technische
commissie
bodembescherming

ECOLOGICAL RISKS OF SOIL POLLUTION

ECOLOGICAL BUILDING BLOCKS FOR RISK ASSESSMENT

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For Risk Assessment

Jack H Faber
DLO/Institute for Forestry and Nature Research (IBN-DLO)
Ecotoxicology Department
P O Box 23, 6700 AA Wageningen
The Netherlands

with contributions from

Bart Bosveld (IBN-DLO, Ecotoxicology Department)
Jan Dolfing (AB-DLO, Soil Ecology Department)
Jan Japenga (AB-DLO, Soil and Environmental ChemistryDepartment)
Chris Klok (IBN-DLO, Ecotoxicology Department)
Anje-Margriet Neutel (AB-DLO, Soil Ecology Department)
Peter C de Ruiter (AB-DLO, Soil Ecology Department)

TCB R07(1997)

The Hague
Dutch version· October 1997
English version. February 1998

Technical Soil Protection Committee, P.O Box 30947, 2500 GX The Hague,
The Netherlands
Tel +31 (0)70 339 30 34; fax +31 (0)70 339 13 42

FOREWORD

In 1995, the Technical Committee on Soil Protection published the report entitled `Protection of Organic Soils'. Following this report it was concluded that the methods and means of substantiating ecological risk evaluation for the soil were limited. The committee decided on a follow-up project entitled `Ecological Risks', which focused on the question: "What is lacking in ecological risk evaluation? The following were seen as major components of this project

- a methodological consideration of human toxicological criteria in relation to ecotoxicological criteria in risk evaluation;
- the exposure of ecosystems to substances,
- spatial and temporal aspects of ecological risks,
- exploration of the concept `ecology related to land use'

It was acknowledged from the start that it would be difficult to put meat on the bones of all these components. The project would be an `explorative' one, searching for new paths to take. In the end, it proved impossible to flesh out `exposure', and to do so only partially for `spatial and temporal aspects'

It therefore took a long time to complete the end-product of the project, this present report Intensive cooperation was required to this end between the person conducting the project and staff of the committee's secretariat, with everyone spending more time and energy on the project than had been foreseen.

As a result of the swift developments in this field and the long completion phase of the project, certain parts of this report are already somewhat dated, e g the present status with regard to ecological risk assessment for purposes of standard setting On the other hand, other topics, such as `ecology related to land use', are presently more topical than they were at the time the project commenced.

The project was conducted by J.H. Faber of the Institute for Forestry and Nature Research (IBN-DLO), with assistance from a number of colleagues The committee hopes that the report will contribute to the still topical discussion on ecological risks and does indeed produce usable `building blocks'. The positions taken in this report are those of the author and are not necessarily shared by the committee.

CONTENTS

SUMMARY

This report looks at the ecological risks of soil pollution Until now the contribution made by ecology and ecotoxicology to ecological risk evaluation as employed and prescribed by the government in the Netherlands has remained fairly limited The development and performance of single-species tests and methods for arriving at an estimate of a risk limit on the basis of the results of these tests was the matter of primary importance Indications were received from various sides that more input from ecology and ecotoxicology was desirable and necessary. Moreover, ecological risks play a part in other areas as well and not just in the derivation of risk limits for standard setting

The report breaks down into three topics, on which the input of more information from ecology and ecotoxicology is deemed desirable and possible

- ecological risk assessment for standard setting (Chapter 2);
- ecological risk assessment and evaluation in cases of soil pollution (Chapter 3),
- ecological soil characterization related to land use (Chapter 4)

The chapters can, if wished, be read separately (together with the introduction)

The section on `ecological risk assessment' for standard setting describes the methods used in assessing risks in both ecotoxicology and human toxicology (Chapter 2) The underlying question is whether ecotoxicology can `learn' from the risk assessment methods used in human toxicology, which methods are fairly generally accepted. The conclusion of this section is that the same indicators for exposure are recognized in ecotoxicology and human toxicology and the same endpoints are used Within human toxicology every indicator can be used to arrive at standards; within ecotoxicology the indicators are limited to those deemed of importance for the continued existence of a population. growth, reproduction and mortality of single individuals Ecotoxicological risk assessment for standard setting is different, but no better or worse than human toxicological assessment It is in principle less protective and can be described as being less subjective than human toxicological risk assessment Ecotoxicological risk assessment could `learn' from human toxicology in particular in the sphere of exposure, the use of field observations (epidemiology) and the use of expert judgement.

In the section on `ecological risk assessment and characterization in cases of soil pollution' a distinction is drawn between the terms `generic risk assessment' and `site specific risk assessment' (Chapter 3) A risk assessment is based on general knowledge acquired in the laboratory and is by nature predictive In this case policy refers to potential risks In a site specific risk assessment, use is made of actual facts on and about the soil pollution in a concrete situation and involves actual risks Depending on the method(s) used or to be used, it is possible to point to combinations; e g deriving a risk from soil pollution based on soil chemical and soil physical observations in the field, combined with a model that describes the uptake by and effects on given species In this section, methods are described which could be used in the short term to estimate and evaluate risks of soil pollution. The methods are divided per biological level of organization, from sub individual (biomarkers), via individuals and populations (population models) to ecosystem level (food webs) Specific attention is focused in these methods on exposure

In the third section, concerning `ecological soil characterization related to land use', it is a question of how to judge whether a soil is suitable for a given use, even if the soil is or will not become completely clean (Chapter 4). First of all, a description is given of use-specific standards currently employed. In addition, this section looks at the possibilities and impossibilities of standards differentiated according to use. The conclusion drawn is that current use-specific standards often fall short where ecological functions necessary for common forms of landuse are concerned As an alternative, ecological parameters are suggested for each form of land use A new element in this is the role of flora and fauna occurring exclusively in the built environment (eusynanthropic species). It is stated that the use-specific ecological parameters need not necessarily be translated into standards, and that the possibilities for this are fairly limited anyway. In the case of determining damage, more is expected from naming indicator species per ecological parameter and basing the characterization on the condition of these parameters The use of expert judgement is desirable. Where achieving a given use is concerned, the ecological requirements to be met by the soil need to be recognized and guaranteed in order to achieve that use properly.

1 INTRODUCTION

The environment in the Netherlands is being polluted by a wide variety of substances which are endangering the quality of the environment (Bink *et al*, 1994; RIVM, 1995). Environmental policy therefore gives high priority to combating the dispersion of pollutants in the environment. The general starting point is sustainable development, with the possibility of guaranteeing good environmental quality in the long term as well (TK, 1993) Policy is developing along two tracks. the source-oriented track and the effect-based track The effect-based track examines the possible effects of a given quantity of a substance in the environment. Based on an evaluation of toxicological risks of a given substance, environmental quality targets are set via integral standards for the concentrations of this substance in the environmental compartments of water, soil and air

For the soil there is, in addition to the preventive source-oriented and effect-based approach, specific policy on sanitation The soil commonly acts as a sink for pollutants Soil pollution is often of a persistent nature and does not diminish once the source has disappeared The use of methods for evaluating the risks of concrete cases of pollution is especially important for soil sanitation A distinction is drawn between three types of risk.

- risks to humans,
- ecological risks to flora, fauna and microbial processes,
- risks of dispersion of the pollution in or of degradation in some other way of ground water stocks, minerals, and effects on the quality of drinking water and substance life cycles

Cleaning up cases of serious soil pollution is motivated by these risks. This then requires an understanding of both potential and actual risks in regard to human and ecological aspects, as well as the risk of further dispersion of the pollution

The present report looks in particular at methods of evaluating the ecological risks of substances for the soil which are or can be used to derive general environmental quality targets and to evaluate specific cases of soil pollution.

Ecological risk characterization can be carried out with various targets in mind:

- setting priorities in soil use and management;
- drawing up standards and guidelines,
- determining risks as input for making decisions in risk management.

These targets are often related to laws and government decrees regarding environmental policy. Also, there is an increasing demand for methods of ecological risk characterization from the point of view of nature policy, both in regard to (endangered) species policy and, for example, in regard to the organization of the national network of important ecosystems (nature development and changes in land use)

Until now risk characterization has focused greatly on underpinning standard setting, with data from laboratory research being converted into standards in line with standardized methods of calculation This approach is limited because ecological risks relate to several levels of biological integration (e.g. individual, population, ecosystem), several levels of scale (e.g from local population to species area and from local biotic community to biomes), and various dimensions (structures and functions) In addition, spatial heterogeneity contributes horizontally and vertically to the diversification of ecological risks

Although the toxic effects of pollution of the environment on flora and fauna in the Netherlands have been well documented in various cases (Denneman *et al* , 1986, Elbers and Douben, 1993, Bink *et al* , 1994), it is still not possible to properly predict the effects when risk limits based on laboratory tests are exceeded This is linked on the one hand to the fact that there is still only very little ecotoxicological information on toxicity available for many substances On the other, ecotoxicological risk characterization is still mainly based on the effect limits of individual substances in individual species, established on individuals in the laboratory How this information can be translated on to the level of the ecosystem is unclear due to insufficient insight into bioavailability, population biology and dynamics, inter-species relationships and system interactions.

These limits of ecological risk characterization are generally acknowledged and constitute a subject of discussion. Consequently, in various contributions to this discussion it is proposed that ecotoxicological research be broadened and made more comprehensive (RMNO, 1993, Eijsackers, 1994, Kammenga and Schobben, 1994, 1995; RMNO/NRLO, 1993; Van Straalen, 1994; Zehnder, 1994; Gezondheidsraad, 1995, Hensbergen and Van Gestel, 1995, Van de Guchte *et al* , 1996, Van Straalen and

Løkke, 1997) or that the application of this research be broadened and deepened (TCB, 1990a; Bergema and Van Straalen, 1991; Van Leeuwen, 1993, Faber, 1995, SOEO, 1995)

Many of these contributions relate to suggestions concerning the direction of research, the results of which can only be expected in the long term This report contains an investigation of the possibilities for giving greater depth to ecological risk characterization in the short term For this purpose three forms of risk characterization are considered:

- the present methods for deriving generic standards,
- for evaluating potential and actual risks on a polluted site, and
- when evaluating the suitability of a polluted site for specific human land use functions

With regard to standard setting, a comparison is made with risk limits from human toxicology and their application. Providing a scientific basis from the direction of human toxicology is far less exposed to criticism because human toxicological risk assessment is assumed to be based on a `hard' interpretation and extrapolation of toxicity data and a good description of exposure routes relating to the subject to be protected. In human toxicological risk assessment, epidemiological research is used in addition to laboratory tests on laboratory animals, and expert judgement is frequently called upon The relationship between these types of standard setting and the possibility to distill a guideline for the further development of ecological risk assessment from a comparison with human health risk assessment is to a large extent of a methodological discussion (Chapter 2) A critical consideration and comparison of much-used methods for dose-response assessments and extrapolation from both human toxicology and ecotoxicology are given in the Annex to this report.

Chapter 2 places emphasis on the methods currently used in standard setting. Within ecology and ecotoxicology new methods are and are becoming available which can be used for setting generic standards In addition, there is a great need for methods that can be used in the relatively short term as building blocks for evaluating the ecological risks of a polluted site, i.e. evaluating the risks or impacts of pollution present in the soil. Chapter 3 will discuss new developments which may be useful both in estimating potential risks (standard setting) and actual risks (evaluating a concrete case of polluted soil)

Chapter 3 will not address old and new developments on which far more research still needs to be done before they can be used. A number of suggestions are made on direction in a relatively short space, with no attempt being made to achieve completeness or go into any depth These suggestions could be worked out in more detail in a different context. The approach is such that examples are given both in the direction of various aspects of exposure and in the direction of effects on various levels of biological integration, from sub individual to ecosystem. It should be possible to incorporate these examples into various procedures relatively swiftly

Finally, the discussion of ecological risks is related to the actual exposure of organisms present and their functioning in relation to the use of the soil The departure point in the Dutch Soil Protection Act is to maintain or restore multifunctionality Ideally, a polluted soil should be brought to this level of quality through sanitation or management If multifunctionality cannot or will not be restored, the question arises as to the purpose for which the site is still suitable. A location-specific, function-based characterization is in that case the obvious answer, with the risks of the various forms of use possible at that location (potential uses) being evaluated An ecological risk characterization is also important in this form of appraisal, and could be called a `soil suitability assessment'.

