1. At its Fourth session (December 2002), the UN ECOSOC Sub-Committee on the GHS (UNSCEGHS) has requested OECD to provide an overview of current and historical work and efforts in the area of terrestrial hazard assessment as background document for its discussion of the possible need to develop harmonized criteria for the classification of chemicals which are hazardous to the terrestrial environment (see report of the 4th SCEGHS session, ST/SG/AC.10/C.4/5, para. 25). This document provides that information.

* As a basis for the decision if terrestrial effect criteria should be developed for the classification of chemicals as “Hazardous for the Environment”.

Transmitted by the Organization for Economic Co-operation and Development (OECD)
INTRODUCTION

2. In February 1995, the first meeting of the Advisory Group on Harmonisation of Classification and Labelling (AG-HCL), agreed that terrestrial environmental hazard criteria (covering both soil and “above ground” compartments) should be developed for the classification of chemicals hazardous to the terrestrial environment. However, the 1st AG-HCL also agreed that in the absence of any existing terrestrial classification criteria or testing/assessment scheme, testing and assessment methodology should first be developed by the Test Guidelines- and Hazard/Risk Assessment Programmes in OECD, before the AG-HCL could address and develop the terrestrial classification criteria (1).

3. In September 1997, the 5th Meeting of the AG-HCL was informed that the work involved in the development of testing and assessment methods for terrestrial effect hazards was led by the Terrestrial Effects Working Group, a joint co-operation of the Risk Assessment- and Test Guidelines Programmes. However, the work was only progressing very slowly because of fundamental scientific differences among experts with respect to preferred approaches.

4. Scientific discussions at several levels are still going on and remain to be very lively and involving a wide plethora of opinions. In addition to the work at OECD, there are also several national and regional efforts and suggestions how to proceed (in the EU mainly led by Germany, Spain and Sweden). Proposals for possible classification systems for the terrestrial environment have been made by Germany, Nordic countries and Spain). This document provides an overview of past and current international activities and includes options for future work.

BACKGROUND AND HISTORY

5. Since the early 1990s the Hazard Assessment Advisory Body (HAAB) and subsequent Risk Assessment Advisory Body (RAAB) and the Test Guidelines Programme (TGP) have carried out a number of activities related to terrestrial testing and assessment. These activities are summarized below.

Survey of Data Requirements for Pesticide Registration in OECD Member Countries

6. The 1994 Survey of Data Requirements for Pesticide Registration in OECD Member Countries (2) encompassed all data requirements and included terrestrial ecotoxicology. Based upon this survey, the Pesticide Programme developed a list of “OECD data points” for pesticides registration. Two guidance documents were developed: “dossier guidance” for industry who submits data for pesticide registration, and “monograph guidance” for governments who evaluate the submitted information for regulatory decision. These guidance documents provide data submission and assessment formats, which include terrestrial hazard/risk information. For example, the dossier guidance includes a format for reporting the following data points:

- acute, dietary and reproductive toxicity to birds;
- toxicity/exposure ratios (TERs) for terrestrial vertebrates;
- effects on honeybees (acute oral toxicity and acute contact toxicity);
- hazard quotients for honeybees
- effects on other arthropod species;
- effects on earthworms;
- TERs for earthworms; and
- effects on soil micro-organisms.
Priority Setting for the Revision and Development of Test Guidelines Applicable to Pesticides

7. In 1994 the joint TGP/HAAB *ad hoc* Task Force for Ecotoxicology made recommendations for work of high, medium and low priority in the area of both aquatic and terrestrial ecotoxicity tests. The highest need was recognized for the tests providing the data points listed above in paragraph 5. These needs were later reflected also in the report of Workshop on Environmental Hazard and Risk Assessment (3). The review updates of the needs for Test Guidelines applicable to pesticides are now done by the Pesticides Working Group. Most recently, the 14th Pesticide Working Group Meeting in November 2002 reviewed document ENV/JM/PEST/RD(2002)11/REV1 (4), which presents the current priorities and the progress of Test Guideline projects applicable to pesticides. From this overview it appears that most of the high priority work on terrestrial tests guidelines has been progressing. The biodegradation test and test on microorganism have been adopted, the worm tests are close to be finalized and the work on plants and avian tests is progressing (see Tables 1 and 2).

