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on Existing Chemicals (BUA)

Risk Assessment of Substances in the Soil

Proposal by the BUA

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Dr. H. Behret
Gesellschaft Deutscher Chemiker
Postfach 90 04 40
D-60444 Frankfurt am Main
E-Mail: bua@gdch.de
Homepage: http://www.gdch.de

Responsible at the BMU:
MinR Prof. Dr. U. Schlottmann
BMU
Postfach 12 06 29
D-53048 Bonn
E-Mail: schlottmann.ulrich@bmu.de

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Preface

The Advisory Committee on Existing Chemicals of Environmental Relevance (BUA) was established in May 1982 to help the German federal government cope with the large task of dealing with existing chemicals. In an agreement between federal government, scientific community, and the chemical industry, it was associated with the German Chemical Society (GDCh, Gesellschaft Deutscher Chemiker) to ensure objective work, carried out in accordance with scientific principles.

At the end of 1997, the Committee was renamed 'GDCh Advisory Committee on Existing Chemicals' (abbreviation 'BUA' as before) and the statutes were revised to include EU level aspects of occupational safety for the handling of existing chemicals from then on. The collaboration with the Employment Accident Insurance Fund of the Chemical Industry (BG-Chemie), with its knowledge on workplace exposure and the toxicologic properties of chemicals, is a valuable addition to the BUA's know-how.

The cooperation between authorities, industry, and the scientific community, upon which the BUA is based, has proven worthwhile. No other national or international body has dealt with the ecological and health-related effects of so many existing chemicals as the BUA. On the national level, the BUA has produced comprehensive reports on about 300 substances and carried out preliminary evaluation and classification (priority-setting) for approximately 200 more, as of 1997. Publication of the process leading to priority-setting, in addition to the BUA Reports, lends transparency to the Committee's work.

Since the EU presently considers only those substances with a production volume of more than 1000 tonnes/year, the BUA began an additional national project in 1997, which also selects and assesses existing chemicals with a lower production volume in the range of 100 - 1000 tonnes/ year. The chemical industry presents about 50 databases for substances each year, for which the BUA sets the priority. Comprehensive reports are published on chemicals suspected of having a hazardous potential. If the data available for substance assessment are insufficient, the gaps in knowledge are documented and, if necessary, investigations recommended.

The BUA, as expert committee, increasingly addresses broad scientific questions and problems, such as 'endocrine disruptors', selection criteria for 'persistent organic pollutants' (POPs), 'risk assessment for soils and sediments', 'assessment criteria for the marine sector', and 'safety factors within the framework of toxicologic risk assessment'. The state of scientific knowledge on these subjects is researched, documented, and published as 'BUA Reports'. The aim is to develop assessment approaches for the German federal government, determine gaps in knowledge, identify necessary research, and last but not least, reduce information deficits in the general population. The present BUA report on the risk assessment of chemicals in soils is the result of intensive investigations and discussions into the topic of preventative soil protection and chemical evaluation.

Weihenstephan, June 2001

Helmut Greim
BUA Chairman

Contents

List of Abbreviations

µg	microgram
^{14}C	carbon-14 isotope (radioactive)
AbfKlärV	German Waste and Sewage Sludge Regulations
AOX	absorbable organic halogen compounds
BBodSchG	Federal Soil Protection Act
BBodSchV	Federal Soil Protection Regulations
BOD	biological oxygen demand
BVB	German Association on Soils
ca.	circa
Cd	cadmium
ChemG	German Chemicals Act
CMR	carcinogenic, mutagenic, reprotoxic chemicals
CO_2	carbon dioxide
Cu	copper
$CuSO_4$	copper sulfate
CVMP	Committee for Veterinary Medicinal Products
d	day
DIABEX	distribution based extrapolation
DIS	draft international standard
DOM	dissolved organic matter
ds	dry substance
DT_{50}	half-life
EC_{50}	concentration of the test substance showing an effect on 50% of organisms
EDTA	ethylene diamine tetraacetic acid
EG-AltstoffV	EC Regulations on Existing Chemicals
EMEA	European Agency for the Evaluation of Medicinal Products
EPA	Environmental Protection Agency
EPM	equilibrium partitioning method
EPPO	European and Mediterranean Plant Protection Organization
etc.	et cetera
EUSES	European Union System for the Evaluation of Substances
FAME	factorial extrapolation method
FOCUS	Forum for the Coordination of Pesticide Fate and Their Use
FRG	Federal Republic of Germany
g	gram
GefStoffV	Hazardous Substances Ordinance
GDR	German Democratic Republic
ha	hectare
i.a.	inter alia (among others)
i.e.	id est (that is)
ISO	International Organization for Standardization
KCl	potassium chloride
kg	kilogram

