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**Task Force on Harmonisation of Classification and Labelling**

**ISSUES TO BE ADDRESSED TO DEVELOP THE CLASSIFICATION AND LABELLING FOR  
TERRESTRIAL ENVIRONMENTAL HAZARDS**

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## **ISSUES TO BE ADDRESSED TO DEVELOP THE CLASSIFICATION AND LABELLING FOR TERRESTRIAL ENVIRONMENTAL HAZARDS**

1. The UN Sub-Committee of Experts on the Globally Harmonized System of Classification and Labelling of Chemicals (UN SCE GHS) requested that the OECD provides i) an analysis of the current national approaches and/or requirements for terrestrial hazard classification and ii) proposals of issues to be addressed to develop the classification and labelling for this hazard class.
2. The OECD document ST/SG/AC.10/C.4/2003/2 [ENV/JM(2003)19] was submitted to the UN SCE GHS at its Fifth session, in response to the work requested under i) above. It is an overview document of historical and current work in the area. Further analysis of specific national classification systems will be done if the decision is made to start the work to develop a harmonised classification system. The document shows that a number of terrestrial test methods are already available and more test methods are currently under development allowing generation of terrestrial ecotoxicological data. In addition, pesticide authorities in the US and several European countries perform classification and labeling for terrestrial hazards. (See annex I, Section 4).
3. The OECD has established an Expert Group for addressing the questions raised by the OECD document ST/SG/AC.10/C.4/2003/2 [ENV/JM(2003)19] and proposing an Issue Document which could help the discussion of the feasibility and need for developing classification criteria covering terrestrial environmental effects. Experts from Austria, Canada, Finland, France, Spain, the UK and the US participated in this Expert Group.
4. This Issue Document has been posted on the OECD Harmonization of Classification and Labelling (HCL) website for its review by the Task Force on HCL, by the UN SCE GHS and by the Sub-Committee of Experts on the transport of dangerous goods. It has been discussed at the Task Force Meeting in May 2004.
5. The questions, arising from document ST/SG/AC.10/C.4/2003/2 [ENV/JM(2003)19], can be divided into those related to the test methods and those focusing on the assessment:

### ***Testing:***

- 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? “

6. The OECD document ST/SG/AC.10/C.4/2003/2 [ENV/JM(2003)19] also suggests conducting a literature and database survey comparing the relative sensitivity of aquatic and terrestrial test organisms and test methods with known substances. Spain offered to take the lead in this survey, the conclusions of which are included in [Annex II](#).

**SPECIFIC RESPONSES TO THE QUESTIONS FORMULATED IN THE OECD DOCUMENT ST/SG/AC.10/C.4/2003/2 [ENV/JM(2003)19]**

7. Below are a summary of the answers and the justifications of the proposed answers.

**Testing:**

- **Do the OECD terrestrial effect Test Guidelines currently available or in development together provide adequate test data for terrestrial hazard classification purposes?**

As showed in document ST/SG/AC.10/C.4/2003/2 [ENV/JM(2003) 19], there is a number of Test Guidelines available for the terrestrial compartment (Table 1) and more test methods are in development (Table 2). These tables have been updated with the recent development of Test Guidelines. In addition, some other validated and widely accepted test guidelines authorized by national authorities for terrestrial hazard identification are listed in [Annex I, Table I](#).

**Table 1. Available OECD Test Guidelines for the terrestrial compartment (soil and above ground).**

Test method	OECD Test Guidelines
Avian Dietary Toxicity Test	TG 205
Avian Reproduction Test	TG 206
Earthworm, Acute Toxicity Test	TG 207
Terrestrial Plants- Emergence and Growth	TG 208
Honeybees, Acute Oral Toxicity Test	TG 213
Honeybees, Contact Toxicity Test	TG 214
Soil Microorganisms, Nitrogen Mineralization Test	TG 216
Soil Microorganisms, Carbon Mineralization Test	TG 217
Enchytraeid Reproduction Test	TG 220
Earthworm ( <i>Eisenia</i> ) Reproduction Test	TG 222

**Table 2. Current activities of the Test Guidelines Programme relevant for the terrestrial effects assessments<sup>1</sup>.**