London Workshop on Environmental Hazard and Risk Assessment

8. The 1995 London Workshop on Environmental Hazard and Risk Assessment (3) addressed environmental fate and exposure, including terrestrial effects assessment (Annex 7 of the document). The general recommendations from this Workshop were to:

- Integrate with other international organizations involved in development of risk assessment and test guidelines (OECD liaison with ISO, EU, EPPO/CoE, IPCS, UNEP, FAO);
- Encourage consistent and transparent assessment reports and provide technical guidance to promote expert judgement.

9. Furthermore, it was specifically recommended to:

- Develop a set of standard terrestrial effects tests;
- Promote the improvement of extrapolation methods and uncertainty analysis, including assessment factors involving the following steps:
  - Review approaches taken in aquatic assessment and other types of risk assessment to identify suitable principles and approaches.
  - Construct database containing relevant published toxicity data for a wide range of terrestrial species.
  - Derive new data for database using standard laboratory toxicity tests on plants and invertebrates.
  - Establish OECD working group to evaluate and make recommendations on how extrapolations be handled for terrestrial effects.
- Advance development of improved methods for assessing no-effect levels and end-points (review range of parameters used as end-points and statistical methods for generating robust measures of toxicity);
- Develop a better understanding of the ecological significance of effects seen in the field on populations and ecosystems (organise a workshop to discuss recommendations for further work for OECD and other bodies);
- Provide criteria to judge validity of non-standard data.

Joint OECD/SETAC Pensacola Workshop on Avian Toxicity Testing

10. At the 1996 Joint OECD/SETAC Pensacola workshop on avian toxicity testing (5) avian testing methods and testing strategies were addressed. Recommendations were made for the revision of Test Guidelines 205 and 206 (i.e. dietary and reproductive toxicity), the development of a new Guideline on acute oral toxicity, and a Guidance Document on Food avoidance studies. The Working Group on acute
avian toxicity recommended that work be done (by OECD and SETAC) to identify the number of species which would need to be tested to provide adequate certainty in risk assessment, and which assessment factors should be applied when smaller data sets are available. They also recommended that the most appropriate test species should be identified. In this work Canada, Germany, The Netherlands and US could provide useful data. These recommendations for test method development have all been taken into account by the Test Guidelines Programme.

Meetings of the Hazard/Risk Assessment Advisory Body (HAAB/RAAB), and the Terrestrial Effects Working Group (TEWG)

11. In January 1995 it was agreed at the 10th Meeting of HAAB (6) that a joint Working Group should be established with the Test Guidelines Programme to make proposals for a standard set of tests taking into account testing strategies and identify discussion issues relating to the possible development of a classification system for the terrestrial environment. This Working Group on Terrestrial Effects (TEWG) met in May 1995 in Paris (7). A number of documents were used to provide background information including: Danish Discussion Paper Regarding Guidance for Terrestrial Effects Assessment prepared by the Danish Water Quality Institute (8), the Dutch Discussion Paper on the Selection of a Set of Laboratory Ecotoxicity Tests for the Assessment of Chemicals in Terrestrial Ecosystems (9) and the draft report of the OECD Workshop on Environmental Hazard/Risk Assessment (3). The agreements and proposals of the TEWG are summarized below:

12. The TEWG agreed that, in general, the need for terrestrial testing should be exposure-driven and only if exposure can be completely ruled out, then there is no need for testing. If exposure is possible, then test should be targeted at the compartment of concern (soil or “above ground”). It was further agreed that there is a strong need to develop testing strategies.

