

A portion of particularly hazardous substances are called PBTs (persistent, bioaccumulative, toxic). These are substances that are long-lived (persistent) in the environment and which can accumulate in the fatty tissue of an organism (bioaccumulative). These substances hazardous to the environment have been exempted from the authorization procedure presented by the EU Commission in the White Paper. This means that they are not automatically subject to an authorization procedure. This is incomprehensible in view of the fact that only relatively few substances are concerned. The Commission itself estimates 150 PBT and vPvB (very persistent, very bioaccumulative) substances in addition to some 1350 CMR substances (carcinogenic, mutagenic, reprotoxic) which are subject to the authorization procedure anyway.

The White Paper's proposed alternative procedure ("Substances subject to further research") could lead to further scientifically unjustified delays in risk management of these substances. Experience has justified this concern. The identification of persistence and bioaccumulation as criteria is already very progressive. The continued discussion process should aim to subject the uses of these particularly environmentally hazardous substances to a registration procedure. Should this not be achieved, then at the very least all persistent and bioaccumulative substances must immediately undergo a so-called prioritization procedure. The results of this test must then lead to classification as a "potential PBT or vPvB substance", and a testing plan for the speedy clarification and reduction of environmental risk must be determined.

The effectiveness of the REACH concept depends on filter criteria taking shape

The assessment system for particularly hazardous substances is of critical significance. In practical terms, it must be decided which criteria will determine the selection of "suspicious" substances in the registration phase, and further selection in the evaluation phase, before a substance is considered for the authorization phase. These problems are of varying significance for existing and new substances.

With regard to existing substances, the shaping of the system must ensure that the submission of required information does not unduly delay decision making. In the previous system, delayed submission of data from the chemicals industry has repeatedly hindered conclusive evaluation and the implementation of risk reduction measures. It would be fatal if this system error were to establish itself in the evaluation phase of the REACH system.

With regard to new substances, it is unclear which data would be available as the basis of investigations into suspicious substances. Especially in cases of small production volumes, it is worrisome that neither

sufficient scientific knowledge nor comprehensive data records would be available to adequately prove cases of suspicious substances. Therefore in practice, it is imperative that a scientifically sound balance be found between foregoing supposedly superfluous data and additional requests for allegedly necessary data. Intelligent strategies are still urgently needed for selecting critical substances reliably and efficiently from among this large number of substances, given the minimum amount of available information and data, so that for the sake of precaution, they can be excluded as the potential cause of future problems.

Elimination of information gaps about existing substances as a sound foundation for future action

Shoring up the lack of data on existing substances is one of the keys to better protection of mankind and the environment. The Federal Environmental Agency therefore welcomes the responsibility placed on industry to begin submission of a logical prioritization of conclusive data on some 30,000 existing substances with a production volume of more than one ton per annum, in keeping with an ambitious deadline of the year 2012. This information will enable the REACH system to undertake further decisive steps towards efficient assessment of risk more simply and speedily than was previously possible.

For substances with a marketed volume of more than ten tons per annum, the basic data records now required will allow for profound prioritization according to uniform criteria. This will enable identification and selection of particularly relevant substances for further investigation. Should there be any indication of especially hazardous properties or uses, the evaluating institutions could demand additional data on the effect and exposure of the substances and thus quickly come to a founded assessment of any associated risks. This is particularly relevant for the identification of the aforementioned PBT substances. Substances or substance uses which should be subject to further risk assessment or an authorization procedure can also be determined. Finally, substances can be classified meaningfully into substance groups.

No compromise of improvements for existing substances by shortcomings in the area of new substances

The Federal Environmental Agency sees it as problematic that the price to be paid for significant improvements in the assessment of existing substances is the near elimination of the current overall successful and functional registration system for new substances. The reason for this is that most of the new substances do not yet reach the relevant threshold volumes defined in the REACH system. This means that almost 80% of the some 3,000 known new substances do not exceed the 10-ton threshold volume of the REACH system above which a complete basic data record would have to be submitted. However, a differentiation between new and existing substances must be made here.

In the name of the precautionary principle, it is hardly justifiable that according to the new assessment system many new substances in future will be tested only a little and could be applied unhindered in

areas affecting consumers and the environment, as the example of registration in Germany shows. Of 420 substance registrations with a marketing volume of one to ten tons, almost 60% were classified as harmful to the environment, and for about one third their risk assessment was grounds for concern.

One of the chemical industry's arguments favoring the *de facto* dissolution of the existing system for new substances is that it would relieve the load placed on evaluating institutions. However, in comparison to the need for resources which will ensue from introducing existing substances into the REACH system, this argument loses weight. The costs of an initial environmental risk assessment with the aid of the tests currently required, which are criticized by the chemical industry, are also comparatively low. The danger of seriously hindering innovation in the chemical industry seems limited in the framework of a more flexible system.

Strengthening the role of the European Chemicals Bureau (ECB) is welcome

The Federal Environmental Agency particularly welcomes the foreseen strengthening of the European Chemicals Bureau (ECB), which has so far been responsible, among other things, for creating the organizational framework for the assessment of existing and new substances as well as for the institution of on-site task forces comprised of members of the Union. In this way knowledge and strength are combined to produce a coordinated efficient procedure. Such expert groups could also undertake substance classification on the basis of basic data records and issue new temporary labels such as "incomplete testing of substance" or "hints of persistence/bioaccumulation".

Firming up industry's burden of proof

The Federal Environmental Agency supports an increase of the industry's burden of proof in chemicals management. It is essential for clear and efficient risk assessment that all relevant information and data, including lack of data, be made known by the manufacturer. This requires not only chemical and physical data, but especially conclusive and reliable data on exposure as according to the guidelines of the corresponding OECD questionnaire. This is a list of information that is indispensable for reliable estimation of exposure. It would avoid the envisioned tailor-made testing plans generating superfluous data and animal testing. Unfortunately, experience in the area of evaluation has often shown that the industry's autonomously conducted evaluations have so far seldom met the demands of providing conclusive proof. There is usually a lack of sufficient exposure data, especially for the users of chemical substances, so-called "downstream users". The focus of independent preliminary work by manufacturers ought especially to be to provide and clearly present all necessary data. The White Paper still lacks measures to indicate that the delayed submission of data bears serious consequences.

Involving downstream users is positive

The Federal Environmental Agency particularly welcomes the fact that downstream users are to be involved in chemicals management. They will be obliged to submit data and initial assessments for those substance uses that were not considered in the manufacturer's risk assessment or that of the parties

who entered the substance onto the market. Lack of knowledge about the patterns of use for these substances and their associated exposure have complicated and delayed sound risk assessment up to now. Further development of chemicals policy should focus on a fair division of the duties and responsibilities between manufacturers and users of the substances.

Concern about the treatment of endocrine-active substances

In light of the intensive debate in recent years and the corresponding resolution passed by the European Parliament, the Federal Environmental Agency believes the White Paper's treatment of endocrine-active (hormonal) substances is insufficient.