A specific type of soil suitability assessment is used in connection with building permit applications, in which a judgement is made on whether the soil is suitable for its intended use. This judgement is presently based to a large extenton actual exposure risks to humans (Moet, 1995). This can result in an area of tension because the suitability of the soil cannot be judged on the basis of the toxic effects on humans alone (TCB, 1995) The soil will also need to meet ecological and other quality requirements, bearing in mind the use of the soil (agriculture, public parks and gardens in an urban environment, vegetable gardens, ornamental gardens) So, the question of the suitability of polluted soils for given forms of use demands a further exploration of these quality requirements The report therefore ends with a consideration of the possibilities for arriving at an `ecological assessment related to land use', so that the usability of soil or of a site is measured not simply in terms of possible health risks to humans (Chapter 4)

The terms `risk characterization' and `risk assessment' are in general used interchangeably. The distinction between these terms is not easy to define. `risk assessment' could be considered a more predictive process than `risk characterization'. In that case `risk assessment' is more applicable to methods by which a

prediction is made of the risks emanating from a specific concentration of a substance in the soil on the basis of general ecotoxicological data and/or models, or vice versa, to predict the concentration of a substance in the soil appertaining to a given prefixed risk limit (standard). In the international literature these methods are labeled "generic risk assessment". In Dutch soil policy this falls within the scope of the definition of **potential** risks `Risk characterization' would then be applicable to methods by which an actual situation in the soil is evaluated and would be based as a minimum in part on location-specific measurement data These methods are generally labeled "site specific risk assessment" in international literature In Dutch soil policy this falls within the scope of the definition of **actual** risks This report endeavors to maintain this distinction (see also diagram 1) The term `risk characterization' could be reserved for the decision-making process in which social considerations are included alongside ecotoxicological risk assessment/appraisal

Diagram 1. Distinction between risk assessment, risk characterization, potential and actual risks

Generic risk assessment	Site specific risk assessment
Prediction of potential risks (the risks that might occur) in the case of a hypothetical concentration of a substance in the soil, based on general toxicological/ecotoxicological laboratory and other data and models. The reverse method, namely predicting the concentration in the soil with a risk having been established in advance is currently used for setting generic standards	Establishing the actual risks (or harm) from a measured concentration of a substance at a concrete site based on location-specific knowledge or bioassays for exposure and/or ecotoxicological effects, often supplemented by extrapolation models

2 RISK ASSESSMENT AND STANDARD SETTING

This chapter compares the procedure pursued in assessing risks for standard setting within the domains of toxicology/human toxicology and epidemiology and assessing risks within the discipline of ecotoxicology A risk assessment is based on the establishment of a `safe' concentration of a substance for objects that are to be protected in Dutch policy these are humans and `the ecosystem' In addition, it is necessary to establish how great is the risk of a safe concentration being exceeded in a given instance, which requires consideration of the risk of exposure

Both in human toxicology and in ecotoxicology use is made of dose-response relationships in indicator species for establishing safe concentrations of substances. There are many methods of establishing these relationships and deriving a safe concentration from them Table 1 summarizes a number of much-used methods When acceptable concentrations of exposure have been established for indicator species, it is usually impossible to use them directly in a risk characterization It is necessary to extrapolate them from laboratory animals to humans, for example (Table 2). These basic ingredients of a risk characterization, together with their advantages and disadvantages, are discussed in the Annex to this report

2.1 HUMAN TOXICOLOGICAL AND EPIDEMIOLOGICAL RISK ASSESSMENT

The crucial component of a risk analysis for the soil is the comparison of the estimated exposure to soil pollutants with `safe' threshold values established in toxicological/ecotoxicological research Various criteria are employed, depending on the discipline and the type of substance For non-genotoxic substances an acceptable daily intake (ADI) is employed in human toxicological risk assessment, together with a hazardous concentration (HCp) in the ecotoxicological pendant (see section 2.2) Genotoxic substances are based for humans on a maximum tolerable risk (MTR) of 10^{-6} $year^{-1}$, whilst for the ecosystem no separate standard has been established for the time being for genotoxic substances due to a lack of data (VROM, 1988)

Table 1. Methods for establishing dose-response relationships. These are discussed in the Annex.

- no observed effect level
- benchmark dose
- Gaylor's linear extrapolation
- bounded effect dose
- no-effect level
- dose-severity diagrams
- various models for genotoxic substances

Table 2. Extrapolation methods plus description of the step These methods are discussed in the Annex

Method	Extrapolation from:
- Safety factor method	- Laboratory animal to humans
- Renwick's safety factor method	- Laboratory animal to humans
- Allometric scaling method	- Animal to animal or humans
- The rule of Haber *et al*	- Length of exposure to different length of exposure
- Route to route	- Exposure route to another exposure route
- PBPK modelling	- External dose to internal dose

2.1.1 MTR for non-genotoxic substances: ADI

In human toxicological risk assessment the ADI[1] is as a rule based on the NOEL from animal experiments, generally supplemented by epidemiological data, divided by a safety factor (see the Annex). Traditionally, this safety factor consists of two factors of 10, for the extrapolation from animals to humans, and for the extrapolation for differences in sensitivity within the human population These factors can be traced back to a study of the literature carried out in the fifties for the US Food and Drug Administration concerning the relative sensitivities of humans to food additives compared with laboratory animals. On the basis of scanty data it was concluded at the time that a safety factor of 100 would provide sufficient protection This means that the derivation of the ADI for humans is not based solely on scientific research. The ADI thus established can therefore be seen as a convention It is advisable to consider this criterion, and every standard derived from it, as a non-exact point surrounded by a broad safety zone (Figure 1), and not as a sharp dividing line between `safe' and `unsafe' (Ferguson and Denner, 1994) Consequently, establishing a

1 In EPA terminology the definition of the ADI is comparable to the definition of the "Chronic Reference Dose" (RfD) *"a quantitative estimate (with uncertainty spanning perhaps an order of magnitude) of a daily exposure to the human population (including sensitive subgroups) that is likely to be without appreciable risk, i e without suffering significant adverse health effects, during a lifetime"* (EPA, 1993) N B sick people are not counted among the "sensitive subgroups"

given concentration as a standard is not exclusively a scientific choice but mainly a policy one, allowing the pros and cons to be weighed up as well

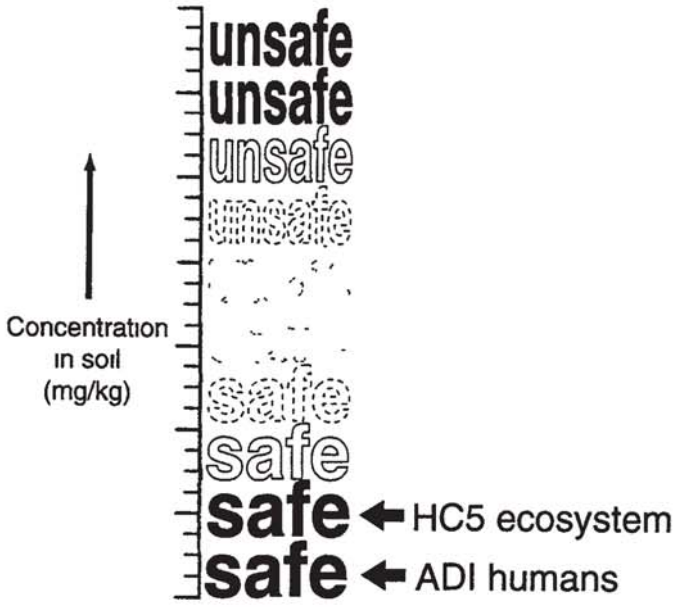

Figure 1. Diagram of `safe' and `unsafe' zones for non-genotoxic substances, separated by gradient zones (developed by: Ferguson and Denner, 1994)

For the sake of completeness it should be noted that in addition to the ADI, a tolerable daily intake (TDI) is also used in cases in which not all the available toxicological data is used in the derivation The TDI can therefore be seen as a provisional ADI[2] . The weak points of the ADI also apply to the TDI no prediction of toxic effects in the event of the TDI being exceeded, no information on individual sensitivities, no probability of effects occurring can be given (at least when based on NOEL data).

It is further possible to break the criterion down according to exposure route. For example, a toxicologically tolerable concentration in air (TCL) can be established for inhalatory exposure, the US literature refers to an oral reference dose (ORD), inhalatory reference dose (IRD), etc In risk assessment in the Netherlands, exposure of the human population is admittedly estimated on the basis of various exposure routes (Van den Berg, 1995), but the risk as total exposure is compared with the ADI

[2] An ADI is established internationally by the WHO Prior to this the RIVM in the Netherlands can establish a TDI Another distinction between the two criteria is drawn according to the type of substance food additives are standardised by the WHO via an ADI, contaminants can be standardised by national governments via a TDI

As is observed *inter alia* in the Annex to this report, the ADI criterion (when based on NOEL data) cannot be used to indicate the probability of the occurrence of effects due, among other things, to the lack of information on length of exposure and differences in individual sensitivities and state of health. However, the complete process of risk assessment requires an uncertainty analysis[3] An ADI that is based on benchmark doses, or an analogy of these, can in principle provide this. To this end, old toxicological data would need to be worked out again in so far as possible. ADI criteria of this kind based on confidence intervals are not yet available. As an alternative approach, a study is therefore currently being made of whether statements about the probability of effects can be based on LOEL data, whereby the number of individual laboratory animals that experiences the effect in relation to the total trial group is interpreted as the risk of the effect If these `probabilities' were computed along epidemiological lines (see section 2 1 3), it would be possible to produce a more complete risk assessment (W. Mennes, oral statement).

2.1.2 MTR for genotoxic substances: 10^{-6} $year^{-1}$

With respect to genotoxic substances, the exposure of the population is compared with an acceptable risk. As regards the level of background radiation, an additional level of risk is established for carcinogenicity in the case of lifetime exposure (in the Netherlands 10^{-6} $year^{-1}$), after which an estimate is made of the associated highest dose at which this risk is not exceeded A different method is therefore pursued when deriving risk limits for non-genotoxic substances The resulting MTR for genotoxic substances cannot be used as a quantitative statement about the risk. The extrapolation of bioassay data to low doses does not permit a prediction about the associated risks (Mantel and Bryan, 1961). If the extrapolation is based on the ED_{50}, and not on the associated confidence interval, no statement can be made about the probability of the effect. It is better to consider the method for genotoxic substances as a way of identifying a dose, with it being unlikely that the risk will be greater than an operationally defined safety level. On this point quantitative risk assessment for genotoxic substances is a convention which expresses the concept of `approximately safe' (Ferguson and Denner, 1994)

It is impossible to predict how many additional cases of cancer would result in the event of lifetime exposure to a concentration based on the 10^{-6} criterion. At this level, the risk may be seen as virtually non-existent instead of the expectation that 1 in a million people exposed to a substance for life will develop cancer (Young, 1987)

[3] An uncertainty analysis for the CSOIL model is being developed by the RIVM (W Mennes, oral statement)

in a million people exposed to a substance for life will develop cancer (Young, 1987) The 10^{-6} is seen by the EPA as a theoretical risk that reflects the upper limit of the plausible risk The actual risk may be much smaller and sometimes even non-existent.

2.1.3 Exposure and actual risk

An inventory of direct and indirect routes by which humans can be exposed to soil pollution and its consequences is given in diagram form in Figure 2 This inventory (Linders, 1990) is based on a distribution of the pollutant over the soil phases (solid particles, pore water and soil air) and the occurrence of a series of transport processes that subsequently result in direct or indirect exposure A distinction is drawn between three direct routes of exposure, namely

- oral intake of soil, water and air;
- dermal contact with soil, water and air,
- inhalation of soil, water and air (not for inorganic compounds)

Added to this, indirect exposure may occur through the consumption of polluted food and drinking water

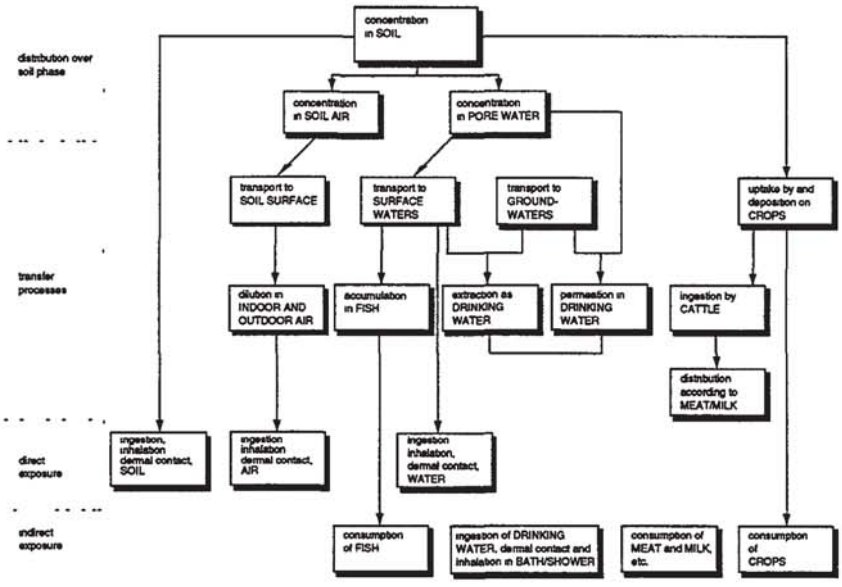

Figure 2. Diagrammatic overview of human exposure routes in the case of soil pollution (from: Van den Berg, 1995).

When proposals for the Dutch Intervention values (former C values) were calculated, a number of direct (surface water as contact medium) and indirect (via meat, fish and other animal products) routes were left out (Linders, 1990). Because

the assessment of the risk in question in the models HESP, SOIL RISK or CSOIL (Van den Berg, 1995) The SOIL RISK model only analyses the exposure for children as the most sensitive group, CSOIL provides a result for both children and adults in the case of lifetime exposure The estimated daily average dose calculated for comparison with the ADI is then based on an adjustment of the lifetime exposure of children and adults

On the basis of the CSOIL model, human exposure to substances from the test table contained in the Soil Protection Guideline in the case of soil pollution appears to be determined mainly by the ingestion of soil, consumption of crops and, in the case of volatile compounds, inhalation of indoor and outdoor air These routes contribute at least 90% to the total dose (Van den Berg, 1995) Exposure to metals occurs solely via the ingestion of soil and consumption of crops The relative contribution of each of these routes is substance specific (Table 3) Cadmium and zinc are mainly ingested through the consumption of crops, chromium and lead mainly through the ingestion of soil

Table 3. Example of the percentage contributions of the various exposure routes to the lifetime average daily exposure for metals, calculated using the CSOIL model. The calculations are based on a concentration in the soil of C_S (mg kg^{-1}) equal to the proposed human toxicological Dutch C value (Van den Berg, 1995)

Metal	C_S	DI_L	VI_L	Dose
arsenic	6 78E-02	49	51	2 10E-03
barium	4.26E-03	32	68	2 00E-02
cadmium	3 48E-01	5	95	1.00E-03
chromium (III)	2 25E-03	68	32	5 00E-03
chromium (VI)	3 15E-01	68	32	7 00E-07
cobalt	4 52E-02	49	51	1 40E-03
copper	1 57E-04	17	83	1.40E-01
mercury	1 97E-02	49	51	6 10E-04
lead	1 46E-03	61	39	3.60E-03
molybdenum	9.11E-02	14	86	1.00E-02
nickel	6 58E-03	20	80	5 00E-02
tin	6 46E-05	49	51	2.00E+00
zinc	5.65E-04	9	91	1 00E+00

DI_L, lifetime uptake via ingestion of soil (%),
VI_L, lifetime uptake of pollution via crops (%),
Dose, daily lifetime exposure (mg $kg^{-1}d^{-1}$)

Each of the parameters for transport processes and exposure routes employed in the CSOIL model contains uncertainties. These can sometimes be of some magnitude When CSOIL is used to underpin standards, the uncertainties are related to the

choices in regard to parameter values average situations and the middle of ranges If CSOIL were to be used to estimate the actual risk of exposure from soil pollution (with local parameter values and exposure routes being filled in later) the greatest uncertainties would lie in estimating the degree of accumulation of the pollutant in the crop and the scale of the soil dehydration flux in the inhalatory route (Van den Berg, 1995) CSOIL was not designed for estimating actual risks, incidentally

Background exposure played no part in determining the Dutch Intervention values using CSOIL. Background exposure, as established by Vermeire *et al.* (1991), for example, contributes to the total burden on humans However, the background does not cause effects and varies considerably locally. Because the Dutch Intervention values were compiled in order to establish a clear overrun of risk limits, no allowance was made for exposure to background concentrations

2.1.4 From exposure to effects on health

The health of the human population can be adversely affected by a wide range of environmental factors of a chemical, physical or biotic nature The chain of steps from exposure to effect on health can be described in terms of various types of indicator of health risks which are the result of environmental factors (De Hollander *et al* , 1995) These indicators are given in Figure 3A. This figure focuses on the individual The ecological consequences of changes in physiology and behaviour are not discussed, although these effects could be of importance to ecosystems (De Kruijf *et al* , 1984).