13. The TEWG could not reach agreement on the following issues:

- Should a fixed number of standard tests be required, or should there be a fixed battery from which test are selected based on exposure route? The opinions were not that far apart since those of favour of a fixed number of standard tests acknowledged that there would be cases where it would not be sensible to perform a particular test. Furthermore, the supporters of a battery of tests did not want the battery to comprise too many tests.
- When assessing terrestrial effects, should the terrestrial environment be considered as two separate compartments (i.e. soil and above soil) as recommended in the Danish Discussion Paper? The group recognized that, at that time, the only part of the terrestrial environment that can be addressed for both pesticides and industrial chemicals is the soil compartment. For the above soil compartment, it was only possible to calculate exposure for some substances such as pesticides where application rates are known. Work on the development of procedures for predicting exposure concentrations for industrial chemicals in the above soil was considered necessary before suitable tests for this compartment could be identified, let alone required.

14. The TEWG proposed tests for initial assessment of terrestrial effects for pesticides taking into account soil and above soil and for general chemicals considering soil compartment only. For assessment of pesticides tests on soil microorganisms, plants, annelids, arthropods and birds were proposed and for general chemicals test with plants, annelids and arthropods only (see Annex 1). The TEWG also proposed a testing scheme for risk assessment and indicated how this scheme could be used for classification (see Annex 2).

15. The TEWG recognized that additional work on identification and/or development of tests for above soil species and higher tier tests for general chemicals would be needed, but recommended that the
HAAB and the Working Group of National Co-ordinators of the Test Guidelines Programme (WNT) would reach first agreement on the initial tests. The TEWG also proposed that criteria and a scheme for classification of substances as hazardous to the terrestrial environment be developed building on the discussions in the group and taking into account physical/chemical properties and environmental fate.

**Initial Work on a Terrestrial Classification System**

16. Following the TEWG Meeting May 1995, a Nordic group, led by Sweden, developed a proposal for a terrestrial classification system based on TEWG recommendations. The Nordic proposal was received by the Secretariat in March 1996 and circulated for comments to the TEWG in April (it was also circulated to the Advisory Group on the Harmonization of Classification and Labelling for information). Comments received were circulated to all TEWG members and to the Nordic Group at the beginning of August 1996.

17. At the December 1996 meeting, most RAAB members felt that it was too soon to develop threshold levels (cut-off criteria) for a terrestrial hazard classification scheme and that the identification and development of appropriate Test Guidelines should have higher priority than to continuing work on the scheme. It was therefore agreed that:

- the Terrestrial Effects Working Group (TEWG) should develop firmer proposals for test method development in light of progress made since their first meeting in June 1995;
- Japan and Spain should be invited to join the TEWG (Japan indicated their interest in joining the working group at the meeting and Spain was active in this work in the context of EU activities);
- OECD work on the development of the hazard classification scheme should be stopped for the moment, but in the realisation that work would continue within the EU, the RAAB should be given the opportunity to comment on EU proposals.

18. With respect to the development of a terrestrial hazard classification scheme, the Secretariat has been aware of follow up activities in the EU since 1996. However, OECD being the UN focal point of environmental schemes has not received proposal from the EU. Some countries (Austria, Germany, Spain and Sweden) had also drafted ad-hoc proposals for the possible Classification Systems and Criteria for the terrestrial environment which were presented during an EU workshop in Madrid in late 1998.

**Work on Terrestrial Effect Test Methods**

19. Although the work on terrestrial effect test methods has been included in the successive Workplans and Schedules of Activities of the Test Guidelines Programme since 1995, until recently, work has progressed only rather slowly. Test developed and adopted since 1995 include 2 Test Guidelines for honeybees (acute oral and contact toxicity) and 2 Test Guidelines for soil micro-organisms mineralization tests (nitrogen and carbon, respectively). In addition, a comprehensive test method was developed on soil adsorption/desorption, providing detailed guidance on standard test soils.