Work item	Expected date of submission to WNT for approval
Avian Acute Toxicity Test (TG 223)	2004
Avian Repellency and Avoidance Test	2004
Updating Avian Dietary toxicity Test (TG 205)	2004 - 2005
Avian Reproduction Test (1-generation)	2004 - 2005
New Two Generation Avian Toxicity Test	2004 - 2005
Updating Terrestrial Plant Test (TG 208)	2004
Terrestrial plant: Vegetative Vigour Test (TG 227)	2004
Dung Beetles and Dung Flies	2004 - 2005

8. In addition, noting that classification under the GHS is hazard based, there are also available OECD test methods covering some fate properties, which, could be potentially employed in a hazard classification scheme. Within this category, existing guidelines for the Inherent Biodegradability in Soil method (TG 304A) and the Aerobic and Anaerobic Transformation in Soil method (TG 307) and the project to develop a new guideline for phototransformation on soil surfaces should be mentioned.

9. These available tests cover the major categories and taxonomic groups considered essential for the soil environment: terrestrial plants, soil dwelling invertebrates and soil micro-organisms, as indicated by different international scientific panels (see CSTEE, 2000; Fairbrother et al., 2002). The endpoints selected for each test are also in line with the recommendations. In particular, the use of “structural” endpoints (e.g. those measuring lethality, growth, or reproduction rates in selected species) for terrestrial plants and invertebrates, and “functional” endpoints (e.g. soil respiration and nitrification) for soil microbial populations, is considered scientifically sound by the Expert Group.

10. Regarding terrestrial vertebrates, the guidelines covering toxicity testing on birds can be complemented with those conducted on mammals. The main objective for mammalian toxicity tests is, obviously, the assessment of human health effects; however, the same test data can be used for covering terrestrial wild mammals if required. This additional use of mammalian toxicity tests is not only in line with the requirements for reducing in vivo testing, but also follows the recommendations for integrating human health and environmental assessments as suggested by WHO (2001).

11. Following current state-of-art of terrestrial (soil) ecotoxicology, tests on additional taxonomic groups, such as specific tests, covering mostly additional groups of soil invertebrates could be usefully developed in the future

12. The GHS classification should be based on easily available data, considered enough for setting a hazard identification and classification system. The tests should be cost/effective and not as exhaustive as for other purposes as risk assessment or the registration of chemicals of specific concerns such as pesticides. OECD methods, both those available and some under development, can provide data needed. .

<sup>1</sup> Many of these test methods are in current use to satisfy data required for pesticides and other chemicals.

*Therefore, it is concluded that the OECD terrestrial effects Test Guidelines currently available or in development provide adequate 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?**

13. The answer to the first question is YES, therefore, this question does not need to be addressed.

Nevertheless, the development of additional guidelines is always welcomed. The guidelines should be initially oriented for producing relevant data for risk assessment; however, as an added value, during the guideline design it should also be considered that the outcome must also provide information for hazard identification and classification.

**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?**

14. The terrestrial classification schemes should cover the concerns for different organisms, compartments and ecosystems than those covered by the aquatic environmental hazards. Correlation studies between aquatic and terrestrial ecotoxicological data have shown that toxicity data for aquatic organisms should not be used for predicting effects on terrestrial organisms. For example Clausen (1999) presented a set of statistical comparisons between aquatic, soil dwelling and foliar invertebrates, concluding that toxicity data of aquatic organisms are bad descriptors of earthworm and bee toxicity, and may not be used for predicting effects on these two groups of terrestrial organisms. Exposure routes, ecological receptors and in some cases even the mechanisms of action are expected to differ for both aquatic and terrestrial environments.

15. The key ecological receptors for the terrestrial environment are terrestrial vertebrates, terrestrial plants, soil-ground-foliar dwelling invertebrates and soil micro-organisms. These terrestrial organisms can be exposed through several environmental compartments (soil, air, water and food). Hazard identification must consider the key combinations of receptor-exposure routes (Tarazona and Vega, 2002). Currently, the aquatic environmental hazards cover exclusively the waterborne exposure route. It has been suggested that aquatic toxicity data could be used in a preliminary assessment as surrogate for soil dwelling organisms exposed via soil pore water (e.g. EC, 2003). However, all other exposure routes will not be covered by this approach, and it should be also considered that the relevant taxonomic groups and endpoints for the soil compartment are different from those representing the aquatic hazards. As already mentioned, several authors have suggested that the use of aquatic data as surrogate for terrestrial hazard identification is not appropriate (e.g. Clausen, 1999; Vega et al. 1999).