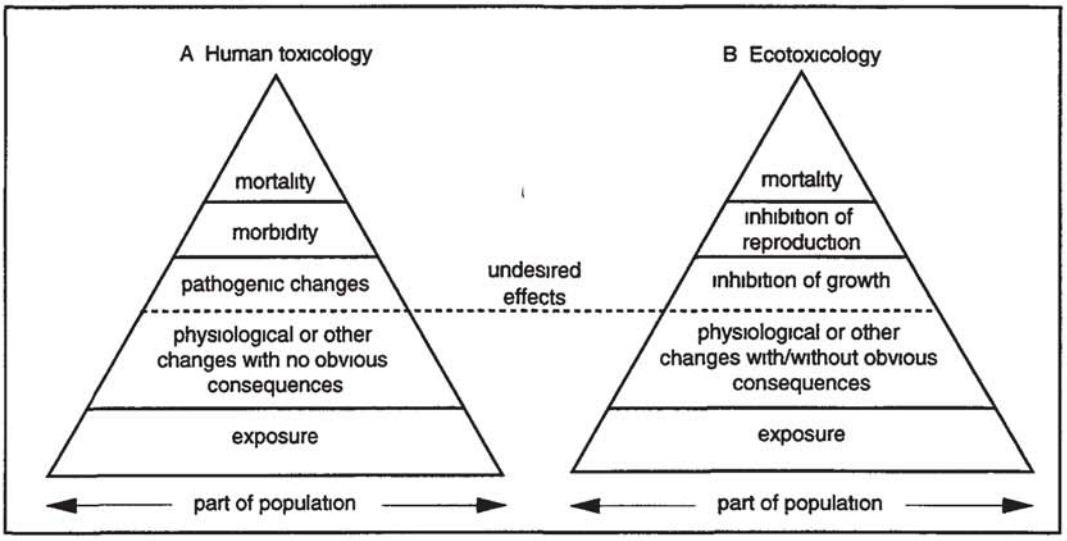

Figure 3. Diagram of indicators for the relationship between environmental factors and health in humans (from: De Hollander *et al*, 1995) and other organisms Behavioural changes are not indicated

Exposure to chemical, physical or biotic factors can be described, for example, as concentrations in air, food and drinking water or the level of noise in the environment The exposure of the individual, which frequently occurs via several routes and in several places in the environment depends as a rule to a large degree on the individual's surroundings and lifestyle. In most cases it is therefore difficult to give an accurate estimate for the (Dutch) population

Body burden as a result of exposure can be established or estimated by measuring the concentration of harmful substances or their metabolites in tissue or body fluids With regard to pathogens it is possible to test for infections

Examples. cadmium in urine, lead in blood, chlorinated hydrocarbons in breast milk; strontium in bone tissue.

Physiological changes as a result of body burden lie within the normal range of biological variation, or slightly higher, with no obvious effect on health

Examples enzyme induction after exposure to solvents, marginal, reversible loss of lung function during smog, induction of HFO enzyme system after exposure to polychlorinated biphenyls or polycyclic aromatic hydrocarbons

Pathogenic physiological changes or reduced organ functions result in sickness or harm social functioning and quality of life.

Examples. disrupted development of the intelligence in children suffering chronic lead exposure; pollen allergy, sleep and concentration disorders as a result of air traffic noise.

Illnesses and complaints may have their origin in the environment With the exception of infectious diseases it is impossible, however, to give a reliable quantitative estimate of the degree to which the environmental factor causes the development of the illness.
Examples: CNSLD (e g asthma and hayfever) and lung cancer as a result of air pollution
Mortality, mainly in the meaning of potential years of life lost.
Examples: excessive mortality during periods of air pollution, infectious diseases

2.1.5 Assessment of health risks from environmental factors

Historically, the toxicological assessment of health risks has mainly been targeted at the nature and scope of effects of single factors at the level of the individual To protect the health of employees or residents it was usually a case of establishing safety levels in their exposure to chemical, physical or biotic stressors These safety levels were based on early responses in laboratory animals and a safety margin or results of models that probably overestimated the risk Most assessments of this type therefore are of less importance for predicting the actual occurrence of effects in terms of public health. From the point of view of public health it is stating the obvious to say that it is also of importance how exposure and the associated risk is distributed within the population, what proportion the sensitivity of the most sensitive individual bears to that of the most insensitive, and to what extent there is an accumulation of health-threatening factors Predicting the effects of environmental factors on health at the level of populations is still in its infancy, however (De Hollander, 1995)

In epidemiological research, the contributions of various risk factors (lifestyle factors such as smoking, alcohol consumption, exercise and diet, as well as biological risk factors such as blood pressure, cholesterol levels, glucose tolerance and body weight index) to mortality as a result of a number of chronic diseases have been quantified recently as population-attributable risks (PARs) (Verschuren *et al*, 1995) PARs are calculated on the basis of the relative risk and the part of the population actually experiencing the risk factors The relative risk (RR) indicates the degree of association between the risk factor and the occurrence of a given disease It indicates how much greater is the risk of developing the disease for the population group confronted with the risk factor, compared with the group not exposed to the risk. The PAR gives the fraction or percentage of the number of cases

of illness that can be attributed to a given exposure, calculated in accordance with the following formula:

$$PAR = \frac{P_e(RR-1)}{P_e(RR-1)+1}$$

where P_e stands for the fraction of the population in which the risk factor is present and RR is the relative risk of the disease in the presence of the risk factor (see above) Thus the PAR is determined by the degree to which the risk factor and the RR are present Figure 4 shows how, with a given RR, the PAR changes as a function of the size of the exposed part of the population.

In the epidemiological approach according to PAR there are still a number of methodological problems relating to, among other things, the causality of the relationship between the risk factor and the toxicological endpoint (the illness or mortality) and the lack of information according to the PAR about the time interval between exposure and death. It is further assumed that the RR is equal for all groups within the population irrespective of age and sex. Often, not enough data is available on this point to arrive at a group-specific PAR. Added to this, data on RRs from the literature is often used which is non-specific to the population to be described Variation in the RR value is in that case possible as a result of differences between studies, for example, the length of the study, choice of population group, corrections (if any) for interaction with other variables, or differences in the level and duration of exposure Furthermore, it is impossible to establish threshold values for a number of risk factors above which the risk increases, so that refuge is sought in categorical classification in order to calculate the RR in question (Verschuren *et al*, 1995).

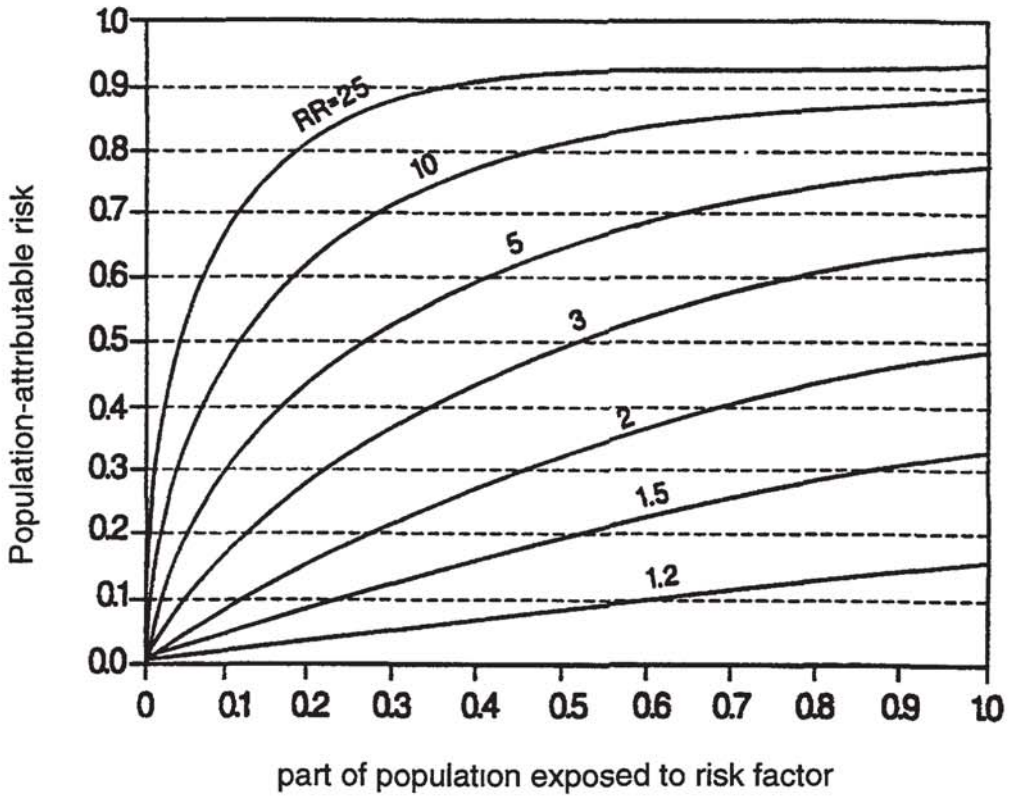

Figure 4. Size of the population attributable risk (PAR) as a function of the relative risk (RR) and of the degree (fraction) to which the risk factor occurs in the population (fraction) to which the risk factor occurs in the population

Also, a development is under way in which indicators for sickness and mortality of the individual are merged into combined indicators that are not only representative for the length of life but also for the quality of that life. These indicators include `healthy life expectancy', `complaint-free life expectancy' and `handicap-free life expectancy' (Van de Water *et al.*, 1995) It goes without saying that in this case the definition of health is of crucial importance. Internationally, the model of the International Classification of Impairments, Disabilities and Handicaps (WHO, 1980) is taken as starting point:

disease/disorder ---> impairment ---> disability ---> handicap.

The fact that some aspects of public health, in particular mental health, receive less attention is consequently mentioned as a point of interest for the further developments in this approach Further refining of the reflection of the quality of life is also desirable to the extent that the differences in the seriousness of poor

health or losses of function should be better expressed, perhaps in the form of correction factors (Wilkins and Adams, 1983)

Notwithstanding these restrictions, the `healthy life expectancy' indicator (HE) is valued above the traditional measures for public health on account of its integral nature HE contains information about mortality as well as illness (and the consequences of illness) Quantitative priorities for public health policy can be formulated on the basis of considerations concerning which measures to combat illnesses contribute most to healthy years of life (Choices in Care Committee, 1991) The strength of the HE is acknowledged by policymakers and politicians, and the elaboration of the HE has consequently been incorporated in various policy memoranda (WHO, 1985, 1991; WVC, 1991).

2.2 ECOTOXICOLOGICAL RISK ASSESSMENT

Much development of environmental quality standards has taken place recently under the heading `ecological risk assessment' (EPA, 1984, 1986; Kooijman 1985b, 1987, Stephan *et al*, (1985), Van Straalen and Denneman, 1989, Barnthouse *et al*, 1990, Van de Meent *et al*, 1990, Fordham and Reagan, 1991, Van der Gaag *et al.*, 1991, Wagner and Løkke, 1991). Various aspects of the process of ecological risk assessment have been fleshed out by these methods The contribution of each individual method must principally be seen in the context of self-specified targets. Thus, Barnthouse *et al* (1990) give a procedure for deriving a substance-specific and species-specific critical concentration in a sector of the environment, the maximum acceptable toxicant concentration (MATC), whilst Van Straalen and Denneman (1989) provide a basis for risk assessment at ecosystem level, the `HC5', based on NOEC data for soil invertebrates in simple exposure situations in the laboratory. In Dutch risk policy a modification (Aldenberg and Slob, 1991) of this last approach is adopted in order to flesh out the maximum tolerable risk (MTR) for pollution of the soil ecosystem. A negligible risk (NR) is then derived from the MTR via a safety factor

2.2.1 MTR for non-genotoxic substances: HC5

A number of the above methods for ecotoxicological risk assessment have been compared (Health Council, 1988, BKH, 1990; Okkerman *et al*, 1991; Calabrese and Baldwin, 1993) The methods of the EPA (1984) and Stephan *et al*, (1985) are deemed less reliable than those of Van Straalen and Denneman (1989), the EPA approach is deemed to have insufficient scientific basis, and the method of Stephan

et al is extremely limited by the departure point of a triangular distribution in sensitivities and selection of the four most sensitive species (Okkerman *et al.*, 1991) These methods have found little support in the Netherlands and are not discussed here any further. A number of the striking aspects of the Van Straalen and Denneman method (currently known as Aldenberg and Slob) are discussed, but no attempt has been made to be complete

Van Straalen and Denneman's approach (1989) was initially developed for evaluating policy proposals for quality standards for the soil based on ecotoxicological effect data (Schobben *et al*, 1989); Traas *et al*, 1989), and was founded on the work of Kooijman (1987) The method gives an estimate of the hazardous concentration (HC) at which p% of the species in the biotic community might feel an effect This approach differs from that of Kooijman, which aims at an HC for the most sensitive species. In the case of species-rich systems Kooijman's method results in a much lower acceptable concentration.