**Previous Joint Meeting Discussions**

20. Not much progress was made with the discussion on assessment approaches other than the initial work on terrestrial hazard classification. Therefore, in October 1998, the Risk Assessment Advisory Body (RAAB) recommended at its final meeting that the Joint Meeting should establish a Task Force to identify exactly what work is needed on terrestrial effects assessment. The rationale was that the absence of guidance on terrestrial effects assessment presents a serious gap in the suite of methods and guidance documents available from the OECD.
21. The issue of creating an OECD Task Force to work on terrestrial effects assessment was first discussed at the 29th Joint Meeting in June 1999. The Meeting thought that more detailed proposals for that work were needed before a Task Force could be established and invited Member countries to submit their priorities to the Secretariat and to indicate what support they could provide for the work. In December 1999, two proposals were received from Germany and Sweden respectively.

22. The German proposal recommended that OECD co-ordinate all activities which may have an impact on testing and risk assessment of chemicals and pesticides with regard to the terrestrial environment. It was further proposed that this could be achieved by setting up an OECD Terrestrial Assessment Task Force which could:

- collect and systematically disseminate information on ongoing or planned activities in other bodies;
- co-ordinate among those activities;
- advise the National Co-ordinators on test guideline needs and priorities in this area;
- review the existing set of tests; identify (if appropriate) and prioritise the need for other tests (e.g., other species in the soil compartment; which/how many plant species; higher-tier tests);
- develop principles on the design of toxicity tests (e.g., exposure routes for arthropod testing);
- develop principles or standard scenarios for exposure assessment for different non-target species;
- develop principles for risk assessment of biological pesticides (micro-organisms, pheromones); and
- develop principles on risk management with regard to non-target terrestrial organisms and crop/off-crop areas.

23. The Swedish proposal suggested that work should be done to develop a proposal for a standard (base) set of terrestrial effects tests for industrial chemicals (which should preferably be a subset of the basic requirements for agricultural pesticides). This would build on the work done by the Terrestrial Effects Working Group (TEWG) which had made a number of recommendations regarding which test methods were needed from a risk assessment standpoint. At the time they felt that there may now had been sufficient progress in tests development (e.g. on soil organisms) to make it possible to develop a proposal for a basic test of tests for industrial chemicals.

24. In February 2000 the 30th Joint Meeting reviewed the proposals from Germany and Sweden and again discussed whether activities on terrestrial effects assessment should be initiated and, if so, how they should be managed. It was agreed that before any new work be adopted, a survey of on-going terrestrial affects assessment activities should be performed. Germany offered the development of an inventory of terrestrial hazard/risk assessment activities taking place in the OECD countries. The questionnaire for this inventory was subsequently circulated in March 2001.

25. Responses were received from ten member countries only (Austria, Canada, Denmark, Germany, Japan, Korea, the Slovak Republic, Switzerland, UK and US), the European Commission and UNEP (11). The responses seemed to be rather inconsistent varying from rather limited national activities to few international co-operation activities. The rather poor success of the survey called for the following remarks:

- The number of responses received was low;
- A small number of countries (Austria, Canada, Denmark, Germany and to a less extent Switzerland) had provided an exhaustive list of their national activities and/or international activities which they were participating in;
For several countries (Japan, Korea, UK and US), one individual had responded and mentioned only one project. Obviously, this did not reflect the amount of activities taking place in these countries;  
Some countries (Austria, Canada) had mentioned projects dealing with remediation of polluted soils or chemical contamination of groundwater, which was not directly relevant to hazard/risk assessment of chemicals;  
A few international co-operation activities (e.g. EU projects, international workshops) had been mentioned by two or more countries (which was fortunate in a sense); those projects had been reported once in the table and had been allocated arbitrarily to one respondent (countries concerned were Denmark, Germany and Switzerland).  
A number of existing activities were missing or incomplete; Those mainly concern (i) the development of testing methods at national and international levels; and (ii) the work on ecological risk assessment (e.g. US EPA, IPCS).