16. Terrestrial environmental hazards identify potential dangers for different environmental compartments, ecosystems, and taxonomic groups than those identified by the aquatic environmental hazards. .

*Therefore, it is concluded that terrestrial environmental hazards should be seen as independent of aquatic hazard.*

- **In case they should be considered as separate hazard classes, would classification in one or the other class lead to different control-management (down stream) measures?**

17. Certain authorities also link hazard mitigation to classification; the development of the criteria for terrestrial hazards can be adequate for application to more comprehensive environmental management

practices. If this is the case, it is really important to consider if the measures established for terrestrial hazard classes are expected to be similar or different from those established for aquatic hazards.

18. The application of control-management measures is directly linked to regulatory options and therefore differs strongly among countries. In some countries, these measures (restrictions, mitigation) will only be driven by risk assessment, while in others, classification will be used directly for risk management, in particular when exposure cannot be estimated (in case of transport, accident and storage for example).

19. Control, management and prevention measures adopted for transport, storage and particularly those related to actions following accidents may differ significantly if the hazards are related to aquatic ecosystems, terrestrial ecosystems or both.

*In conclusion, different control-management measures are expected due to the fact that the receptors, exposure routes and, therefore, the environmental consequences are different.*

- **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?**

20. This last question, formulated regarding to the possibility to override the aquatic hazard criteria by the terrestrial hazard criteria, is not relevant taking into account the previous answers.

The terrestrial environmental hazards should be considered as a different class than the aquatic terrestrial hazards. No override processes are recommended. If terrestrial classification criteria are developed, it is expected that some substances will be classified as hazardous only for the terrestrial compartment, other substances will remain classified as hazardous only for the aquatic compartment, and other will be classified as hazardous for both compartments, but not necessarily in similar categories.

## **Final Conclusion**

**21. On the basis of the recent OECD efforts for updating and developing new ecotoxicity tests guidelines, it is concluded that it is technically feasible to establish a hazard classification scheme for terrestrial organisms. The terrestrial environmental hazards are to be seen as different from and complementary to aquatic hazards and could produce a different classification scheme.**

**For those authorities which also use classification criteria to establish control or management practices for environmental effects, classification for aquatic and terrestrial hazards should be distinguished from each other.**

The development of the terrestrial hazard classification scheme should consider several issues. Those considered of special interest are addressed in [Annex I](#).

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## ANNEX I

### DISCUSSION OF GENERIC ISSUES TO BE ADDRESSED WHEN DEVELOPING A CLASSIFICATION SCHEME FOR THE TERRESTRIAL ENVIRONMENT

The general rules and principles for developing hazard classification criteria are indicated in the GHS guidelines. However, specific hazards require specific considerations and several key elements to be addressed when establishing the scheme for terrestrial environmental hazards are discussed in this annex.

- **Role of terrestrial taxonomic groups on hazard assessment**

Terrestrial systems cover a wide range of human-modified systems, from close to naïve terrestrial ecosystems to completely modified urban environments. The scheme should cover those terrestrial systems potentially endangered by hazardous chemicals, including agricultural areas, pasture land, forest systems, recreation zones, etc. In most areas, terrestrial communities have been modified as the result of anthropogenic impacts, but the basic taxonomic groups are still similar and can be merged as key terrestrial taxonomic groups.