Van Straalen and Denneman's method (1989) expressed as a formula

$$HCp=\exp(x_m-s_m d_m k_p)$$

where·

x_m= average of m NOEC data (standardized for the clay and organic matter content of the test substrate), each transformed into the natural logarithm;

s_m= standard deviation of the m ln(NOEC);

d_m= a factor dependent on the size of the random sample m (Kooijman, 1987);

k_p= a factor dependent on the percentage of unprotected species p

The extrapolation methods of Kooijman/Van Straalen and Denneman are technically comparable and are based on a distribution of sensitivities of species which is founded on four basic assumptions (Kooijman, 1987)

1. The LC_{50} or NOEC values of all existing species for a given substance form a log-logistical distribution,
2. The available LC_{50} or NOEC values for m test species for a given substance constitute part of the same log-logistical distribution (the LC_{50} distribution is of course different from the NOEC distribution);
3. The available LC_{50} or NOEC values for m test species for a given substance constitute a random sample;
4. The input data (LC_{50} or NOEC values) constitute fixed numbers, not counting experimental inaccuracies

The assumption of a log-logistical distribution was attractive from a technical point of view but leads to results similar to those of a log-normal distribution (Wagner and Løkke, 1991) Both the log-logistical and the log-normal distribution constitute a unimodal, symmetrical curve, when plotted on a logarithmic scale In the case of substances that have an effect on a specific species, e.g pesticides, it is likely that the true distribution of sensitivities is not unimodal but has several peaks, as the presence of relatively insensitive species on the right-hand side of the curve is not reflected on the left-hand side In principle, this results in a high extrapolation factor In its original form the method produces an estimate of the ecotoxicological risk of these substances which is too low

On the other hand, various researchers have argued that the method is also less suitable for substances that occur in given concentration ranges like essential micro nutrients, e g zinc and copper (Hopkin, 1993, Van Tilborg and Van Assche, 1996) If concentrations are very low, a lack of these nutrients may occur in organisms, whereas in the case of high concentrations the substances can have a toxic effect A major prerequisite appears to be that organisms should not be tested at concentrations at which a deficiency may occur (Janus *et al*, 1996) The medium in which the substance is tested must therefore satisfy one of the basic requirements of toxicology, namely that the organisms to be tested be able to live comfortably in the medium

It does not seem wise to use NOEC values relating to various effect parameters (e g , mortality, growth and reproduction) interchangeably when deriving the HCp The method is based on differences in sensitivity (variation in Noes) of species to a substance, the use of various effect parameters probably introduces an additional source of variation in Noes

Obtaining a representative sample of species through random selection likewise forms an essential assumption It is not clear to what extent this assumption can be satisfied with current ecological know-how and to what extent there are disproportionate deviations as a result In principle, this departure point requires the entire biotic community to be named right up to species level before the test species to be examined (randomly) are selected A statistically reliable procedure of selection is in principle of importance because species may differ widely in their sensitivity to a given substance (Blanca, 1984). In addition to the sensitivity of the species examined, the number of species (or rather: the standard deviation in sensitivities) is extremely decisive for the value of the HCp. The more species are examined, the sharper the reduction in uncertainty and hence the size of the factor

d_m (Aldenberg and Slob, 1991). As a rule, the value of the HCp is consequently less conservative, but not always (Okkerman *et al*, 1991) The number of species is less decisive than the variation in sensitivities

It goes without saying that available NOEC data do not constitute a random sample The selection of test species is based on various applicable or non-applicable scientific criteria (high sensitivity, perishability under laboratory conditions, representativeness in terms of ecological characteristics relating to position in the food chain, habitat, foraging habits, seasonalness and population dynamics), economic value or cuddliness (pet appeal).

The ecotoxicological data available contain only a part of the taxonomic diversity On the one hand, some taxa have not been studied in ecotoxicological tests, or hardly at all (Van Straalen and Van Gestel, 1993; Keddy *et al*, 1994, Léon and Van Gestel, 1994, Wiles *et al*, 1994), on the other large taxa are not represented in proportion

Differences in the value of NOECs are interpreted as species-specific differences in sensitivity The assumption that the NOEC has a fixed value is therefore a necessary one Factors other than inter-species differences in sensitivity can in principle also play a part, although these are disregarded (Kooijman, 1987) If the differences in sensitivity are very small, the contribution made to variability by other factors cannot be denied.

Other factors that may contribute to the variability of the input data include, for example, the experimental conditions during the test period and the reproducibility of the experiment (even between laboratories)

With regard to LC_{50} values, the use of NOEC values contributes more to the variability of the input data as the NOEC is not a calculated value like the LC_{50}, but the highest experimental concentration in which no statistically significant effect occurs. Because a factor of 2-5 is generally employed between test concentrations, this results in far greater inaccuracy than results from a calculation of the LC_{50} Added to this, NOEC values are fixed for various effect parameters (growth, reproduction), so that a new source of variation is introduced

Van Straalen and Denneman's original procedure constituted an ecosystem risk assessment limited to the effect of cadmium on soil invertebrates, without taking into account other soil organisms or terrestrial vertebrates. NOEC data for other

organisms can, in principle, be included in the analysis without restriction, however Only microbiological data such as enzyme activities and soil process speeds are discussed because they are frequently sum parameters. This data is currently computed into an HCp separately but analogously to the procedure for single species (T Crommentuijn, oral statement) When ecotoxicological data from field studies is used, it is mainly data on higher taxa than the species level that turns out to be available This data can in principle be extrapolated to an HCp as well, but again preferably separate from single species and sum parameter data (Faber *et al*, in preparation)

Aspects like degradability of contaminants, bioaccumulation and biomagnification are disregarded in the original procedure In order to put meat on the bones of ecotoxicological risk estimation for aspects of secondary poisoning, methods of calculation have been developed (Romijn *et al*, 1993, 1994) which enable maximum tolerable concentrations in water and soil to be calculated For the terrestrial situation, the soil-earthworm-bird/mammal food chain is described as a model For this chain a maximum tolerable concentration in soil (mg kg^{-1} soil) is calculated as the quotient of an NOEC (mg.kg^{-1} food) for birds or mammals obtained from extrapolation and the bioconcentration factor (BCF) between soil and earthworms. The extrapolated NOEC is derived using the Aldenberg and Slob method or the EPA method, based on toxicological data for reproduction, mortality or growth in birds or mammals. In a number of cases this estimation results in a more conservative standard than via the single species risk assessment

NOEC data is not always available in sufficient quantity for at least four different main groups of organism If insufficient NOEC data or only effect data is available, estimation factors of 10, 100 or 1,000 can be used in line with the EPA method, depending on the type of data (Van de Meent *et al*, 1990, Slooff, 1992)

2.2.2 Combination toxicity

Research into mixtures of toxic substances within the domain of ecotoxicology has a tradition that is about 10 years older than that within human toxicology (Evenblij, 1995) The reader is referred to a recent report on combination toxicity in the terrestrial environment (Hensbergen and Van Gestel, 1995) for an overview of the formation of theories and concepts in this field as well as an evaluation of a number of models For the time being ecotoxicological risk estimation for combination toxicity has been fleshed out by finding the aggregate of toxic units for estimating

the MTR. In addition, in environmental policy allowance is made for combination toxicity in regard to substances when a safety factor of 100 is applied between the MTR and the negligible risk level (NR) (VROM, 1988) Admittedly, this factor was originally the result of a very arbitrary selection, but could tentatively be underpinned on the basis of the specificity of the operating mechanism of the substance or group of substances in question.

2.3 COMPARISON OF HUMAN AND ECOTOXICOLOGICAL RISK ASSESSMENT

In human toxicological risk assessment much has been invested in developing methods which could perhaps be used productively in ecological risk assessment, in which case it is important to recognize how the targets of the two approaches differ Unfortunately, there is still insufficient communication between the two `worlds', with confusion and discussion about less relevant matters as a possible consequence (Calabrese and Baldwin, 1993; Moen *et al* , 1994)

Table 4 gives an overview of tools and models used in the two approaches to risk assessment No attempt has been made to achieve completeness The overview is built up in accordance with the individual, not necessarily sequential steps of a quantitative risk assessment (NAS, 1983)

1) identification of risky substances or other environmental factors (hazard identification),
2) estimate of the risk of exposure (exposure assessment),
3) description of the dose-response relationship (dose-response assessment), and
4) description of the actual risk (risk characterization)

Table 4. Overview of models used in quantitative risk assessment for soil, broken down into human toxicological and ecotoxicological origin.

Level of risk assessment	Discipline: Human toxicology	Ecotoxicology
1 *Hazard identification*	*environmental fate modelling* P_{ow}, K_s QSAR	*environmental fate modelling* P_{ow}, BCF, K_s QSAR
2 *Exposure assessment* (potential exposure risk) QUALITATIVE QUANTITATIVE	GEOTOX SOILRISK HESP CSOIL CONSEXPO PAR	MOVE SMART CATS BKH model BIOMAG IBN model
3 *Dose-response assessment*	NOEL; BM, LED_{10} ADI or RfD TDI TCL 10_{-6}	NOEL; BED HC_5 MATC of fCv, TRV QSSR ITC, MATissueC
4 *Risk characterization* (actual exposure risk)		

1+2+3+4	= *risk assessment*
2+3	= *risk estimation* (NAS, 1983)
fCv	*final chronic value* (Stephan *et al*, 1985)
ITC	*internal threshold concentration* (Van Wensem *et al.*, 1994)
MAT	*maximum acceptable toxicant concentration* (aquat ecotoxicol. USA)
MATissueC	*maximum acceptable tissue concentration (Fordham and Reagan, 1991)*
RfD	*(chronic) reference dose*
TCL	*toxicologically tolerable concentration in air*
TRV	*terrestrial reference value (HLA, 1991) (terr ecotoxicol USA)*

Attributing the methods mentioned in Table 4 to a given step in risk assessment is difficult and should be taken as a suggestion; in practice, the same method is sometimes used, for example, for an assessment of potential risk and an actual characterization of the exposure risk

It is striking that where the same or analogous methods are used in parallel in the basic phases of risk assessment (steps 1 and 3), there is a sharp division between the set of models relating to exposure and to actual risk In human toxicology, models are used (and are being further developed) in which exposure to substances via all relevant absorption routes can be fleshed out at the level of the individual or that of specific population groups Conversely, the set of ecotoxicological models for exposure is much more limited. Here one finds the models mainly fleshed out (with

partition coefficients and bioconcentration factors) for the uptake of substances from the water phase in the soil and for transfer via a number of simple food chains.

Table 5. Summary of the methodological comparison of human toxicological and ecotoxicological risk assessment.

Criterion	Human toxicology		Ecotoxicology
	ADI/TDI	10^{-6}	HC5
A. Risk estimation			
Level of effect parameters	individual	individual	individual, population
Target	individual, target groups	individual	biotic community, processes
MTR threshold value	yes	no	no
Scientific nature of MTR	convention	convention	semi-objective
Safety factor	explicit	implicit	implicit
Standardization of soil types	no	no	yes
Combination toxicity	no	no	yes
B. Actual risk			
Exposure route	yes	yes	limited
Background exposure	disregarded	no	in development
Safety factor	yes	no	no

The comparison between the human toxicological and ecotoxicological approach is summarized in Table 5 Human toxicological risk assessment and ecological risk assessment are made up of the same components. Whereas these components are conceptually comparable, they are used to achieve different goals For example, in the human toxicological risk assessment the aim will be to estimate the response of the population for each level in the case of lifetime exposure. From this point of view the concern is to identify factors that have an impact on sensitivity, including quantifying groups with an increased risk. Both the number of individuals affected and the size of the additional risk are the subject of study. In other words, the general reaction of the population is described on the one hand, and that of sub populations with an increased risk on the other. Conversely, in ecological risk assessment attention focuses on the effects of exposure on species in terms of growth, reproduction and mortality. As a result, sometimes only sensitive stages of life are considered A general distinction therefore is that human risk assessment focuses on the individual, whereas the ecological variety aims more at the survival of populations of species as a whole and not so much of the single individuals This distinction is in principle less applicable to the protection of endangered species, in

which the protection of each individual is desired However, policy on protection of the environment in the Netherlands has not (yet) been integrated with nature conservation policy[4]

Within human toxicological and ecotoxicological research, the same indicators for exposure are identified and the same endpoints used Within human toxicology all the indicators can be used to arrive at a standard, within ecotoxicology standards are only based on a number of key parameters, namely growth, reproduction and mortality. Changes in behaviour and biochemical and physiological effects occurring earlier and at lower concentrations are therefore disregarded (compare Slobodkin, 1980, De Kruijf *et al*, 1984). It follows from this that compared with ecotoxicology, in the human toxicological underpinning of standardization (at least in a broad sense) and evaluation and prognoses about public health, effect limits are involved which occur at lower levels of integration Because these biochemical and physiological effects may manifest themselves earlier than effects on growth and reproduction, it has to be concluded that the human toxicological limit values are in principle tighter than the ecotoxicological ones This point has been acknowledged within ecotoxicology; recently, possibilities were explored for incorporating indicators at lower levels of integration in ecological risk assessment for standard setting, but then only for higher species of animal (Health Council, 1997).

In human toxicology the derivation of the ADI and TDI for non-genotoxic substances is based on the assumption that no significant negative effect occurs in the event of lifetime exposure, allowing for sensitive groups in the population. The maximum tolerable risk level for humans is therefore a no-effect level For genotoxic substances this assumption is estimated using the 10^{-6} level. Within ecotoxicology, the maximum tolerable risk level is based on the no-effect level being exceeded by 5% of the species theoretically present in an ecosystem In this sense too human toxicology appears to set stricter standards than ecotoxicology A few remarks are in order here

On account of the form of the curve supposed to describe the distribution of sensitivity of all species in an ecosystem, 100% protection or exceeding the no-effect level by 0% is practically impossible. The left-hand edge of this curve approaches zero asymptotically: the MTR appertaining to a near 0% overrun is unrealistically low. At present it is stated that the tolerable 5% overrun is an estimation of

[4] This integration has taken place in the US, where ecological risk assessments analogous to the human variety are carried out for endangered species and migratory birds additional toxicological parameters may be included, e.g chronic toxicity, interindividual variation in sensitivity, and higher safety factors for acceptable exposure

complete protection of the ecosystem Because this method is fairly theoretical in nature, it will probably never be possible to establish the level of the MTR for a concrete biotic community of plants, animals and micro-organisms.

Human toxicology also argues that it is precisely the use of an `effect level' within ecotoxicology that results in principle in `harder' MTRs, which can be established using scientific methods, than the human toxicological departure point of no effect, which is far more difficult to establish scientifically (oral statement J van Wijnen) Weinberg argued as early as 1972 that no or very minor effect levels can in theory be established scientifically, but in practice cannot be assessed with sufficient accuracy In order to be able to establish very small effects, such big samples (number of laboratory animals) are needed that it is impossible to conduct the experiment in practice Weinberg called these scientific issues trans-scientific.

