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**Methodology of Biotic and Abiotic
Testing in 6th Amendment**

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METHODOLOGY OF BIOTIC AND ABIOTIC

TESTING IN 6TH AMENDMENT

(Documents EM-41,ter and WP-AD/1)

APPROVED PAPER ON
BIODEGRADATION METHODOLOGY IN THE 6TH AMENDMENT

1. RATIONALE

It is normally accepted that the most important process leading to the disappearance of organic compounds from the environment is biodegradation. The 6th Amendment requires that initial data on biodegradation be supplied in the Base Set, and that further data be provided, if appropriate and necessary, at the different stages of Annex VIII.

The OECD Expert Group on Degradation/Accumulation has described a well-developed scheme that proceeds in 3 stages from relatively simple tests of Ready Biodegradability through determination of Inherent Biodegradability, to more complex Simulation Tests. The rationale behind this system is based on a desire to steadily increase the scientific understanding of the process of biodegradation of a compound by a series of logical steps which provide the amount of information needed, at minimum cost in time and resources.

The similarity between the 3 stages of the OECD scheme and the 3 levels of the 6th Amendment leads to a strong temptation to regard them as identical. The attraction of this apparently simple solution must not be allowed to conceal the fact that the 3 levels of Annex VII and VIII are based on arbitrary tonnage triggers, which may bear no relation to the scientific criteria envisaged by the OECD Group. If the framework of the OECD scheme is to be used to develop data for notification at the different levels of Annex VII and VIII, a considerable degree of flexibility must be incorporated.

2. METHODOLOGY

2.1. Base Set Level

Any of the 5 Ready Biodegradability Test methods recommended by the OECD may be used to provide the biodegradation data requested from the notifier at this level.

These methods are : Modified OECD Screen Test
MITI Test
Closed Bottle Test
Modified Sturm CO₂ Test
AFNOR 90-302 Test.

The general reproducibility is often poor because of the natural variability in the inoculum. This is a real gap in our knowledge, and further fundamental studies will be necessary to master these problems.

However, for regulatory purposes a finding of ready biodegradability in any one of the above stringent tests should be accepted.

For this low tonnage level, a negative result on Ready Biodegradability would only require more work on biodegradation testing if the material is particularly toxic or has a very high bioaccumulation potential. It must be stressed that a negative result in the above tests does not mean that the chemical is necessarily non-biodegradable in the environment.

Where the structure of a new compound suggests to the notifier, by analogy with other similar compounds, that it is most unlikely to show Ready Biodegradability, he should in appropriate cases be able to report it as such without actually carrying out a test ; this could occur, for example, in the case of a compound of high molecular weight.

2.2. Level 1 Tests

If Ready Biodegradability was established previously, no further biodegradability testing is required at this stage. If a chemical is not Readily Biodegradable, it should be tested as recommended by the OECD, with a suitable Inherent Biodegradability Test procedure, providing more favourable conditions for microbial activity.

Unless there is a special concern about possible adverse effects of intermediates, a positive indication of significant Inherent Biodegradability would generally indicate that there is no need for more biodegradability work at this level.

A negative result of Inherent Biodegradability would generally indicate that biodegradation will play only a minor role in the removal of the chemical from the environment and that further biodegradation testing is likely to be unrewarding.

In this case, other elimination mechanisms may be investigated, but only if predicted concentrations in the environment are likely to approach those that would cause adverse effects.

2.3. Level 2 Tests

At this stage a careful review of the data from the Base Set and the Level 1 tests on Fate, Predicted Environmental Concentration (PEC) and Potential Effects will have allowed a preliminary assessment of the environmental safety margin of the chemical to be made. Only for those chemicals where this safety margin would suggest a reason for concern, will a more precise estimate of the PEC be necessary. For these chemicals, well-selected Simulation Tests will be chosen, with biodegradation or treatment conditions that are relevant to the environmental compartments exposed.

Level 2 tests may also be required independently of Level 1 tests, for example when the chemical loading of effluents is normally reduced by sewage treatment processes.

The report of the OECD Expert Group Degradation/Accumulation gives further details of the information that Simulation Tests should provide at this level.

TF - ECOTOXICITY METHODOLOGY
AND
SCIENTIFIC COMMITTEE

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APPROVED PAPER ON
ABIOTIC DEGRADATION TESTING IN THE 6TH AMENDMENT

A. INTRODUCTION

The 6th Amendment calls for testing of abiotic degradation in the Base Set, and for further testing for degradation (unspecified) at Level 2. A recommended rationale for such testing is given in this document.

1. If the chemical is biodegradable, no assessment of abiotic degradation is necessary.
2. If the chemical is not biodegradable, then its destruction by hydrolysis, oxidation, reduction or photolysis should be considered under certain circumstances, and at the appropriate Level, as described below.

A review of those physico-chemical properties of the chemical listed in the Base Set, and of its production, uses and disposal will indicate into which compartment of the environment it may enter. This will determine which, if any, abiotic degradation tests may be appropriate. Other properties such as dissociation constant in water, complex formation ability in water, adsorption - desorption, etc cannot be regarded as a measure of abiotic degradation.

3. For the small tonnages involved in the Base Set there is no scientific reason why studies of abiotic degradation should be obligatory at this level. At production levels of 1-10 tonnes/year, the accumulation of significant concentrations of the chemical in the environment is highly improbable. However, in some exceptional cases it may be helpful to submit information on abiotic degradation when consideration of the physico-chemical properties, and the results of toxicity or ecotoxicity testing, so indicate.

B. HYDROLYSIS

For the assessment of possible removal of the chemical by hydrolysis, the OECD screening test ("preliminary test", 1 week at 50°C, as in the OECD document A 80/13, of 31.12.79) is sufficient for the Base Set. It should be carried out at pH's relevant to environmental conditions.

C. OXIDATION AND REDUCTION

Degradation in the environment by oxidation or reduction is rarely a truly abiotic process. The notifier may submit evidence of such degradation, based on his own methods, but no generally - applicable test methods exist.

D. PHOTODEGRADATION

If the chemical is degradable by one of the above mechanisms, then no test for photodegradation need be carried out.

The chemistry of photodegradation in air, water and soil is complex, and poorly understood.

- a) Air. There are no simple test methods for assessing photodegradation in air, and this need not be considered for the Base Set.

If the physico-chemical properties, and the results of toxicity or ecotoxicity testing indicate it, an appropriate photodegradation study could be carried out at Level 2. Such measurements are expensive, and can be performed only in certain specialised laboratories.

- b) Water. There is no adequate screening test for assessing photodegradation in water at the Base Set Level.

When the physico-chemical properties, and the results of toxicity or ecotoxicity testing indicate a need, a test for photodegradation in water would be appropriate at Level 2.

- c) Soil. There is no generally-accepted screening test for assessing photodegradation on soil. At Level 2, the notifier may submit evidence of such degradation based on his own test methods, if the physico-chemical properties, and the results of toxicity or ecotoxicity testing indicate a need.