The CSTE (2000) has identified the main adverse effects which can result from the exposure of terrestrial systems to toxic chemicals. These effects or threats offers the basis for selecting the relevant taxonomic groups and endpoints, and are described below:

i) effects on soil functions, and particularly on the capacity of soil to act as substrate for plants including effects on seed germination, and those on organisms (invertebrates, micro-organisms) important for proper soil function and nutrient cycle conservation.

ii) effects on plant biomass production, related to contamination of soil or air including deposition on plant surfaces. Plants are the source of food for the whole system (including humans) and have additional roles in terms of land protection, nutrient cycles, equilibrium of gases in the atmosphere, etc.

iii) effects on soil, ground and foliar invertebrates which represents food for other organisms, and covers essential roles as pollinators, detritivores, saprophages, pest controllers, etc.

iv) effects on terrestrial vertebrates, domestic and wild species, exposed to contaminated food, soil, air water or surfaces, with obvious economic and/or social consequences. Poisoned birds and mammals probably constitute the highest social concern, while reproductive effects, although less evident, represent a higher ecological hazard.

v) accumulation of toxic compounds in food items and through the food chain. It is a typical exposure route for animals within the contaminated ecosystem and represents an additional concern related to the consumption of this food by humans and domestic animals.



The selection of measured parameters on those taxonomic groups selected for covering the above mentioned threats must consider ecologically relevant properties for the terrestrial environment including both soil functions and ecosystem structure. The functional and structural endpoints are also relevant for heavily modified systems such as agricultural soil, pasture land, or cultured forest as the anthropogenic intervention focuses on an intended modification of the equilibrium but maintaining the same functional and structural foundations. Taking into account all potential effects, the main taxonomic groups to be considered when setting terrestrial hazard criteria are:

1. **Microorganisms** Effects of chemical substances on microbial populations can affect many soil functions as mineralization of detritus and those associated to plant-microbe interactions. Microbial activities are used in standardized methods as ecologically relevant endpoints (e.g. soil nitrification and carbon mineralization), which are also agronomically relevant. The only exposure route to consider in this group is exposure via soil.
2. **Plants** Terrestrial animals depend directly or indirectly on vegetation for feeding, nesting, breeding and hibernation. Damage on terrestrial plants can be measured through biochemical endpoints (changes in chlorophyll patterns, enzymatic alterations, etc.) and physiological endpoints (mortality, growth). Two main exposure routes should be considered for all species of this taxonomic group: exposure via air (atmospheric deposition, volatilization and spraying) affecting aerial parts and soil exposure affecting plant roots.
3. **Invertebrates** The activity of invertebrates is important for the dynamic of terrestrial ecosystems. Test guidelines with invertebrates should include species of the most important trophic levels and also contemplate different routes of exposure. Earthworms contribute to maintain soil porosity and are representatives of soil dwelling invertebrates. Other soil dwelling groups (e.g. collembola, isopods and enchytraeids) should be useful to address the complexity and diversity of species and ecological functions of terrestrial invertebrates. On the other hand, bees and many other flying insects are important in pollination processes. Ground and foliar invertebrates constitutes a large group, playing essential ecological and agronomical roles. Three exposure routes can be identified for this group: exposure via soil, via food, and a combination of contact and inhalation exposure resulting from atmospheric deposition.

Opposite to plant, not all invertebrates are exposed by all relevant routes. The species behavior and role determine which exposure routes should be considered. Several species can be considered as soil-dwelling invertebrates where the exposure via soil is assumed to be the only relevant pathway. Flying and foliar invertebrates are mostly exposed through the contact, oral and inhalation routes. The species behavior and development may modify significantly the relevant route, for example, several ground dwelling invertebrates spent the initial developmental stages within the soil and then emerge and remain in the ground/foliar boundary, with the obvious modification of the potential exposure routes.

4. **Vertebrates** Amphibians, reptiles, birds and mammals must be considered into this main group. Nevertheless standardized test with vertebrates are usually reduced to birds and mammals. Although mammals test methods have been developed for the evaluation of human health, they can be used for the protection of terrestrial ecosystems by selection of ecologically relevant endpoints. Additional effects such as endocrine disruption or genotoxicity should be covered. The main exposure route for this taxonomic group is oral exposure, contact and inhalation is also possible but less important.