K_{OC}	sorption coefficient standardized for the organic carbon content
K_{OW}	n-octanol / water partition coefficient
l	liter
LAWA	Working Group on Water of the German Länder
LC_{50}	concentration of the test substance at which organisms exhibit 50% mortality
LOAEL	lowest observed adverse effect concentration
log	logarithm
m^3	cubic meter
mg	milligram
mm	millimeter
MPC	maximum permissible concentration
n	number
N	nitrogen
NER	nonextractable residues
NOAEL	no observed adverse effect level
NOEL	no observed effect level
NTA	nitrilotriacetate
P	phosphorus
PAH	polycyclic aromatic hydrocarbons
Pb	lead
PBT	persistent, bioaccumulating and toxic substances
PCB	polychlorinated biphenyls
PEC	predicted environmental concentration
PELMO	Pesticide Leaching Model
pk_a	acid constant
PNEC	predicted no effect concentration
POP	persistent organic pollutants
QSAR	quantitative structure activity relationship
resp.	respectively
SETAC	Society of Environmental Toxicity and Chemistry
SLV	German Educational and Experimental Institute
sol.	solution
SSD	species sensitivity distribution
t	tonne
TA	German Technical Instructions
TER	toxicity exposure ratio
TGD	Technical Guidance Documents
TME	terrestrial model ecosystem
TOC	total organic carbon
TV	test value
VPVB	very persistent and very bioaccumulative chemicals
y	year
WHC	water holding capacity
WS	water solubility
Zn	zinc

Summary and Outlook

In Germany, the estimation of tolerable soil contamination levels through chemical emissions is subject to both the Chemicals Act (ChemG) and the Soil Protection Act (BBodSchG). The Chemicals Act is geared to protecting humans and the environment from the harmful effects of hazardous substances and preparations (chemical substances legislation). The preventive soil protection requirements set down in the Soil Protection Act aim at preventing the occurrence of harmful changes or adverse effects to soils (media-based legislation). Preventive levels have thus far been derived for the following substances: polychlorinated biphenyls, benzo(a)pyrene, polycyclic aromatic hydrocarbons (PAH), and the heavy metals cadmium, lead, chromium, copper, mercury, nickel and zinc.

In applying the two acts, a risk assessment must be carried out with respect to determining tolerable emissions onto or into soils. Using the TGD on chemical evaluation as a basis, this project group was geared to demonstrating where action is necessary and suggesting solutions. The criteria and strategies of the Soil Protection Act were also included in the new test strategies for risk assessment of chemicals in soils, so that it would appear possible to achieve uniform approaches, which satisfy both laws and avoid differing methods, an increased testing load, and possibly different evaluation results.

Emissions via the air route (deposition) and through the application of sewage sludge, as given in the TGD, represent only a portion of the multitude of possible emission routes. This report thus includes additional routes, quantifying them to the extent possible. A determination of which emission routes are relevant for a chemical substance and should be considered in a PEC calculation depends on the compound's properties and pattern of use.

In discussing estimates of exposure to organic substances, the abiotic and biotic degradation in the soil should be considered to be the decisive parameter. Half-lives, calculated according to correlations based on data from aquatic degradation tests and given in the TGD, can be seen as only rough estimates. If a substance is emitted into the soil, a degradation test in soils is recommended to determine valid half-lives.

This report shows under what conditions a simpler and more economical determination of primary degradation in the soil suffices and when the mineralization of the compound in the soil should be determined. Adequately tested methods are available and the necessary bordering conditions for testing (e.g. suitable reference soils, soil deposits and pre-incubation) are presently being clarified by research activities.

To determine the exposure of organisms, the bioavailability of the toxic substance in the soil is a key property. Since the bioavailability depends on the properties of both the compound and the soil concerned, as well as on the uptake route of the organisms under consideration, a sufficiently accurate estimate is not yet possible. Available calculating models and their methods and limitations for various substance groups are presented and discussed. Research is urgently needed here, however, as a better characterization of the bioavailable proportion of the toxic substance would permit the extrapolation of test results from one soil to another. This is imperative to reduce the number of tests presently employed and to create the strongly defined statement of risk assessment required.