Ecotoxicological risk assessment for standard setting is different, but neither better nor worse than human toxicological risk assessment Ecotoxicological risk assessment is in principle less conservative (protective), and can be described as less subjective than human toxicological risk assessment. At the same time, the lack of a national or international expert view in ecotoxicological risk assessment is seen as a deficiency Within human toxicological risk assessment, exposure is computed better qualitatively and quantitatively. If available, epidemiological data have a clear part to play within human toxicological risk assessment. Conversely, within ecotoxicological risk assessment there is at present no room for the use of field studies

3 ECOLOGY FOR THE ASSESSMENT OF POTENTIAL AND ACTUAL RISKS

The value of ecologically substantiated standards is beyond dispute. Standards permit categorization and the setting of priorities In addition, standards are anchor points for emission reduction targets Chapter 2 shows that the `recipe' for deriving (ecologically substantiated) intervention values, MTRs and NRs is of a rather theoretical nature. The link between these standards, and in particular between the exceeding of standards and the actual situation at the location where the standard is exceeded, is limited Exceeding the standard certainly does not mean that there are actual risks in every case; it is rather an indication that the ecosystem at this location needs to be examined better In this sense the use of standards can be interpreted as a trigger instrument what effects should perhaps be examined?

Within ecology and ecotoxicology new methods are and are becoming available which can be used for setting generic standards Added to this, there is a great need for methods that can be employed in the relatively short term as building blocks for evaluating the ecological risks of a specific polluted site, i e. evaluating the risks or effects of pollution present in the soil This chapter will discuss ecological building blocks that can be used to assess potential risks and to evaluate actual risks (see Introduction, page 1)

.

The same methods can sometimes be used to determine potential risks and to evaluate sites actually polluted (actual risk characterization). By, for example, proceeding from laboratory data on the effects at low levels of organization of biological information (e.g individual mortality), it is possible to predict changes at higher levels of biological organization using models If this method is fed exclusively with generic data and effects ascertained in the laboratory, a potential risk can be assessed By using location- and system-specific data it is possible to use this method to evaluate actual risks as well

Environmental policy and nature policy as well focus *inter alia* on the protection of ecosystems. This departure point involves problems in the sense that it is often not clear what should be understood by `ecosystem'. Ecosystems are influenced by other ecosystems and the abiotic environment, it is usually not easy to designate boundaries Each ecosystem is part of a larger whole, but also contains smaller units. In practice, the term ecosystem only becomes clear if the name of the system concerned is added to describe it the `Waddenzee', `wooded bank', `broads', `gut' or `oral cavity' ecosystem. This problem complicates every discussion on the protection of `the' ecosystem

This chapter draws a distinction between various levels of biological organization There appear to be no methods that say anything about the condition of the ecosystem in general In the case of higher levels of biological organization they at most cover major processes in parts of defined ecosystems The current state of affairs therefore warrants policy objectives being targeted at more concrete levels of biological organization, both in regard to the environment and in regard to nature.

It is stressed that no attempt has been made in this report to produce complete recipes for ecological risk characterization. The report only provides a number of suggestions about the ingredients that could be used for this purpose. The list of ingredients is not exhaustive either.

3.1 THE SUB INDIVIDUAL LEVEL[5]

When an individual is exposed to toxic concentrations of a pollutant, this will first result in reactions at biochemical, physiological or histological level. If there are insufficient feedback mechanisms available and it is impossible to compensate for the effect, these initial reactions may have an effect at a higher level of biological organization. Effects then may be possible, in succession, at individual level (growth, development, mortality), population level (reproduction) and, finally, at ecosystem level (species diversity, processes) (see Figure 5)

The effects at sub individual level can be detected and quantified on the basis of specific effect parameters or biomarkers. Biomarkers which can be used for assessing risks in the event of exposure to environmental contaminants have been identified

5 Author: A T C Bosveld

for various substance groups One of the biomarkers for exposure to polycyclic aromatic hydrocarbons (PAHs) studied in most detail is the induction of metabolic reactions catalyzed by cytochrome P450 isoenzymes Dose-response relationships between the internal concentration of PAHs and the hepatic activity of microsomal ethoxyresorufin O-deethylase (EROD) or aryl hydrocarbon hydroxylase (AHH) as a measure of the activity of the cytochrome P450 1A1 isoenzyme in the liver (Bosveld and Van den Berg, 1994b) have been demonstrated both in the laboratory and in the field

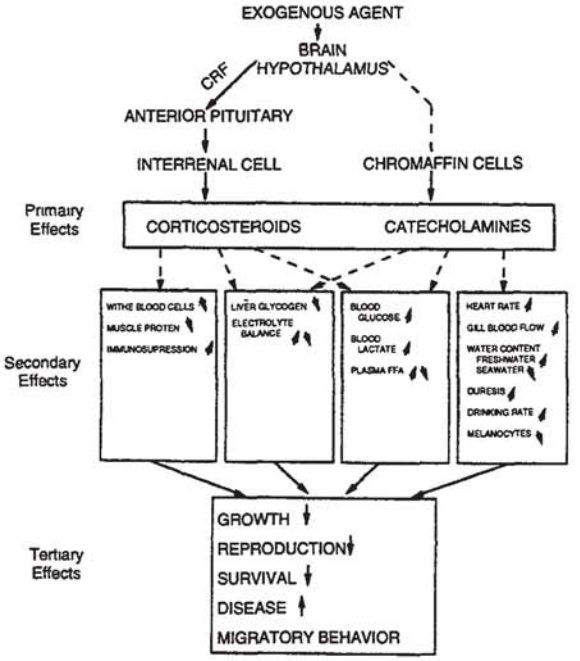

Figure 5. Example of the impact of external stress effects at biochemical level on effects at population level From· Mayer *et al* , 1992

A biomarker suitable for ecological risk characterization must satisfy a number of parameters. First of all, it is necessary to know how the effect is induced and whether it is clearly linked to a given environmental contaminant or group of contaminants The significance of a biomarker is only relative if non-chemical stress interferes with the effect of chemical stress For example, it has been demonstrated that in the yellow-legged herring gull (*Larus cachinnans*) the dose-response relationship for PCBs in the liver versus aldrin epoxidase activity varies with the different seasons (Figure 6, Fossi *et al* , 1988) These fluctuations need to be taken

into account when biomarkers are used for ecotoxicological risk assessment. Besides variations in time, variations in space can also occur.

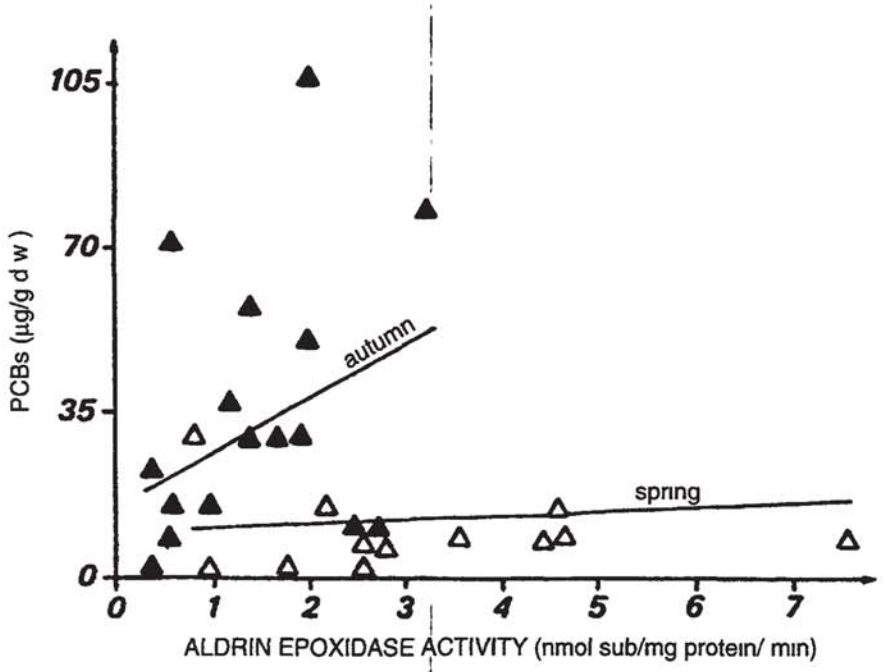

Figure 6. Seasonal variation in the relationship between PCB and aldrin epoxidase in the yellow-legged herring gull. From. Fossi *et al*, 1988

Environmental factors that are not related to chemical stress but do have an impact on the response of the biomarkers can have a disruptive effect if they vary in space For use in practice, it is therefore necessary to confirm the response relationship of a biochemical marker established in the laboratory in field studies In this context, location-independent relationships have been found between concentrations of PCB in the liver and microsomal EROD activity in day-old chicks of various types of bird, including the common tern (Figure 7) and the pipping heron (Figure 8) (Bellward *et al*, 1990, Rattner *et al*, 1993; Van den Berg *et al*, 1994; Bosveld *et al*, 1995)

The significance of ecotoxicological risk characterization using biomarkers is greatly enhanced if there is a clear link between the marker effect (at a low level of organization) and an effect at a higher level, as increased enzyme activity is in itself of little significance if no link can be established with consequences for growth, reproduction or survival of the individual as a minimum The induction of

(Figure 9) and a loss of body weight (Figure 10) On the basis of these correlations it is possible to translate the observance of a marker effect to higher levels of biological integration On the basis of these `translatable' biomarker responses it is thus possible to make predictions about ecological risks at polluted locations

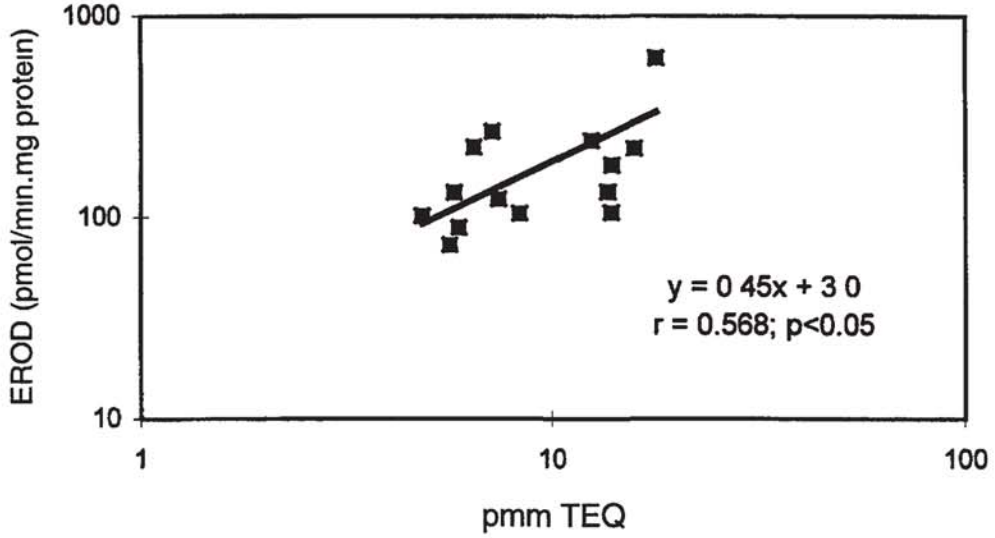

Figure 7. Relationship between the concentration of PCB (expressed in toxic equivalents (TEQ) in yolk fat and EROD activity in the liver of day-old common tern chicks from various colonies in the Netherlands and Belgium From Bosveld *et al* , 1995

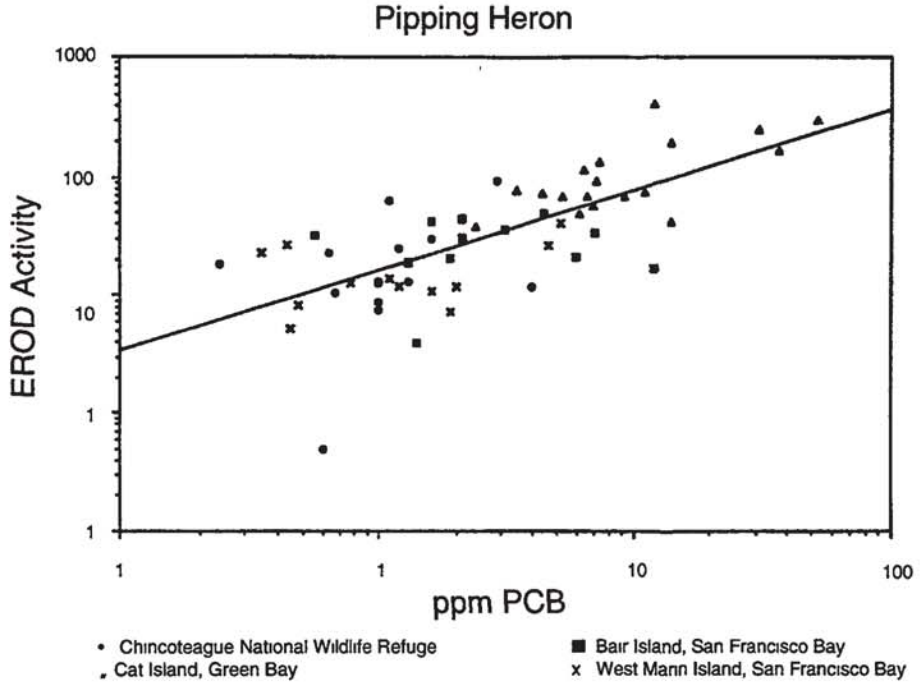

Figure 8. Relationships between the concentration of PCB in the chick and microsomal dealkylase activity in the liver of the pipping heron, collected at four different locations. From: Rattner *et al*, 1993

