# The New EU Chemicals Policy – Discussions on Details Relevant for Animal Welfare

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Summary
*The European Commission is planning to put forward drafts for a new chemicals legislation by June 2002. In fulfillment of an Environmental Council Conclusion, Working Groups have been set up for consultation during the ongoing preparatory stage. There, members of the General Directorates Environment and Enterprise discuss relevant topics with representatives from authorities, industry, environmental and animal protection organisations. There is agreement that animal tests shall be reduced to a minimum. However it is still unclear how this goal can best be achieved. In this context, the designing of testing strategies will play a major role. It is explained, why fixed test catalogues should be replaced by flexible tiered testing strategies and how concrete waiving strategies can contribute to avoiding animal tests. Another important aspect is the EU-wide implementation of a clause on the avoidance of duplicate testing, which is already enforced in Germany and Austria. In these Member States, first parties have to provide data from previously performed animal tests to second parties. Finally, it is discussed that the application of new non-animal tests can be promoted, if the revised EU chemicals policy once again contains the legal framework for an EU-specific acceptance of new test methods.*

Zusammenfassung: Die neue EU-Chemikalienpolitik – Diskussionen über tierschutzrelevante Details
*Die Europäische Kommission hat angekündigt, bis zum Sommer 2002 die Entwürfe für eine neue Chemikaliengesetzgebung vorzulegen. In der derzeitigen Vorbereitungsphase hat sie in Erfüllung einer Ratsschlussfolgerung des Umweltministerrates vom Juni 2001 Arbeitsgruppen eingerichtet, in denen Mitarbeiter der Generaldirektionen Umwelt und Wirtschaft mit Behördenvertretern und Interessensvertretern von Industrie, Umwelt- und Tierschutzorganisationen wesentliche Sachverhalte diskutieren. Einigkeit herrscht darüber, dass Tierversuche auf ein Mindestmaß reduziert werden sollen. Diskutiert wird noch, wie dieses Ziel am Besten erreicht werden kann. Hierbei spielt die Frage nach der Ausgestaltung der Prüfstrategien eine wichtige Rolle. Es wird dargelegt, aus welchem Grunde feste Testkataloge durch flexible, stufenweise aufgebaute Prüfstrategien ersetzt werden sollten, sowie welchen Beitrag konkrete Verzichtstrategien zur Vermeidung von Tierversuchen leisten können. Ein weiterer wichtiger Aspekt ist die EU-weite Verankerung einer sogenannten Zwangsverwertungsklausel, wie sie bereits in Deutschland und in Österreich umgesetzt wurde. In diesen Ländern werden Erstanmelder verpflichtet, gegen eine Gebühr Daten aus bereits durchgeführten Tierversuchen Zweitanmeldern zur Verfügung zu stellen. Abschließend wird dargelegt, dass die Anwendung neuer tierversuchsfreier Verfahren dadurch beschleunigt wird, wenn in der überarbeiteten EU-Chemikaliengesetzgebung wie bisher die gesetzlichen Rahmenbedingungen für eine EU-spezifische offizielle Anerkennung neuer Verfahren verankert werden.*

*Keywords: chemicals policy, non animal test methods, testing regimes, waiving strategies, avoidance of duplication of testing, OECD acceptance*

## 1 Introduction

The stakes are set and they are high. The new EU chemicals policy is intended to be better in every aspect. Its key elements are laid down in the White Paper Strategy for a Future Chemicals Policy (Commission of the European Communities (2001). They are to ensure a sound protection of humans and the environment, to take into account economic issues and to keep animal experiments to a minimum. From the point of view of animal welfare, this results in a demand for a tiered step-wise non-animal testing strategy. The way forward to fulfill this request has previously been discussed (see ALTEX 4/2000, pp. 250-251 and 4/2001, pp. 281-284).

Conclusion No 37 of the meeting of the Council of Environmental Ministers from June 2001, during which the future EU Chemicals Policy was discussed, calls upon the European Commission "*to set up a task force as soon as possible with representatives from Member States, working in consultation with industry, NGOs and other stakeholders concerned in the transitional period until the new legislation has come into force, to explore ways in which chemicals of concern can be identified to allow prioritisation for taking action, developing clear and transparent screening criteria, essential information requirements, and exploring the use of chemical grouping and modeling*

*techniques"*, (Environment Council, 2001). In fulfillment of this request, the Commission set up Working Groups[1], in which to discuss relevant issues surrounding the new chemicals policy.