OECD test methods are available for each main taxonomic group: microorganisms (TGs 216 and 217), plants (TGs 208 and 227), invertebrates (TGs 207, 213, 214, 220 and 222) and vertebrates (birds) (TGs 205 and 206). Nevertheless additional information about methods other than OECD test guidelines used in pesticide risk assessment in the EU can be considered for further development of test methods on terrestrial effect assessment (Table I)

TABLE I

TAXONOMIC GROUPS		ENDPOINT	TEST METHOD	Source
Microorganisms		CO <sub>2</sub> evolution, NH <sub>3</sub> and NO <sub>3</sub> soil content	Soil microbial community test 850.3200 (5100) <sup>2</sup>	U.S. EPA, 1996 <sup>1</sup>
Plants	Plants (monocots and dicots)	Developed mainly for pesticides:		U.S. EPA, 1996 <sup>1</sup>
		target area phytotoxicity (effects on life cycle of plants);	Target area phytotoxicity 850.4025	
		seedling emergence and early development;	Seedling emergence 850.4100 <sup>2,3</sup>	
		vegetative vigor;	Vegetative vigor 850.4150 <sup>3</sup>	
		test to determine phytotoxicity to plants in the field	Terrestrial plants field study 850.4300	

		Developed mainly for industrial chemicals:		
		seedling emergence and growth;	Early seedling growth 850.4230 <sup>2,3</sup>	
		phytotoxicity on plants and their nitrogen-fixing bacterial symbionts;	<i>Rhizobium</i> -legume toxicity 850.4600	
		uptake and translocation in plants and potential for entry into food chains	Plant uptake and translocation 850.4800	
Invertebrates	“Non target arthropods”	Mortality (LR50, lethal rate) on two sensitive standard species: parasitoid (e.g. <i>Aphidius rhopalosiphi</i> ) and predatory mite (e.g. <i>Typhlodromus pyri</i> )	SETAC, 1994 SETAC, 2001	Barrett et al., 1994 Candolfi et al., 2001
		Collembola reproduction test	ISO 11267	ISO 1999
		Litter bag test under field conditions		EPFES (2002)
		Acute contact	Honey bee acute	U.S. EPA, 1996 <sup>1</sup>

		Toxicity to honey bees	Contact test 850.3020 <sup>2</sup>	U.S. EPA, 1996 <sup>1</sup>
		Residue toxicity to honey bees	Honey bee residue 850.3030	
		Hazards to honey bees under actual field conditions	Field testing pollinators 850.3040	
	“Non target non arthropods”	Mortality, sublethal effects and growth of earthworms over 28 days	Earthworm subchronic toxicity test 850.3150 (6200)	
Vertebrates	Multi-species and general field tests	Acute oral toxicity (mortality and sublethal effects) on birds	Avian acute oral 850.2100	U.S. EPA, 1996 <sup>1</sup>
		Dietary toxicity and sublethal effects on birds	Avian dietary 850.2200 <sup>2,3</sup>	
		Reproductive effects on birds	Avian reproduction test 850.2300 <sup>2</sup>	
		Acute oral LD50, dietary LC50, or dietary no-effects on wild mammals	Wild mammal toxicity 850.2400	

		Potential fate and ecological effects (on primary productivity, nutrient loss, plant injury, bioconcentration, distribution and abundance of soil organisms) in model terrestrial systems	Terrestrial soil core microcosm 850.4900 (2450)	U.S. EPA, 1996 <sup>1</sup>
		Effects on distribution and abundance, in the field, on terrestrial organisms	Field testing, terrestrial wildlife 850.2500	

<sup>1</sup> The U.S. EPA Series 850 Ecological Effects Test Guidelines appeared as public drafts in April, 1996 (EPA712-C-96-xxx). They are currently being revised and finalized; this activity should be completed in 2005 or 2006.

<sup>2</sup> U.S. EPA 850 test guidelines that contain common elements with similar OECD test guidelines listed in Table 1 of the issues document.

<sup>3</sup> U.S. EPA 850 test guidelines that contain common elements with similar OECD current activities as listed in Table 2 of the issues document.

- **How to deal with the information obtained from tests methods when developing terrestrial hazard criteria**

When hazard identification is applied to sort chemicals in a generic way, the assessment is based on the “intrinsic properties” of the chemical. The danger for human health and the environment are mostly related to the so called “inherent toxicity” represented by a set of measurable parameters (LD50, LC50, NOEC, NOAEL,...). The outcome of the hazard quantification process can be a set of ranges representing hazard categories. The number of possible categories is limited by the capacity to produce sound criteria to distinguish between categories. It has been recommended to use either a bi-levels (YES/NO) or a multi-levels (several levels of concern from very high to very low or no concern) approach for each type of hazard (CSTEE, 2000). It should be taken into account that the current GHS scheme for aquatic environmental hazards considers a multi-levels approach.