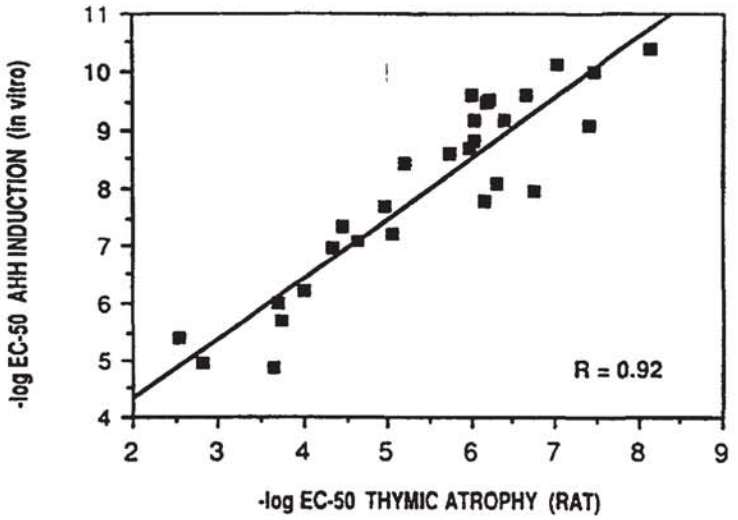

Figure 9. Correlation between the -logEC_{50} values for *in vitro* AHH induction versus the -logED_{50} values for thymic atrophy caused by PAHs in rats. From. Safe *et al.*, 1989

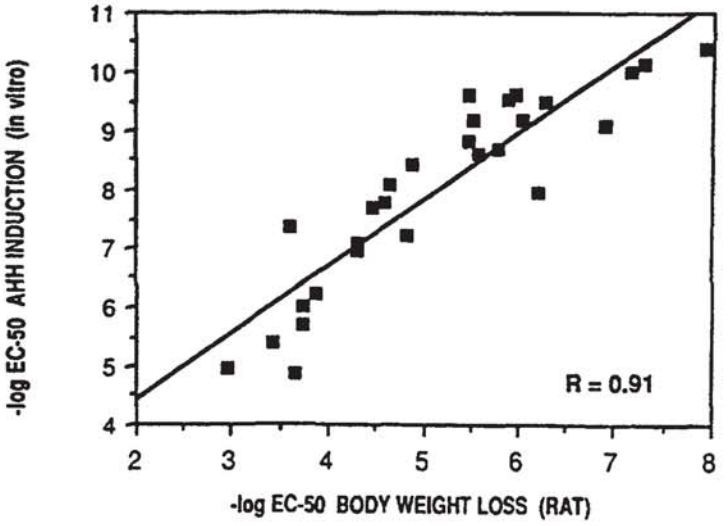

Figure 10. Correlation between the -logED_{50} values for *in vitro* AHH induction versus the -logED_{50} values for growth inhibition caused by PAHs in rats. From Safe *et al*, 1989.

Besides the induction of cytochrome P450 isoenzymes, various other dose-response relationships have been demonstrated in the field in fish-eating birds which suggest a causal relationship between exposure and biomarker responses. The responses comprise disorders in haem synthesis, neurotransmitter function, vitamin A concentrations and hormone balances (Bosveld and Van den Berg, 1994a) Further, thyroid gland hormone concentrations in the plasma appear to be correlated to the concentration of PAHs in the yolk fat in the case of chicks of the cormorant and common tern (Van den Berg *et al*, 1994, Murk *et al.*, 1994) Similar relationships have been demonstrated for vitamin A concentrations Although there is still no absolute certainty in the relationships observed, it points to a dose-dependent influencing of the hormone balance. Both thyroid gland hormones and vitamin A are directly involved in growth and development As such, a response at this level has a predictive value (qualitative) in terms of effects at a higher level of organization.

Another biochemical effect with toxicological relevance is the accumulation of porphyrin in the liver A dose-dependent accumulation of porphyrins occurs both in the laboratory and under field conditions after exposure to chemical stress (Fox *et al*, 1988, Elliot *et al*, 1990, Miranda *et al*, 1992) Porphyrin accumulation is an expression of the disruption of haem synthesis, whereby intermediary products

accumulate. If a haem deficiency occurs, it can have consequences for various bodily functions in which haem-containing proteins play a part, e.g phase 1 metabolism for haem-containing cytochrome P450 isoenzymes and the transport of oxygen by hemoglobin.

In addition to the biochemical responses, biomarker responses are also conceivable at a higher level of organization. Hoffman *et al* (1993) discovered relationships between PCB concentrations and a number of different morphometric, development and reproduction parameters in the common tern and the pipping heron.

In the case of the various levels of organization discussed above, the number of possible compensation mechanisms in the sequence from sub individual to population increases in order to neutralize the adverse effects of contaminants. The earliest perceivable effects occur at the sub individual level or are of a behavioural type. In time these will precede effects at population level. At a higher level of organization the ecological relevance of the effect increases Conversely, the link to concrete toxicological effect mechanisms decreases in this direction (Figure 11) However, for various early biomarker responses it is possible to establish a clear link with effects at population level that occur later. Characteristic histological, biochemical or physiological effects can, in principle, be used as early warning effect parameters to characterize the ecotoxicological consequences of contaminants.

A biomarker can therefore be used for ecotoxicological risk characterization if clear dose-response relationships have been identified and their ecological relevance demonstrated. In other words, if a biochemical effect in a biological measuring system has been clearly correlated with the concentration of a given substance or group of substances, this effect can be used as an alternative to determining substance concentrations in a sector of the environment through chemical analysis. For example, well-validated bioassays are available for demonstrating the presence of dioxins and structure-related substances. These can be used to determine the concentration of TCDD equivalents (TEQs). These assays use *in vitro* induction of cytochrome P450 1A in primary hepatocyte cultures or cell lines of target species (Safe, 1989; Kennedy *et al*, 1993) Kennedy *et al* found a significant relationship between TEQ concentrations determined using a bioassay and TEQ concentrations calculated on the basis of gas chromatograph/mass spectrometer (GC/MS) analysis (Figure 12) (Kennedy *et al*, 1992)

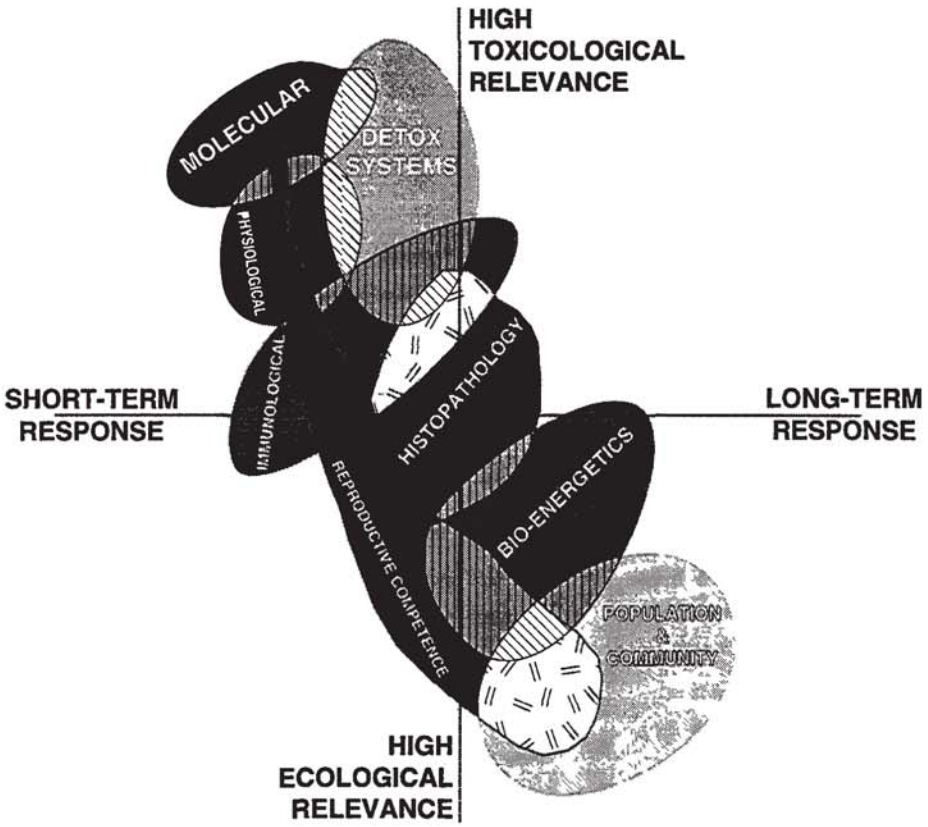

Figure 11. Relationship between the responses at the various levels of biological integration and the relevance and time span of responses From: Adams *et al* , 1989

In the context of the WHO a development is under way to start using data from bioassays based on biomarkers for dioxin equivalents, validated using dose-response tests for birds, fish and mammals, for generic standard setting. The initial results can be expected shortly.

Using biomarkers and bioassays to monitor effects of exposure to chemical stress has a number of advantages over measuring substance concentrations. The principal advantage is that testing takes place on the basis of an effect instead of on the basis of a substance concentration, obviating the need for a translation from concentration to ultimate effect This can increase the reliability of a prediction of the expected effect Naturally, the statements apply only to effects that are mechanically associated with the response of the biomarker.

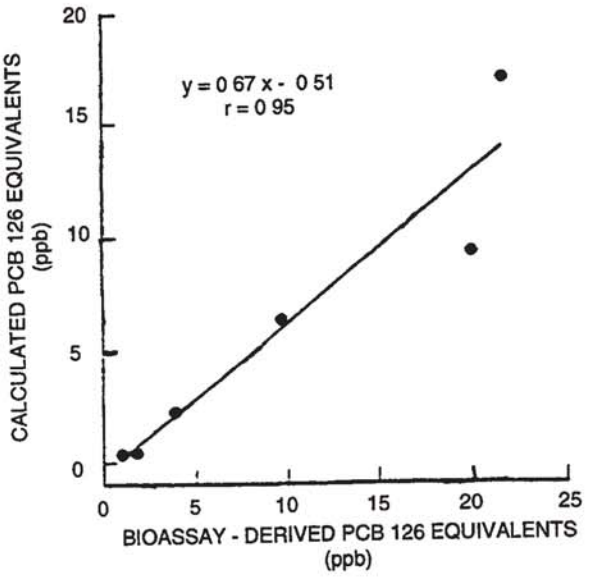

Figure 12. Comparison of bioassay-derived TEQs and TEQs calculated on the basis of GC/MS analysis. From Kennedy *et al*, 1992.

Besides the use of validated, substance-specific and ecologically relevant biomarkers in monitoring research and in evaluating environmental quality, the method can also be used for setting generic standards. As illustrated above, sufficient knowledge of effect thresholds is already available for a limited number of substances.

3.2 FROM INDIVIDUAL TO POPULATION[6]

3.2.1 Population models

At the present, ecotoxicological research still focuses frequently on the individual level, it being assumed that effects on the reproduction and mortality of individuals can be translated direct into population effects The knowledge of and formation of theories about effects of toxic substances at the population level (Van Straalen, 1988) has only recently got under way. An explanation that can be put forward for this late development is that there are practical objections to experimental research into effects at population level (in particular the controllability of experimental situations, the costs attached to the experiments and the

6 Author C Klok (with the exception of section 3 2 2)

interpretability and reliability of the data). Experimental toxicity data at population level are therefore still sparse One of the exceptions is Kooijman's (1984) model approach, which shows that physiological effects of toxic substances on growth and metabolism can have an impact on the population through reproduction (Kooijman, 1985a).

The life history theory predicts that a reduction in reproductive success or reduced survival at the adult stage (at population level) exerts selection pressure towards early maturation and an increase in reproductive efforts at an early stage of life (Michod, 1979, Charlesworth, 1980). These life-history changes have indeed been demonstrated in populations of a small number of species in polluted areas (Donker *et al*, 1993; Posthuma *et al*, 1993, Tranvik *et al*, 1993) Added to this, there are pointers from experimental laboratory research that changes in life cycle and tolerance can occur when NOEC values are exceeded by only a small amount and that toxicity tests carried out with several generations can produce lower effect thresholds (Postma and Davids, 1995).

Risk assessment at population level can on the one hand be based on experimental systems of testing (often yet to be developed), but on the other can also be based on synthesizing existing toxicological data by applying model-type extrapolation from individual to population. Recent developments in theoretical ecology involving individual-based models as well as structured- population models (DeAngelis and Gross, 1992, Metz and Diekman, 1986; Nisbet *et al*, 1989) constitute one possibility for increasing ecotoxicological understanding of the qualitative and quantitative effects of toxic substances on populations

Contrary to unstructured models (such as the logistical growth equation and Lotka-Voltera predator-prey models), structured models assume that the individuals in a population are not identical Allowance is made for the internal structure, i.e. the structure towards/at stages of life, classes of size or age. Population dynamics is described as the result of life history characteristics (the population dynamics behaviour of individuals, by which is meant the growth, development, reproduction and survival of the individual) of each single individual in the population. Insight into life history characteristics in principle renders it possible to extrapolate effects on individuals established in the laboratory to the population. Sensitivity to toxic substances reveals itself in single individuals as a change in mortality, growth

and/or reproduction, as a result of which the population dynamics change. Individuals are seen as separate units that influence each other This mutual influence expresses itself in competition for food, among other things. Thus, lower reproduction will cause the number of juveniles to decline so that if the food density remains the same the juveniles will have more food and so will be able to grow faster Individuals are single members· each individual will perform differently in terms of mortality, growth and reproduction. Thus, in risk assessment at the population level, variation in sensitivity to toxic substances between individuals can be taken into consideration.

The dynamics of a population is the result of the life history characteristics (growth and development, reproduction and mortality) of all the individuals that make up the population This life history can be described clearly in accordance with specific rules and depends on the physiological condition of the individual and environmental conditions (predation pressure, availability of food, degree of pollution of environment, etc.) With the aid of the energy budget it is possible to predict effects of pollution present in relation to expected changes in life history characteristics

Put simply, the models consist of an individual-based model (using which the impact of toxic substances is translated into effects on life history characteristics via a description of the individual's energy budget) and a population-based model which consistently calculates (keeps account of) the life history characteristics for every individual and translates these into a population parameter, e.g. population growth rate (Figure 13). Thus, structured population models present the possibility of making predictions at population level based on the biology of the individuals

The concept outlined above has been elaborated for a number of cases, including the permanent burden of copper on the population dynamics of the earthworm *Lumbricus rubellus* (Klok *et al.*, 1997; Klok and De Roos, 1996) and the periodic burden of pesticides on the population dynamics of *L rubellus* and *L terrestris* (Baveco and De Roos, 1996) Klok *et al* (1997) posit that sublethal chronic copper pollution results in detoxification mechanisms being activated, with the result that the maintenance metabolism of the species is increased. According to the energy budget model this results in a reduction in the speed of growth, development and reproduction. This corresponds with the experimental data (Ma, 1982) on which this analysis is based.