The setting up of new legal instruments for the revised EU Chemicals Policy is a co-decision procedure. The European Commission will take into account the European Parliament resolution on the Commission White Paper (European Parliament, 2001) and the relevant Council Conclusions when drafting the new pieces of legislation. In addition, it will make use of the documents compiled by the Working Groups as an outcome of their discussions. It is expected that initial drafts for the new chemicals legislation will be put forward by the middle of the year 2002.

The new EU chemicals policy is a great challenge presenting the unique chance to strive for a better hazard assessment as well as an improved risk assessment and management of chemical substances. However, in order to ensure that the new policy will function properly, many factors have to be considered. In the following, some details relevant from the point of view of animal welfare will be discussed.

## 2 Laying open existing information – avoidance of duplication of testing

In chapter 2.1 of the White Paper it is explained that *"existing substances amount to more than 99 % of the total volume of all substances on the market"* and that *"there is a general lack of knowledge about the properties and the uses of existing substances."* To overcome this knowledge gap, chapter 4 of the White Paper calls for the establishment of a single coherent system of chemicals control. All chemicals produced will have to undergo the process of registration. Taking into regard their production volume and level of concern, they might also be subject to evaluation and authorisation[2]. This means that the vast majority of substances that will be submitted to the new system in the coming years will be substances that already have been on the market for many years.

In the White Paper it is also acknowledged that the lack of information on these existing chemicals might really be a lack of publicly available knowledge. Action 3A of the White Paper recommends that: *"The available information should be thoroughly examined and best use made of it in order to waive testing, wherever appropriate."* Additionally, Action 5F of the White Paper requests that: *"Specific provisions should be included in the legislation that duplicate tests involving vertebrate animals should be avoided. Any duplicate testing will not result in an exemption from the duty to reimburse the party who owns the property rights for the first test."*

It is unlikely that industry should have no information on the hazardous properties of the substances they have been using for many years. Therefore the implementation of the discouragement of duplicate testing in the new EU chemicals legislation is of utmost importance to ensure that all existing information has been made use of when the former existing substances – that oftentimes are being used by different companies simultaneously - are submitted to the new system. However, it will also remain important after all of these substances will have undergone the REACH system. In any case, the ultimate goal for the animal welfare movement is to strive for an abandonment of all animal testing. However, also then should the avoidance of duplicate testing continue to be encouraged and if only for economic reasons.

Currently, the avoidance of duplicate testing is not mandatory on EU level. Only two EU member states, Austria and Germany, have enforced such a clause in their respective national legislations. For example, Article 20a of the German Chemicals Act (Anon., 2001) states that a company has to ask the notifying authority whether a test with vertebrate animals is inevitable before it performs any animal tests for the preparation of a notification. Data from previous animal tests have to be used. The property rights of the party who performed the test in the first place are ensured by the legal duty of the second party to reimburse the first party. In addition, the second party has to withhold the notification of the chemical for the period it would have taken to perform the animal test in question.

Such a legally based discouragement of duplication of testing will prevent even more animal tests when implemented on an international level. The respective article in the revised EU chemicals legislation should be sufficiently detailed to ensure an effective avoidance of duplicate testing. Before the performance of any animal testing for a given purpose is considered, industry should be requested to ask the registration authority whether data for the registration of the substance under consideration already exist. In case an approval system for animal experiments is in force in the respective Member State, industry should be requested to forward a written confirmation to the responsible animal testing approval authority that data on the respective substance to not yet exist.

The European registration authorities must run a joint database on animal tests, which should also cover ongoing animal tests to avoid accidental duplication of ongoing testing. At best, this database would also encompass tests performed during research and development. However, since this is a phase that is likely to be exempted from the full REACH system, this latter demand might not

[1] Members of the Working Groups were stakeholders from industry as well as from animal welfare and environmental protection organisations and representatives of authorities. Different Working Groups were assigned with different tasks covering topics, such as the testing, registration and evaluation of chemicals, risk assessment and risk management, the question of how to deal with substances of high concern or the classification and labeling of chemicals. It was mainly the Working Group Testing, Registration and Evaluation that dealt with issues relevant for animal welfare. The Working Groups met twice in fall and winter 2001/2002 and were chaired both by representatives of the General Directorates Environment and Enterprise of the European Commission. As an outcome of the work of these groups, documents were compiled presenting the different opinions of the experts involved in the discussions.