A set of items can arise when developing terrestrial hazard criteria:

- 1. Whole terrestrial ecosystem or terrestrial subcompartments?**

Terrestrial systems are built-up around the soil/air interface and, as presented above, should cover different exposure routes. The difficulty for combining the information produced for addressing different exposure routes and the experience achieved for the terrestrial environment created a tendency for combining the information provided on taxonomic groups exposed via soil, but maintaining independent assessment for other routes and taxa. This pragmatic approach should be reconsidered following recent advances in terrestrial ecotoxicology. The main advantages and disadvantages are presented below:

- i) The first option is to consider a terrestrial scheme including data from all main taxonomic groups as only one hazard class (e.g. “hazardous to the terrestrial

environment”) with different categories. This is the best option from a scientific view-point, but the main difficulty is the development of classification schemes and criteria covering ecotoxicological data expressed in different units as the result of the route of exposure selected for each taxonomic group. The advantage is that the criteria will address a realistic hazard assessment for the terrestrial system as a whole, producing a scheme perfectly comparable to the current aquatic environmental hazards.

- ii) The second option is to consider terrestrial subcompartments and to address different hazard classes: For example a hazard class for the soil compartment and one or several classes for the above soil compartment. This assessment has the “apparent” advantage of avoiding the problem of different units for expressing the toxicity. However, in reality this benefit is only observed when grouping the soil toxicity tests, when all values are expressed in the same units for the soil (mg/kg). But the problem of different units remains for the other sub-compartments. In addition, this approach could lead to confusions in the hazard communication process, because both compartments are interconnected and the effects will not be restricted to a particular sub-compartment (as suggested by the hazard classes) but would affect the terrestrial system as a whole.

## **2. long-term vs. short-term effects**

It should be desirable to include acute and chronic endpoints to cover concerns about short- and long-term effects. The present classification system for the aquatic ecosystem includes four chronic categories based mainly on acute endpoints and potential to persist and to bioaccumulate. Current discussions about the incorporation of chronic toxicity data in the aquatic classification system are ongoing in the OECD expert group on Aquatic Environmental Hazards.

The design of the ecotoxicological methods for the terrestrial ecosystem should be considered when selecting the endpoints and their relevance for hazard identification.

This aspect is particularly important for the soil toxicity tests, where the exposure conditions are similar to those expected for accidental or incidental (spillages, etc.) releases. The chemical is mixed with the soil at the beginning of the test, and then can suffer degradation and dissipation processes. Therefore, the situation is very different from chronic oral or aquatic tests where efforts are conducted for keeping a constant exposure level through the whole exposure period.

## **3. Type of chemicals to be covered**

The GHS criteria are based on hazards, and not related to specific uses of the chemicals. Thus, the same criteria can be applied to all chemicals as the hazards during transport, storage, accidents, etc. are independent of the intended uses.

It should be considered that in addition to the GHS classification scheme some chemicals with specific uses, such as pesticides or biocides, that are spread intentionally in the environment require additional classification and labeling based on risk criteria, but the development of those risk based schemes is outside the scope of the GHS.

#### **4. Terrestrial Classification Systems in Current Use**

Terrestrial criteria have been developed for pesticide labelling in the United States and in European nations. These classification systems combine hazard criteria, but can also be based on incident data. For example, the criteria in the United States for birds and mammals are based on results of mammalian acute oral testing ( $LD_{50} = 100$  mg/kg, avian acute oral testing ( $LD_{50} = 100$  mg/kg, or subacute dietary results in avian species ( $LC_{50} = 500$  ppm). Criteria for bees are (highly toxic to bees when  $LD_{50} \leq 2$  microgram/bee and toxic to bees when  $2$  microgram/bee  $< LD_{50} \leq 11$  microgram/bee. Incident data in birds or mammals can also lead to hazard labelling. (USEPA Label review Manual Chapter 8: Environmental Hazards).