A change in the population growth rate can be calculated from the changes in life history characteristics Figure 14 shows an extrapolation of the decline in the population growth rate as a function of copper pollution The population will become extinct at a soil concentration of about 300 mg Cu kg^{-1} soil This 'critical level' applies to *L rubellus* in sandy loam in optimum conditions (maximum food, no other stress factors)

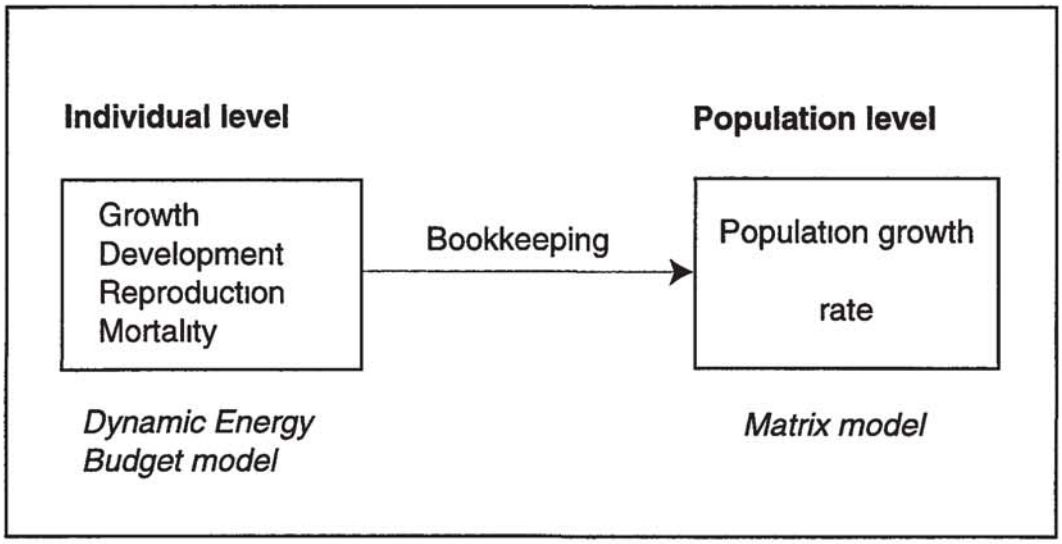

Figure 13. Diagram of a structured model for extrapolating toxicity data from individual level to population level.

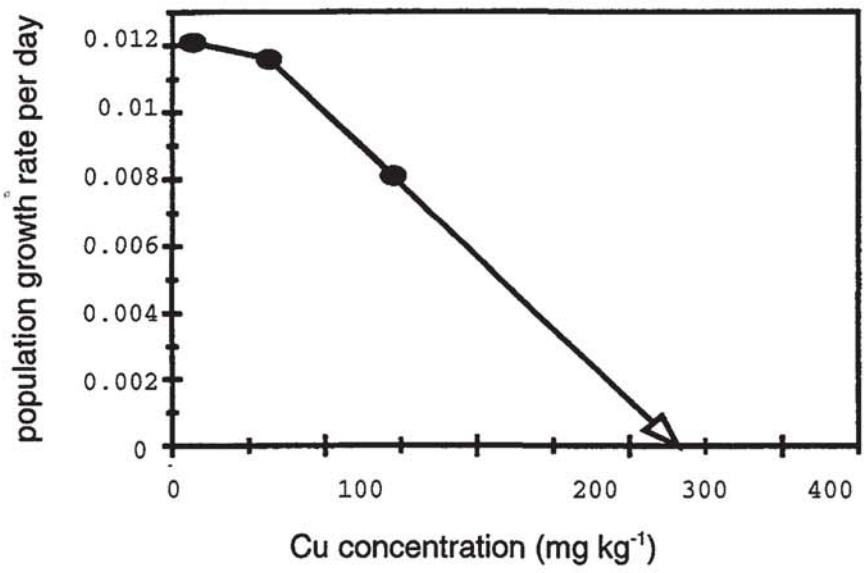

Figure 14. Impact of copper on the population growth rate of the earthworm *Lumbricus rubellus*

A sensitivity analysis for changes in life history characteristics as a function of copper pollution has shown that the population will become extinct because individual growth will be inhibited such that a large percentage of the individuals will not reach the adult (reproductive) stage. Due to the high reproductive capacity of earthworms, inhibiting growth will have greater consequences for the population than inhibiting reproduction A different study focusing on a situation of fluctuating pollution (pesticides) likewise shows that effects on individual growth and development are of greater importance than effects on reproduction (Baveco and De Roos, 1996)

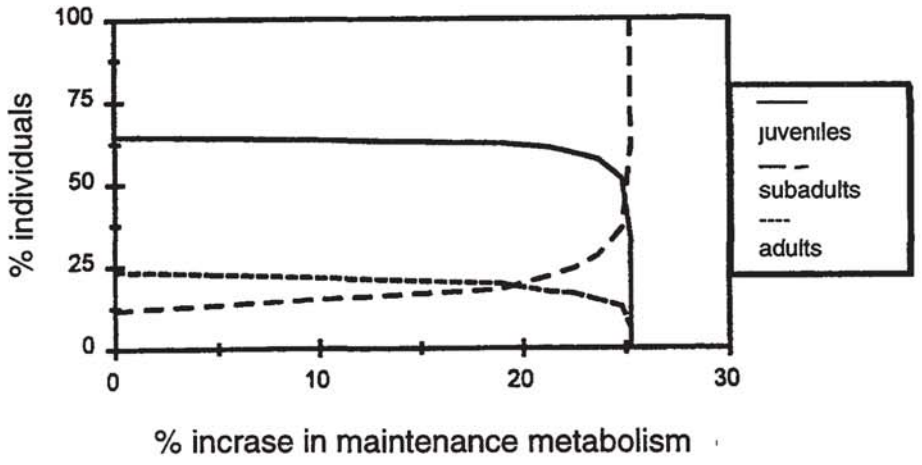

Figure 15. Impact of copper on the relative distribution of developmental stages of the earthworm *Lumbricus rubellus*

In addition to critical soil concentrations in which the population is not expected to survive, these model-type analyses show that it is virtually impossible to estimate the state of health of the population on the basis of the size distribution of individuals in the field (Klok and De Roos, 1996). Low levels of copper pollution have virtually no impact on the relative distribution of juveniles, sub adults and adults (Figure 15) The state of health of the population can only be derived from the size distribution of the individuals when soil concentrations approach the `critical level'.

Although effects on the growth, reproduction and mortality of individuals can be easily extrapolated to the population using stage-structured population models, it is still difficult to state what the consequences are for the functioning of the ecosystem

(TCB, 1990a) The method is interesting as a supplement to and theoretical validation of ecotoxicological data at individual level for setting generic standards In addition, these models seem better suited to risk assessment in relation to key species in ecosystems, and mainly species of importance in nature policy such as protected species, target species and other species of special concern General environmental and soil conditions should be built into the model for location-specific risk characterizations.

3.2.2 Exposure of individuals and populations

Terrestrial ecotoxicological dose-response research in the Netherlands has mainly concentrated on uptake via food as regards exposure (Donker, 1992, Van Wensem, 1992, Belfroid *et al*, 1993, Van Brummelen, 1995) In addition, direct exposure from the sector of the environment (in this case confined to the soil) is mainly estimated using bioconcentration factors or partition coefficients (Van Gestel and Ma, 1988, 1990, Van Gestel *et al*, 1991; Belfroid, 1994) Thus, in research into the effects and model-type predictions of these effects the uptake of substances by the low trophic levels in the soil -microorganisms, soil fauna and plants - is presumed to be linked to the solubility of the substances in the soil solution (e.g. Romijn *et al*, 1994; Noppert *et al*, 1993; Notenboom and Posthuma, 1995, Smit, 1997) Research into the biodegradation of organic compounds in relation to biological availability also focuses on exposure via the pore water (Rogaar *et al*, 1995). BCF values are usually taken from the literature, however, and vary widely in their dependence on local soil and hydrological factors, among others, and are mainly specific to species or groups of species (McCarthy, 1986; Plette, 1996). Partition coefficients as referred to in the literature also appear to vary widely (Bockting *et al.*, 1993). For this reason there is a great need for methods of describing exposure to and the uptake of pollutants in the soil in the field. A model that describes the uptake in heterogeneously polluted soils could, for example, be based on the daily radius of action of an organism related to its body size (Southwood, 1978, Marinussen and Van der Zee, 1994). On the other hand, the problems of availability and uptake can to an extent be overcome by targeting research into effects at internal exposure and effect thresholds (McCarthy, 1986; Van Hoogen and Opperhuizen, 1988, Fordham and Reagan, 1991; Van Wensem *et al*, 1994).

3 3 THE ECOSYSTEM LEVEL[7]

3.3.1 Introduction

More and more recommendations are coming from researchers and government advisory bodies that risk assessments of soil pollution should focus on the potential effects on the biological diversity and functioning of the soil ecosystem (RMNO/NRLO, 1993) This section looks at these two challenges to ecotoxicology, the starting point being that policy has need of a simple, easy to interpret and useable system of characteristics and not large quantities of complex data sets These system characteristics need in any event to be related to the three linked aspects of the functioning of the soil ecosystem: the soil chemical interactions, the terrestrial food web and soil ecosystem processes (Figure 16)

Ecotoxicological research will need to produce a limited number of soil ecosystem health indicators that can be used for policy Recently, the term 'ecosystem health' was proposed as a basic concept for the development and application of ecological risk assessments of environmental pollution (Shrader-Frechette, 1994, Constanze, 1992; Rapport, 1989) The aim is for the health of an ecosystem to be deducible from the ability of the system to maintain its ecological life cycles and to offer resistance to stress In the case of the soil it is a question of maintaining soil ecological processes such as the dynamics of organic matter and nutrient life cycles and maintaining the structure of the biotic community of soil organisms whose activity constitutes the basis of these processes

7 Authors P C de Ruiter, J Dolfing, A Neutel and J. Japenga

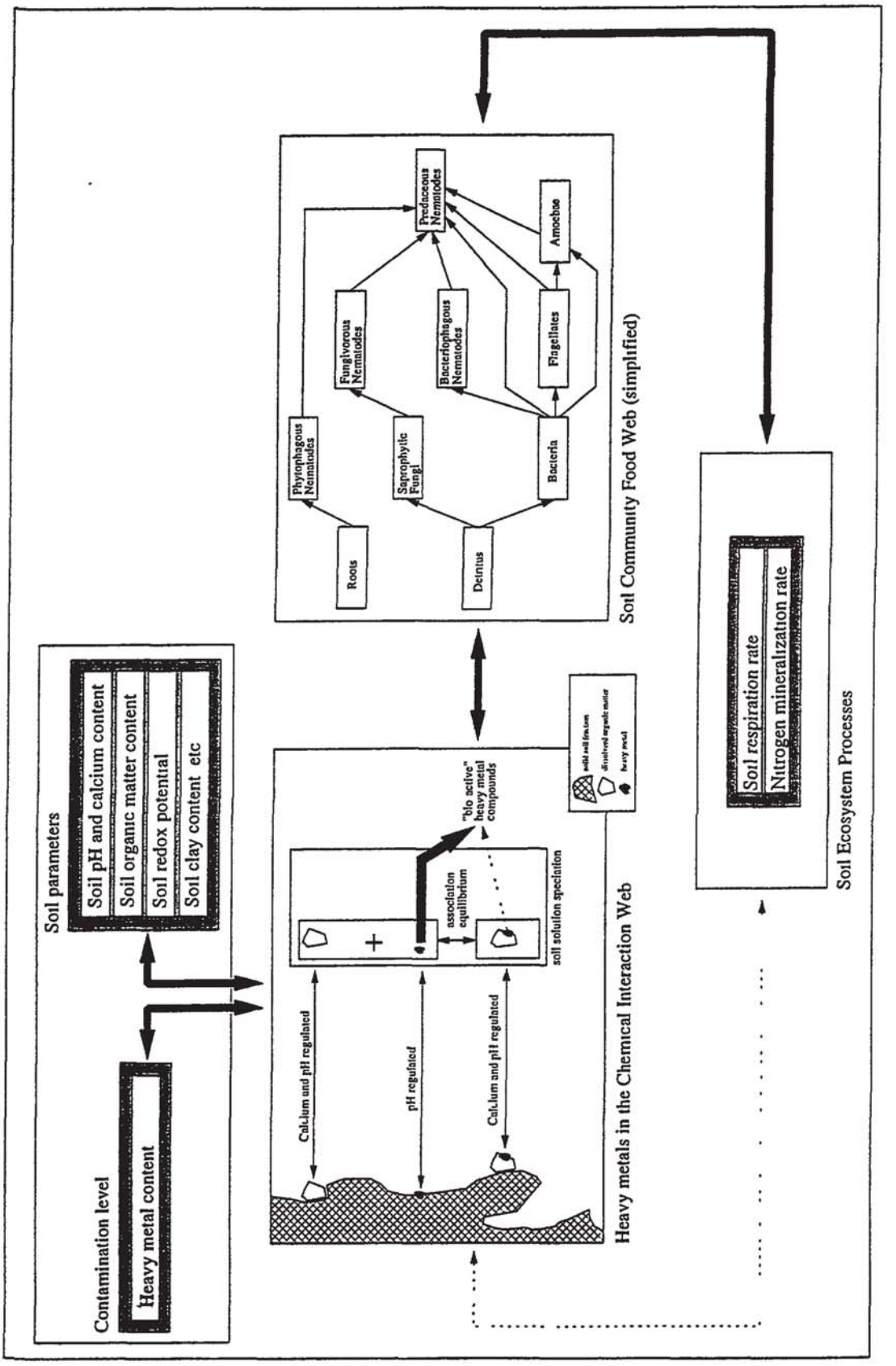

Figure 16. The three related aspects of the functioning of the soil ecosystem: the chemical interaction web, the soil community food web and soil ecosystem processes.

