**Bundesärztekammer**
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# Resolution of the German Medical Association on the Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH)

[Status: 12 June 2005]

The Commission of the European Union has submitted a draft of a Regulation concerning the Registration, Evaluation and Authorisation of Chemicals (REACH). The objective pursued is to in future register all chemicals produced in the European Union or imported into the internal market in a central database. This also includes the systematic recording of existing substances, i.e. substances which were launched on the market before 1982 and for which registration and risk evaluation were not required to date. Registration of the chemicals, and evaluation of the risk to health and the environment potentially emanating from them, are to take place in a multi-stage procedure that is primarily geared to the annual production volume. The Regulation is intended to shift the obligation to evaluate hazards from the authorities to the manufacturer or importer. The authorities retain the right of review, as well as the right to formulate obligations and impose restrictions on the use of the substance to be registered.

The German Medical Association welcomes the intention of the European Union (EU) to put its chemical policy on a new footing with REACH and, in particular, to assign a key role to protection of the environment and human health. The German Medical Association is of the opinion that, from the point of view of health protection, it is no longer acceptable that the more than 100,000 existing substances put into circulation before 1982 are not sufficiently evaluated and regulated as regards the risk emanating from them. It thus considers the equal treatment of existing and new substances, proposed in the framework of REACH, to be overdue.

The EU formulated principles for a new European chemical policy in its "White Paper on a Strategy for a Future Chemical Policy" in 2001. On essential points, however, the current draft Regulation falls far short of these principles in relation both to health and consumer protection and to environmental protection. In the opinion of the German Medical Association,

the following points need to be corrected or supplemented with a view to preventive health protection:

1. The current draft dispenses with the registration of chemical substances with an annual production volume of less than 1 t. Moreover, substances with a production volume of less than 10 t/a are only insufficiently tested, even if there is contact with consumers. Thus, the draft Regulation contains no mechanism for ensuring that substances produced in small quantities and involving high risks are detected and their fields of use controlled. The German Medical Association therefore demands that data-based risk evaluations also be performed, and fields of application defined, for substances with a low annual production or import volume, if it must be assumed that they can constitute a potential threat to man or the environment.

2. It is acknowledged that, in the latest version of the draft, Chemical Safety Reports (CSR) are already necessary upwards of a production volume of > 1 t/a, if a classification exists. At the same time, however, the associated requirements have been substantially reduced, particularly as regards toxicological safety. In the opinion of the German Medical Association, however, adequate toxicological studies must be ensured for all production volumes, and checks carried out by the authorities at a reliable sampling rate of 10 to 20%.

3. The criteria are unclear according to which the substances requiring authorisation are selected. The history of medicine shows that long latency periods and human-specific effects can lead to CMR properties only becoming apparent after the substance has been in use for a long time (e.g. asbestos, thalidomide). Consequently, for chemical substances to which humans are exposed, test methods must be prescribed which ensure that REACH will in future make it possible to detect harmful effects of this kind at an early stage and independently of the production volume.

4. The current draft must be criticised for the fact that it disregards potential cumulative effects of substances in the ultimate consumer, the combined effect of different substances and the effect of decomposition products, as well as products from which chemicals are released unintentionally, although these can likewise lead to severe damage to human health and the environment.

5. In the opinion of the German Medical Association, a monitoring procedure should be implemented in parallel with REACH, on the basis of which the effects of sub-

stances on man and the environment can be specifically detected after substances have been put into circulation.

6. The instrument of registration imposes on the manufacturer or importer the responsibility for the environmental and health-related compatibility of his products upwards of a production volume of 1 t/a (per producer). It must therefore be ensured that the volumes produced or imported are not split up among different manufacturers / importers, thus circumventing obligatory registration and risk evaluation.

7. REACH must create clear regulations that protect the user or consumer against harmful exposure to substances released from imported products and goods. Imported products and goods must be subject to the same safety standards as substances produced in the EU.

8. Regarding substances subject to authorisation, incentives taking effect in the short term must be created to encourage their substitution by less toxic substances.

9. Up to now, the REACH system is only intended to cover basic chemicals. In the opinion of the German Medical Association, however, many health risks for consumers emanate from finished products that so far do not require registration and authorisation under REACH. Therefore, REACH should particularly be extended to also cover products that are of great importance for the health of consumers in terms of exposure, such as textiles and leather goods, paints and coatings, plastic products, toys.

10. Much of the information submitted for registration or authorisation is not accessible to the consumer. The German Medical Association therefore calls for a simple, easily understandable labelling system for indicating the ingredients of consumer products.

11. Insufficient clarification is provided regarding the changes and deletions that will result from REACH in previously applicable, competing regulations on consumer protection and occupational health and safety (e.g. additives, ordinance on maximum permissible quantities of contaminants in foodstuffs). It must be ensured that the planned Regulation does not weaken regulations relating to consumer and health protection.

12. A general "duty of care" of the manufacturer for his products, i.e. liability for damage possibly only occurring after a lengthy latency period, is no longer provided for in the latest draft. This is criticised by the German Medical Association.

13. In the opinion of the German Medical Association, one important prerequisite for effectiveness of the causation principle in the event of damage possibly occurring is that at least the manufacturer be registered, together with the CAS No., for all substances, regardless of their production volume.