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USEPA: Label Review Manual Chapter 8: Environmental Hazards

## ANNEX II

### COMPARISONS OF AQUATIC AND TERRESTRIAL ECOTOXICITY DATA.

1. The development of criteria for terrestrial environmental hazards should be coherent with the current scheme for aquatic environmental hazards. Therefore, in addition to the feasibility of the terrestrial criteria, previous works have been conducted for establishing comparisons among aquatic and terrestrial ecotoxicity data.
2. An ad hoc EU Workshop conducted in 1998 presented and summarized the available information (Vega, 1999). The conclusions not only confirmed the expected lack of correlations among the different organisms and endpoints, but offered some statistical comparisons which could be valuable when setting the terrestrial classification criteria.
3. It was clearly identified that a large majority of toxic chemicals may require classification as hazardous for both aquatic and terrestrial systems. However, there is also a significant number which represent a hazard only for aquatic or for terrestrial systems. The final values would depend on the finally selected criteria.
4. A key problem for comparing aquatic and terrestrial data, as well as terrestrial data covering different exposure routes, is the use of different expressions for expressing the toxicity, which are obviously associated to the exposure route covered by the assay. The difference is not only in the expressions, but also on the concepts behind these expressions. For example toxicity from oral exposures are mostly based on doses, while the estimation of doses is very difficult for all other routes and expressions based on concentrations are employed. But even for expressions apparently similar, the reality is very different. Thus, for aquatic organisms, tests are designed to increase bioavailability of chemicals, while for soil assays the concentration is based on the total soil level, with very different bioavailabilities depending on the chemical and the soil characteristics.
5. These difficulties require the development of methods for comparing the toxicity data obtained by the different assays. The study of the distribution curves offers a sound alternative.
6. Statistical analysis of the available data on high production volume chemicals and pesticides, indicated that for each ecotoxicity endpoint the data relevant for classification purposes (a single figure for each chemical representing the lowest validated value; e.g. the lowest 96h LC50 on fish) followed log-normal distributions.
7. The distributions obtained for each toxicity test can be compared using statistical evaluations. The results observed similar distributions for all aquatic toxicity tests, allowing a normalisation of the aquatic values and the comparison of aquatic toxicity distributions with those observed for terrestrial assays. Then, data and classification criteria can be compared based on the relative position within the sensitivity distribution curve (e.g. comparing similar percentiles for each distribution curve). (See Tarazona et al, 1996 and Tarazona and Fresno, 1997; and Vega et al 1999 for additional information).

8. Within this OECD activity, the European Chemicals Bureau has provided the working group with information on an additional group of chemicals, the notified chemicals. The submitted information has been analysed and the data confirm that for chemicals where valid data are available (e.g. excluding limit tests where the results is expressed as higher than instead than as a real value), this group of chemicals, with very different chemical identities, also follows log-normal distributions when enough data are available. This statistical study leads to several main conclusions:

1. The terrestrial toxicity data present lognormal Chemicals Toxicity Distributions (CTDs) as aquatic toxicity data, but the average values are different from those observed for aquatic organisms.
2. The Euclidian distances between aquatic and terrestrial organisms are between 6 and 10. In other words, in average the LC50 and EC50 on earthworms and terrestrial plants are about one order of magnitude higher than those observed for aquatic organisms.
3. The similarity between the CTDs is no related to a correlation of toxicity data among taxonomic groups. In fact the analysis clearly indicate poor correlations, confirming the need for a test battery covering several taxonomic groups within each environmental compartment.

9. Therefore, it is confirmed that the use of Chemicals Sensitivity Distributions (CSD) can offer valuable information when setting classification criteria, as an additional tool for setting comparisons. Fitting the data to log-normal distributions allows statistically based comparisons, such as the percentiles (percentage of chemicals exceeding a certain value, including the confidence intervals) associated to each proposed criteria.

10. The capability of this tool will depend on the statistical power (representativeness of the database regarding the “general universe” of chemicals). Therefore, it is considered that efforts for compiling a large database including as many substances, chemicals structures and chemicals categories as possible, would be highly valuable for the further development of criteria for terrestrial hazard classification.

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