[2] The new system is called REACH system, which stands for Registration, Evaluation and Authorisation of CHemicals.

seem feasible. Thus – in order to prevent duplicate toxicity testing from taking place during research and development, legal ways should be found to discourage the performance of *in vivo* toxicity tests during that phase.

## 3 How should the testing strategy be designed? – "top down" versus "bottom up"

In the White Paper it is said that the data requirements are to be kept flexible to ensure that (providing there is no existing information) only those tests are performed for a specific substance that are actually necessary for its evaluation. However while this request goes undisputed, controversial opinions have been put forward on how best to implement it.

Many representatives from national authorities favor the "top down concept". This concept calls for a fixed test catalogue laid down for each production volume category. If a company submitting a registration dossier believes that it does not have to perform one of the tests of the list, it must justify this decision, and this justification will be subject to acceptance by the authorities. The company must either prove that the data requested is already provided through other data or that it is not necessary to provide the respective data at all, either for scientific or technical reasons or because the expected exposure scenario renders the data irrelevant.

The animal welfare movement, on the other hand, is in favor of implementing a "bottom up concept" in the new chemicals legislation. Already before the publication of the White Paper, Eurogroup for Animal Welfare had been calling for a flexible step-wise tiered testing strategy, in which the data collected would be evaluated after each step of the testing and decisions on remaining data requirements would be made upon the results of the steps previously performed (Wilkins, et al., 2000). Representatives from industry are also in favor of a "bottom up concept".

Those favoring the "top down concept" argue that this would be the only way to ensure that incomplete data sets are no longer submitted for registration. Those favoring the "bottom up concept" argue that this strategy puts more emphasis on the specific data requirements tailored to a specific substance and thus encourages the avoidance of unnecessary tests by ensuring that the data collected is evaluated scientifically already during the data gathering process. Taking into account the fact that the White Paper aims at placing the responsibility for the safety of a chemical on the industry, it would seem appropriate to assign industrial toxicologists with the task to decide on the data requirements necessary for a specific registration. In order to make the decision strategies transparent, the company should be obliged to provide justification of its decisions upon registration. However care should be taken that such a request for justification does not become an unsurpassable hurdle that would prevent the waiving of tests.

There are two prerequisites for the success of flexible testing strategies. First, it is of paramount importance that those responsible for the registration of chemicals both on the side of the industry and on the side of the authorities are adequately trained toxicologists. In addition, the waiving of tests should be fostered by the setting-up and implementation of concrete waiving strategies.

## 4 Waiving strategies: How to decide not to test

Already now, a few concrete waiving strategies have been set up for specific purposes with the aim of avoiding unnecessary testing, and some of these have reached the level of OECD a cceptance. For example, in OECD, 2001, it is laid down that *"possible skin corrosion has to be evaluated prior to consideration of eye irritation/corrosion in order to avoid testing for local effects on eyes with skin corrosive substances"*.

Detailed waiving strategies for all relevant endpoints should be laid down along these lines, also taking into account different data requirements for different classes of chemicals and different exposure scenarios. When deciding which data to collect for the registration of a specific chemical, the aim of the data gathering should always be kept in mind. In the end, all collection of data serves to classify a chemical substance according to its expected hazard; necessary restrictions in the use of the substance are laid down according to the respective classification. The restrictions implemented for the so-called CMR substances, chemicals that are carcinogenic, mutagenic or toxic for reproduction, are especially strict.