Hence, the results of the survey suggested that there was not enough substance to make an accurate inventory of the existing terrestrial effects activities in OECD countries, and they were clearly insufficient to guide decisions on the work needed at OECD.

International Activities Other Than in OECD

Outside OECD a number of international activities were that time under way or being planned which deal with different aspects of environmental risk assessment for the terrestrial environment. These included, among others, (i) the revision of the EPPO (European and Mediterranean Plant Protection Organisation) Council of Europe Environmental Assessment schemes; (ii) the development of a guidance document on terrestrial ecotoxicology of pesticides within the EU; (iii) the organisation of the ESCORT II Workshop on European Standard Characteristics of beneficials Regulatory Testing on non-target arthropods; and (iv) the test soil standard development within ISO. These activities dealt with aspects like defining data requirements, developing test methods, evaluation of tests and exposure, trigger values and risk assessment. They were clearly related, but links were not clearly defined or in many cases coincidental (e.g., experts working in several of those activities at the same time).

In November 2000 the EU Scientific Committee on Toxicity and the Environment (CSTEE) expressed its opinion on the available scientific approaches to assess potential effects and risks of chemicals on terrestrial ecosystems (12). The committee was in favor of the integration of both Human Health and Ecosystem Risk Assessment. However, it was also stated that first an adequate understanding of each part and their linkages is needed. In brief, the CSTEE recommended that:

The final goal for the environmental hazard and risk assessment should be the evaluation of ecosystem effects. Effects on the soil compartment should not be only part of the expected effects and other receptors (plants, ground and foliar invertebrates, terrestrial vertebrates) should be considered in the assessment;  
This recommendation should apply for all legislation, even legislation related to a single compartment, such as those producing maximum acceptable levels for soil or air. For example, a soil ecotoxicological threshold should guarantee the protection not only the soil community, but also of the terrestrial system associated with the soil which could be exposed, for example, via food chain transfer;  
Therefore, the evaluation of the terrestrial compartment should require consideration of several hazards, corresponding to the combination of exposure routes and relevant ecological targets;  
Similarly, the connections between the terrestrial and aquatic systems should also be considered, in terms of both transfer of the chemical and ecological relationships;
• The relevance of the different effect assessment tools and protocols should be assessed establishing programmes for the comparison of results from laboratory, semi-field and field studies;
• There should be a much higher integration between chemicals control and the protection of biodiversity;
• A further research effort of ecotoxicology and environmental chemistry in the terrestrial area was required to support the balanced use of scientific information in the decision-making; and
• Tiered approaches were considered suitable for achieving a proper equilibrium between scientific information, uncertainty and precaution. Tiered protocols, commonly used in risk analysis, could be valuable for terrestrial hazard identification.

CURRENT OECD ACTIVITIES

29. Although the initial intention of the RAAB was to develop a Guidance Document for terrestrial effects assessment similar to the one which exists for aquatic effects assessment (13), member countries were reluctant to initiate additional work due to their already heavy workload. As a result, the initial project was abandoned and it was agreed to limit the work to improving co-operation and information exchange by making an inventory of the national and international activities in the area concerned. It is expected that this information would help guide future decisions on the work needed at the OECD level.

30. Most of the recommendations resulting from previous work at OECD have been taken into account by the relevant programmes. The Test Guidelines Programme (TGP) has included all proposals for development of ecotoxicity test guidelines for terrestrial effects (Table 1) and several different groups of organisms are already covered. The Programme on Harmonisation of Classification and Labelling (HCL) has placed the development of a classification scheme for the terrestrial environment in its future work plan; however, the Task Force on HCL agreed that the work on criteria for the classification of chemicals which are hazardous for the terrestrial environment should be initiated only when all essential test methods for terrestrial toxicity would be available.

Table 1. Available OECD Test Guidelines and corresponding EU and ISO methods relevant for the terrestrial compartment (soil and above ground).