With regard to the determination of effect concentrations, the database for terrestrial tests was shown to be inadequate in many cases. This is an unsatisfactory result and an attempt is being made to compensate, at least in part, for the lack of terrestrial tests by including aquatic test results. The sections of this report regarding this point confirm that there is presently no scientific verification by means of valid correlations for an extrapolation of aquatic toxicity data to the terrestrial compartment. “Normally ”, therefore, data from at least two acute terrestrial tests should be available. If few or no ecotoxicity data are available for the terrestrial compartment, it may be useful to include, in addition to an acute terrestrial test, an estimate by the EPM (**E**quilibrium **P**artitioning **M**ethod) for screening purposes. This applies only to water-soluble substances, however, for which soil solution represents the main exposure route. For substances for which this is not to be assumed due to their physicochemical data (log K_{OC} > 4 or log K_{OW} > 5), an acute test and a chronic test should be conducted. At a PEC/PNEC ratio of > 1, aquatic toxicity tests can also be used as the basis for selecting suitable terrestrial tests, in order to determine the sensitive characteristic values for the substance-specific effect.

This report gives an extensive overview of the testing and derivation strategies currently proposed in the literature. It may be seen that the test strategies presented in

4.2 for detecting the effect on soil organisms are quite similar regarding the tests suggested, due to the fact that their selection was based primarily on criteria of ecological relevance and practicability. The proposals are also similar in that they provide little guidance on when which test should be carried out. And this is just what is needed for multistage test batteries. Differences exist mainly with respect to the particular application (e. g. pesticides versus environmental chemicals) and the environmental compartment considered (e. g. soil versus aboveground biotope). As none of the proposed test strategies have gained international acceptance so far, the determination of a single test strategy appears to be urgently needed.

The situation is markedly clearer for the derivation strategies. Apart from the simple, long-used factor model (FAME), only the distribution model DIBAEX is in frequent use, e. g. by a BVB expert committee for working up test values (Wilke et al. 2001). In the evaluation of industrial chemicals, the PNEC was previously derived exclusively via evaluation factors (factor model). In the revised version of the TGD, it will also be possible, in principle, to determine the PNEC by the methods of Species Sensitivity Distribution (SSD model), if certain minimum requirements for the available data set are met. To determine the PNEC, however, the derived HC5 value must then be divided by an evaluation factor, which reflects the remaining uncertainties in the extrapolation of monospecies laboratory tests onto the entire ecosystem as protection target. The use of the SSD for soils is made more difficult by the fact that sensitivity differences can be partially caused by the use of different soils.

On the whole, an adequate foundation exists for making a coordinated proposal for a risk assessment of chemicals in soils, based on the summary of previous experience (see Chapter 5).

The reservation should be made, however, that both in the evaluation of existing propoals and in the formulation of an improved terrestrial test battery, apart from pure scientific criteria (such as the ecological relevance of potential test organisms), other criteria must also be taken into account (e.g. the scope and the general cost-effect ratio).

The test strategies summarized in Chapter 5 are preceded by the model calculations on the various relevant introduction routes:

- Wet or dry deposition (model calculation according to the TGD)
- Sewage sludge application (model calculation according to the TGD)
- Irrigation (model calculation proposed in this report)
- Direct emissions (calculation model proposed in this report).

To calculate the PEC_{soil}, the degradation of the compound in the soil as essential elimination route, and thus the concentration in the soil, must also be taken into account. The extent to which a simpler determination of the DT_{50} value is sufficient, and under what conditions the mineralization should be determined, is explained in this report and integrated into a multistage plan.

The determination of the $PNEC_{soil}$ is analogous. Soil-biological tests suitable for a multistage plan are performed with microorganisms, plants and animals, so that, through the compilation of standardized test methods, the user is assisted in selecting a suitable, case-specific test concept. At a PEC/PNEC ratio > 1 after the first stage, one can carry out additional tests (e. g. degradation tests) for a valid calculation of the PEC, as well as other terrestrial ecotoxicologic tests (primarily chronic procedures) to further improve the determination of the $PNEC_{soil}$. If no clear evaluation is possible at this stage either, indications are given for handling decision-making on such individual cases.

Much less experience is available for a risk assessment in the terrestrial compartment than in the aquatic compartment, although the terrestrial compartment has increasingly gained in importance and attention – as shown by the fact that the Soil Protection Act (BBodSchG) was passed in Germany. Therefore, the proposed scheme should be tried out on selected compounds to examine and document the usefulness and practicality of the multistage method, and thus gain further important experience in the risk assessment of soils. In addition, such a demonstration could confirm that the proposed test schemes fulfill the criteria, principles, and requirements of both the Chemicals Act and the Soil Protection Act.