In the following, a concept is proposed on how to classify CMR substances while avoiding animal testing. First, the substance should be tested *in vitro* in a point mutation and a cytogenetics assay. If the substance is negative in both of these tests, it should be tested in a further *in vitro* assay, which should include aneuploidy as an endpoint. In order to find those substances that only become mutagenic after metabolic activation, it is important to add a relevant metabolically active component to the test system (see also ECVAM, 2002). In order to avoid animal testing, *in vivo* mutagenicity tests should not be performed. Instead, substances should be classified as mutagenic, if they test positive in a relevant in vitro mutagenicity test. Furthermore, mutagenic substances should be considered to be carcinogenic without further testing, since genotoxicity is a starting point for the development of cancer. Only if a substance is not found to be genotoxic, should carcinogenicity testing be considered (and suitable *in vitro* tests should be developed and validated for this purpose). Reproduction toxicity tests should not be performed, if a substance has been found to be genotoxic or carcinogenic. The outcome of the testing of that endpoint would be irrelevant for the classification of the substance, which has already been classified as CMR.

Waiving should be possible, whenever exposure scenarios make the evaluation of a specific endpoint irrelevant. However waiving should also be possible if the decision sought for can be made without the respective test, either by making use of other information sources or by showing that the respective endpoint is irrelevant for the respective substance.

## 5 Which test methods should be used in the testing strategy? – OECD versus EU test acceptance

Another question under discussion is the level of acceptance that test methods should have obtained in order to be considered adequate for the testing of chemicals. Currently in the EU, only the standardised testing methods listed in Annex V of Directive 67/548 on the Classification, Packaging and Labeling of Dangerous Substances may be used to determine the hazardous properties of chemicals. This restriction also applies for the evaluation of other substances, such as pesticides, cosmetics and biocides, which are covered by other pieces of EU legislation. In the face of the current trend towards increasing globalisation, it has been questioned whether a tool such as Annex V of Directive 67/548 will still be necessary and appropriate in the new EU chemicals legislation. It has been suggested that only tests already accepted on the level of the Organization for Economic Co-operation and Development (OECD) should be considered for inclusion into the future testing strategy. The following example serves to show why this second option would be very deplorable.

In 2000, the EU officially accepted an *in vitro* phototoxicity test and two *in vitro* skin corrosivity tests and included these test methods in Annex V of Directive 67/548. Thus, these non-animal test methods could be used (and had to be used) for hazard testing of chemicals, pesticides, biocides and cosmetics in the EU, even though they had not even been considered for acceptance as OECD test guidelines. In the following, the EU acceptance of these validated *in vitro* tests did not lead to international legal problems. Instead, it has put pressure on the international community also to accept these tests as OECD test guidelines. This example shows two benefits of a legal tool such as the current Annex V: Firstly, since OECD decisions are based upon unanimity, to rely solely on OECD acceptance of test methods could mean that a non EU member state could prevent the EU from making a decision favored by the EU member states. Secondly, a legal means such as the current Annex V of Directive 67/548 is a possibility to speed up the international decision process and to encourage international acceptance of new tests.

## References


Anon, (2001). *Gesetz zum Schutz vor gefährlichen Stoffen (Chemikaliengesetz - ChemG)* in der Fassung, die sich aus Artikel 1 des Gesetzes zur Umsetzung der Richtlinie 98/8 des Europäischen Parlamentes und des Rates vom 16. Februar 1998 über das Inverkehrbringen von Biozid-Produkten (Biozidgesetz) (Fassung des Regierungsentwurfs) ergibt.

Commission of the European Communities (2001). *White Paper – Strategy for a future Chemicals Policy.* COM(2001) 88final. February 27, 2001.

ECVAM (2002). The ECVAM initiative on alternative methods for chemicals testing. A draft report prepared by ECVAM and the ECVAM working group on chemicals. *15 January 2002 pre-publication draft, intended for publication in ATLA.*

Environment Council (2001). *Report on 2355th Session of the Council "Environment"*, Luxembourg, 7 June 2001.

European Parliament (2001). *European Parliament resolution on the Commission White Paper on Strategy for a future Chemicals Policy.* Text adopted at the sitting of Thursday 15 November 2001. A5-0356/2001.

OECD (Organization for Economic Co-operation and Development) (2001). *Harmonized integrated classification system for human health and environmental hazards of chemical substances and mixtures.* OECD Series on Testing and Assessment, Number 33. August 14, 2001.

Wilkins, D., Phillips, B., Sauer, U. (2000). *Eurogroup for Animal Welfare's Position on the New EU Chemicals Policy.* Eurogroup for Animal Welfare, Brussels.



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