<table>
<thead>
<tr>
<th>Test method</th>
<th>OECD</th>
<th>EU</th>
<th>ISO</th>
</tr>
</thead>
<tbody>
<tr>
<td>Avian Dietary Toxicity Test</td>
<td>TG 205</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Avian Reproduction Test</td>
<td>TG 206</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Earthworm, Acute Toxicity Test</td>
<td>TG 207 C.8 11268</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Terrestrial Plants- Emergence and Growth</td>
<td>TG 208</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Honeybees, Acute Oral Toxicity Test</td>
<td>TG 213 C.16 11269</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Honeybees, Contact Toxicity Test</td>
<td>TG 214 C.17</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Soil Microorganisms, Nitrogen Mineralization Test</td>
<td>TG 216 14238</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Soil Microorganisms, Carbon Mineralization Test</td>
<td>TG 217</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Enchytraeid Reproduction Test</td>
<td>TG 220 draft</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Earthworm (<em>Eisenia</em>) Reproduction Test</td>
<td>TG 222 draft 11268</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Collembola Reproduction and Test</td>
<td>11267</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

31. The current activities of Test Guidelines Programme relevant for the terrestrial ecosystem are summarized below in Table 2.
Table 2. Current activities of the Test Guidelines Programme relevant for the terrestrial effects assessments.

<table>
<thead>
<tr>
<th>Work item</th>
<th>Expected date of submission to WNT for approval</th>
</tr>
</thead>
<tbody>
<tr>
<td>New TG for Avian Acute Toxicity</td>
<td>2003 - 2004</td>
</tr>
<tr>
<td>Updating Avian Dietary toxicity Test (TG 205)</td>
<td>2003 - 2004</td>
</tr>
<tr>
<td>Avian Reproduction Test (1-generation)</td>
<td>2003 - 2004</td>
</tr>
<tr>
<td>New Two Generation Avian Toxicity Test</td>
<td>2004 - 2005</td>
</tr>
<tr>
<td>Updating Terrestrial Plant Test (TG 208)</td>
<td>2003 - 2004</td>
</tr>
<tr>
<td>Enchytraeid Reproduction test (TG 220)</td>
<td>May 2003</td>
</tr>
<tr>
<td>Earthworm (Eisenia) Reproduction Test (TG 222)</td>
<td>May 2003</td>
</tr>
</tbody>
</table>

32. Terrestrial effects (toxicity to terrestrial plants, earthworms, and birds) are also included as SIDS element in the assessment of High Production Volume (HPV) Chemicals, when significant exposure is expected or identified in terrestrial environmental compartment. Although in practice reporting of terrestrial effects is rather exceptional, there are some examples of initial assessments, such as trichloroacetic acid, where terrestrial toxicity was a major reason for concluding that risk management measures are needed.

**DISCUSSION AND OPTIONS**

33. The history of efforts in the area of harmonized terrestrial hazard assessment and possible development of harmonized terrestrial classification criteria of chemicals has been quite cumbersome. The question has always been whether there should first be an adequate set of harmonized terrestrial test methods or should adequate assessment strategies be developed first to provide guidance which test would be needed. It now appears that the development of Test Guidelines has proceeded significantly in the area of terrestrial testing. A number of methods are already available covering several groups of organisms (Table 1) and more test methods are currently in development (Table 2). Hopefully data is currently accumulating by laboratories using these tests.

34. With respect to terrestrial assessment approaches, apart from the enthusiastic pioneering work done by a limited number of member countries in the EU, international activities seem to be at a relatively low level of interest. Most notably, Spain has provided several national and international background documents to be considered at the international level (12) (14) (15) (16) (17) (18) (19) (20) (21) (22).

35. **Option 1:** In the case of a revitalisation of terrestrial assessment work in OECD, taking into account the lukewarm interest of member countries in substantial work on terrestrial effect assessment strategies and concepts, it may be preferable to focus initially only on the limited and well-defined area of terrestrial hazard classification. However, before developing classification criteria in this environmental hazard area, probably first the following issues should be considered and questions answered:

**Testing:**

- Most importantly: do the OECD terrestrial effect Test Guidelines currently available or in development together provide adequate test data for terrestrial hazard classification purposes?
- If not: which soil or above soil tests/test species should be considered in addition to the available methods?
Assessment:

- Should terrestrial environmental hazards be seen as independent of aquatic environmental hazards? In other words, should they result in separate classification and/or labelling?
- In case they should be considered as separate hazard classes, would classification in one or the other class lead to different down-stream measures?
- In case they should be considered as interlinked, should one override the other? In other words, is there a chance that, once terrestrial hazard criteria have been developed, these criteria could be more sensitive than aquatic hazard criteria?

36. In order to answer these questions, rather than to send another questionnaire to member countries, it may be preferable to conduct a literature and database survey comparing the relative sensitivity of aquatic and terrestrial test organisms and test methods by a detailed comparison and analysis of actual assessment cases, taking into account comparisons of effective concentrations and doses in terrestrial and aquatic tests. The draft report of the survey would be circulated for review to all OECD expert groups involved in environmental testing and assessment, including the Working Group of National Co-ordinators of the Test Guidelines Programme (WNT), the Pesticide Working Group, the Task Force on Existing Chemicals, the Task Force on Exposure Assessment and the Task Force on Biocides.

37. **Option 2:** Alternatively, the Joint Meeting could decide that it is too early to revitalise the terrestrial hazard assessment work as more test methods need to be developed first.

THE ROLE OF OECD AS GHS FOCAL POINT FOR FUTURE WORK ON ENVIRONMENTAL HAZARD CLASSIFICATION

38. Based on the recommendations for future work as included in the OECD Integrated Document on Hazard Classification [ENV/JM/MONO(2001)6] and on similar proposals made by OECD member countries to the UN SCE GHS in December 2002, the fourth session of the UN SCE GHS welcomed and accepted OECD’s offer to continue as a Focal Point for the already identified work on human health and environmental hazards. However, with respect to terrestrial hazard classification, the UN SCE GHS agreed that a decision on the scope of work and on a possible mandate to OECD could only be made after discussion of an OECD document on its historical and current work in this area (this document).

39. Considering OECD’s leading role in international work on environmental assessment, including terrestrial assessment and taking into account the extensive networks of environmental experts in member countries, the Joint Meeting (11-13 June 2003) may wish to confirm that OECD would be very well-placed to co-ordinate the international work with respect to the classification of chemicals hazardous to the terrestrial environment.

REFERENCES

(1) ENV/MC/CHEM/HCL/M(95)1. Draft Record of the First Meeting of the Advisory Group on Harmonization of Classification and Labelling.

(2) OECD (1994) Data Requirements for Pesticide Registration in OECD Member countries: Survey Results, No. 1 in the Series on Pesticides.


(6) ENV/MC/CHEM/HA/M(95)1 Draft Record of the 10th Meeting of Hazard Assessment Advisory Body.


(17) EC (2001) Note on current discussions on criteria for classification and labeling for the terrestrial environment. ECBI/38/01, ECB, Ispra, Italy.


# Proposed tests for initial assessment of terrestrial effects

<table>
<thead>
<tr>
<th>Taxonomic group</th>
<th>Pesticides (soil and above soil)</th>
<th>General chemicals (soil compartment only)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Test required?</td>
<td>Comment</td>
</tr>
<tr>
<td>Soil micro-organisms</td>
<td>Yes</td>
<td>OECD Guideline, based mainly on EPPO method, under development</td>
</tr>
<tr>
<td>Plants</td>
<td>Yes</td>
<td>Revision of OECD Guideline 208 is high priority. Establish working group to review work available elsewhere (e.g. Canadian scheme, US EPA, EPPO, Free University of Amsterdam paper) and to draft proposal(s).</td>
</tr>
<tr>
<td>Annelids</td>
<td>Yes</td>
<td>OECD Guideline 207, Earthworm acute toxicity test is satisfactory - some revision may be appropriate (see recs from Task Force) but of low priority. (See note 2)</td>
</tr>
<tr>
<td>Arthropods</td>
<td>Yes</td>
<td>Four species, driven by exposure and use (at least one would be ground dwelling). High priority for method development. However, no immediate action - await proposals from European group (see note 3), but circulate information on their activities to TG National Co-ordinators.</td>
</tr>
<tr>
<td>Birds</td>
<td>Yes</td>
<td>Revision and development of avian tests already being addressed. Workshop held in Florida in December 1994.</td>
</tr>
<tr>
<td>Mammals</td>
<td>No</td>
<td>Data available from human health studies (see note 4)</td>
</tr>
</tbody>
</table>

**Notes:**

1. Existing test used for pesticides not suitable since exposure of soil organisms to general chemicals will be of a longer duration and at (probably) lower concentrations than exposure to pesticides (existing test suitable for pesticides since it simulates a short-term exposure - sudden change in environment as occurs in the field). Different type of test therefore required for general chemicals, but since research is still needed in this area, a suitable method is unlikely to be available for another 5 years or so.
2. Earthworm reproduction test would be in next tier. High priority for OECD guideline development. A BBA guideline was published in 1994 and this method is being considered by ISO, i.e. ISO TC 190 (soil quality), Sub-committee 4 (Biological methods). At the request of one of the ISO member countries, a third international ring test has been initiated and the results are expected within months. A final draft method will be submitted to the ISO committee at the end of the year.
3. A joint initiative by IOBC, BART, COMET and EPPO on the development of tests with beneficial arthropods is in progress.
4. US has option to require wild mammal data on case-by-case basis.
**ANNEX 2**

**Proposals for a terrestrial testing scheme for risk assessment and how this may lead to classification**

The Terrestrial Effects (TEWG) Working Group proposed the following approach to terrestrial effects testing for substances for risk assessment purposes. The classification which may result from the testing is also indicated. With respect to classification, note that other data (e.g. physical/chemical properties, environmental fate) should also be taken into consideration in the development of a classification system (as is the case for the proposed classification criteria for the aquatic environment).

<table>
<thead>
<tr>
<th>Testing tier</th>
<th>Aquatic tests</th>
<th>Terrestrial tests for risk assessment</th>
<th>Possible classification leading from terrestrial tests</th>
</tr>
</thead>
<tbody>
<tr>
<td>Initial</td>
<td>Fish</td>
<td></td>
<td>Dangerous to the Environment (aquatic)</td>
</tr>
<tr>
<td></td>
<td>Daphnia</td>
<td></td>
<td>Dangerous to the Environment (e.g. toxic to mammals, i.e. direct toxicity)</td>
</tr>
<tr>
<td></td>
<td>Algae</td>
<td>equilibrium partitioning (where possible)</td>
<td>Note: Also need criteria for toxicity via secondary poisoning</td>
</tr>
<tr>
<td></td>
<td></td>
<td>mammalian data from human health studies</td>
<td></td>
</tr>
<tr>
<td>Level 1</td>
<td></td>
<td>Testing using initial set of tests</td>
<td>Dangerous to the Environment (e.g. toxic to terrestrial soil organisms)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>PEC/PNEC</td>
<td></td>
</tr>
<tr>
<td>Level 2</td>
<td></td>
<td>Further tests (e.g. birds)</td>
<td>Dangerous to the Environment (e.g. toxic to birds)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>PEC/PNEC</td>
<td></td>
</tr>
</tbody>
</table>

**Notes:**
1. Not all steps can be applied to all chemicals (e.g. equilibrium partitioning)
2. At this point in time, first priority has been given to testing strategies as proposed in current EU guidance documents (i.e. risk assessment for new and existing chemicals). These documents, and therefore the scheme above, may be modified as more experience is gained.
3. Note that for pesticide active ingredients, information on birds will be available at an initial stage.
4. As further testing is done beyond the initial tier, there will be the possibility to refine the risk phrases.