3.3.2 Behaviour and bioavailability of contaminants in the soil

Soil contaminants are generally present as molecules or ions adsorbed to the soil particles and occur only to a limited degree in the soil solution

Factors known to play an important part in the degree to which contaminants occur in the soil solution are organic matter and clay particle concentrations. For organic micro pollutants the organic matter is the most important factor and for heavy metals it is the clay content as well as the organic matter. Dutch soil quality standards take these factors into account by defining them for a standard soil with 10% organic matter and 25% clay. Actual cases of soil pollution are then standardized to this norm However, this procedure is subject to increasing criticism because it is possible that significant effects of the chemical composition of the soil solution on bioavailability are being disregarded For example, dissolved organic matter can desorb contaminants from the solid phase, and the pH regulates the desorption and the solution of contaminants In other words, the pH and the dissolved organic matter influence the concentration of the contaminants in the soil solution and hence their bioavailability. Contrary to the percentage of organic matter and the clay content of the solid phase, the composition of the soil solution can change swiftly, for example in situations of altered land use, acidification and the use of organic fertilizer In order to understand the bioavailability of contaminants it is therefore necessary to know how a number of physical and chemical soil properties have an impact on the bioavailability of contaminants. Using a chemical equilibrium model such as SEKTRAS (Simulation of Equilibria, Kinetics and Transport in Soils) it is possible to calculate the biological activity of the contaminants on the basis of these parameters (Bril *et al*, 1993). The validation of this model requires a number of data relating to the chemical composition of the soil solution, in particular the absorption of contaminants in the dissolved organic matter.

3.3.3 Food web interactions and ecological life cycles in the soil

Soil community food webs, energy flows and nutrient cycles

Food webs are networks of consumer food source interactions (Figure 17a). These trophic interactions are deemed to be important for the functioning of many populations of organisms because their 'success' depends especially on the availability of food and mortality as a result of predation Trophic interactions form the basis of major components within ecological life cycles, e.g the decomposition of organic matter and the mineralisation of nutrients (Figure 17b).

These are biological processes because they are the result of the consumption and processing of material, energy and nutrients by soil organisms Although microorganisms play a dominant role in these processes, soil fauna can also make a significant contribution - on the one hand directly, on the other indirectly by influencing the microorganisms via grazing and/or by substrate improvement and dispersing microorganisms Food web models have been developed to assess the contributions made by soil organisms to these ecosystem processes, e.g. the so-called Detrital Food Web Model (Hunt *et al*, 1987, De Ruiter *et al*, 1993) The soil biological parameters needed for these are the size of the population and energy balance of the various groups of soil organisms The model can be validated on the basis of experimental carbon and nitrogen mineralisation or the mineralisation of these substances observed in practice Use of this model on a number of mainly agrarian soil ecosystems shows that the calculated speeds of mineralization frequently correspond fairly well with the observations (De Ruiter *et al*, 1993, 1994)

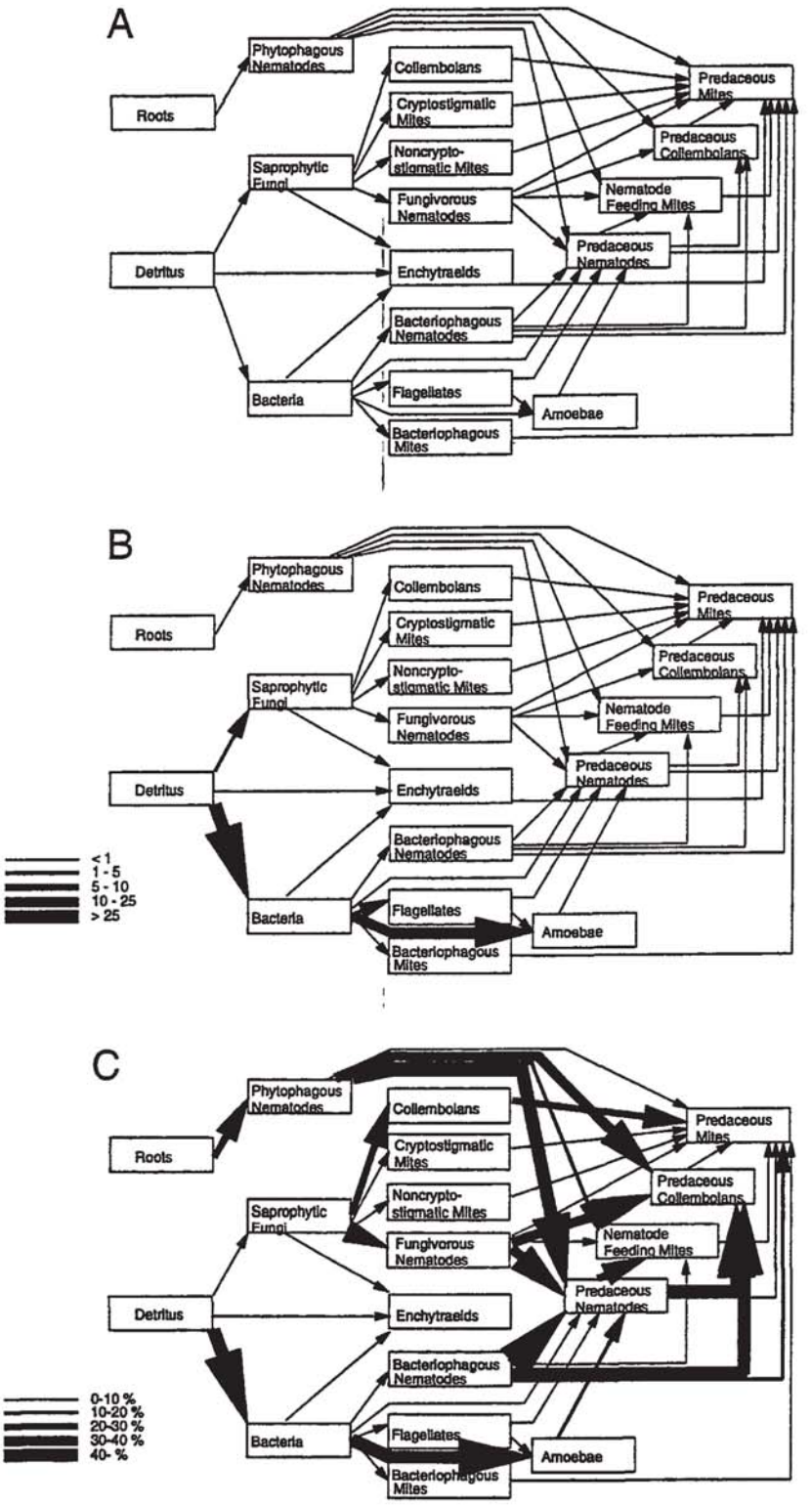

Figure 17. Diagram of a food web established for the fields of 'de Lovinkhoeve', an experimental farm in the Netherlands' Northeast polder A. Qualitative description of functional groups and their trophic interactions B. Energy fluxes of the food web, in which the thickness of the arrows reflects their relative contribution to the energy cycle (in kg C ha^{-1} $year^{-1}$). C. Effect of change (0 < factor < 2) in the strength of an interaction on the stability of the system, expressed as the chance (%) of the system becoming unstable.

Exposure of soil organisms to contaminants

Soil organisms can be exposed to contaminants in a number of ways. First of all, there is direct exposure as a result of their supply from `outside', of the primary absorption of soil or soil solution via consumption, dermal contact and respiration This exposure can have a negative impact on the functioning of the populations sensitive to the contaminant in question Secondly, there is the progress of the pollutant through the food web via the trophic interactions, from food source to a consumer exposed directly or indirectly This can result in dilution or biomagnification of the contaminant depending on the energy conversion efficiencies with which organisms assimilate, respire and convert material into new biomass Analogous to the streams of nutrients and parallel to the energy flows, an estimate could be made using the Detrital Food Web Model of the substance flows of contaminants To this end data on uptake and assimulation efficiencies and the like should be collected from the literature. Finally, there is a third level at which the contaminant can affect the functioning of the soil organisms, namely via indirect ecological effects, as the direct toxic effects result in a disruption of the physiology and hence the functioning of the organisms This can then have an effect on the other populations in the food web, for example because they are preyed on less or on account of altered competition ratios (Moore and De Ruiter, 1993) This will change the sizes of populations and substance flows between the groups of organisms The ultimate effect of soil pollution in that case is not only determined by the characteristics of the immediately vulnerable groups, but also by the characteristics of the soil biotic community as a whole. Both theoretical and experimental studies of these indirect effects show that these effects are frequently unpredictable as regards both scale and direction (Figure 17c) (Paine, 1980; Yodzis, 1988, De Ruiter *et al.*, 1995). Again, an altered pattern of substance flows changes the progress of the pollutant through the food web and hence has an impact on the `direct' toxic effects

Risk assessments at ecosystem level

The above shows that trophic interactions need to be drawn into risk assessments because ecological effects cannot be assessed on the basis of toxicity for individual species However, in order for these risk assessments to be useable for policy it is necessary to arrive at simple, easy-to-interpret system characteristics as a basis for ecological characterization

In describing and quantifying effects at ecosystem level we might consider the degree of influence of two system characteristics the ecological functioning (productivity) and the structure (biodiversity) of the biotic community. Evaluating the toxicity of a substance depends on the degree to which it affects functioning and structure.

Effect evaluations at the productivity level can be based on the relationship generally assumed between the importance of groups of organisms in the ecosystems flow of energy (and their mutual interactions) and their role in guaranteeing the maintenance of system functions (Figure 17b). Effect characterizations at the biodiversity level are more difficult to derive direct from effects on individual populations. Biodiversity is directly linked to stability, because stability determines whether the (often numerous) species can continue to exist side by side In a soil system with high stability, species run less of a risk of extinction in the event of disturbances than in a system with low stability This may also involve the system's ability to recover. A system that has great resilience will be capable of returning to its original situation of equilibrium relatively swiftly following a disturbance. Theoretical (Paine, 1980) an experimental stability research (Yodzis, 1988; De Ruiter *et al*, 1995) into the vulnerability of the composition of a biotic community to disturbances from outside shows (as already mentioned above) a diverse and often contra-intuitive picture (Figure 17c) Moreover, it has been shown that no link need exist between the energy role of populations and their importance for the conservation of the biotic community (Paine, 1980, De Ruiter *et al*, 1995) (compare Figures 17b and 17c) Recent research points, however, to a link between the energy organisation of a biotic community (the way in which population sizes and energy efficiencies are organized at trophic level) and its ability to withstand disturbances (De Ruiter *et al.*, 1995). These principles (which may be universal) in the food web construction plan, which are of importance to stability and resilience, could constitute the point of departure for quantifying effects at ecosystem level. In this type of approach the scale of an effect is expressed in the degree to which the construction plan is affected The consideration of whether the effect is serious is then derived from the degree to which the effect on the construction plan influences stability and resilience This possibility of relating the effect to stability and

resilience is new compared with effect characterizations at ecosystem level proposed earlier, e.g the Shannon-Wiener diversity index as used by Warwick[8]

Towards a scientifically realistic framework of characterization

The above findings of soil chemical and soil biological research show that when studying the behaviour, functioning and survival of organisms in stress situations it is important to take into consideration the abiotic (bioavailability) and the biotic (soil food web) environment into consideration. At present this type of system approach still frequently produces an unpredictable and confusing picture of the possible effects of disturbances This appears to be a complicating factor to arriving at an adequate research strategy intended to result in the desired simple and easy-to-interpret system characteristics that are to form the basis of ecological risk characterization. On the other hand, large-scale international scientific focus on the structure and functioning of food webs increases understanding of universal principles and patterns in the organization of food webs (see, for example, Pimm *et al*, 1991) Good knowledge of these patterns and of the way in which pollution can result in disturbance of these patterns appears to be the most appropriate way of arriving at a scientifically sound framework of characterization at ecosystem level

In conclusion:

1. A system-based approach in ecotoxicology can make a contribution towards the challenges referred to in 3 1.1. However, this approach cannot replace toxicity tests, which are still necessary, but needs to be seen as a necessary complement
2. Research into bioavailability should focus on the universal principles within the so-called soil chemical interaction network (Japenga and De Ruiter, 1995) This research is intended to result in a method by which bioavailability can be derived from the smallest possible set of measurable soil characteristics.

3. System-ecological research into the transmission of substances (biomagnification) and into indirect effects via ecological interactions should focus on identifying universal principles in the organization (the structure) of (soil) food webs Of principal concern are aspects that are of immediate importance both to ecological life cycles and to the stability and resilience of the system. The effects of

8 In this, the Shannon-Wiener index is expanded by the population sizes of the species, both in numbers and in biomass. The degree of stress is deduced from the changes that occur in the way in which numbers of individuals and biomass are distributed among the various species. See further Warwick, 1986

pollution can then be evaluated on the basis of the degree to which the organization of the food web is affected This requires soil biological research at the level of the functioning of the biotic community (as ecological entity), instead of at the level of individuals or populations

4 ECOLOGICAL SOIL CHARACTERIZATION RELATED TO LAND USE

4.1 INTRODUCTION

The importance of good soil quality is generally recognized in the Netherlands. Soil quality requirements are not only followed by government but also by an increasing number of different market players. Prior to land transactions and before the drafting of zoning plans and building plans, for example, there is a wish to establish a picture of the environmental quality of the soil in order to prevent direct or indirect risks to public health as well as material or financial damage Soil pollution is regularly found during such investigations Sites with levels of contamination which exceed target values but contain concentrations of substances which are below intervention values will not generally qualify for cleaning Despite this, use restrictions may be required for sites of this kind In addition, there has recently been a shift in soil cleaning policy (Kabinetsstandpunt, 1997) Severe mobile soil pollution will be tackled more quickly and a more functional approach will be adopted in other cases. This may mean that contaminants are left in the soil if that is acceptable given the present or future use of the site

Here, a question which repeatedly occurs is what is still possible on a contaminated site What functions are still possible and in what conditions? It is not easy to answer these questions. There is a strong desire in society at large for simple numerical lists of standards for specific uses below which it is 'safe' to carry out a particular operation and above which it is unsafe to do so A popular example of this can be found in a brochure from the Association of Netherlands Municipalities (VNG) which contains four critical values for substances in specific situations These are as follows (Moet, 1995)

- residential with vegetable garden
- residential with garden
- residential without garden/traffic/social/cultural work
- recreational/green amenities.

Another way of answering this question is to look at the requirements based on particular ways of using a site These requirements need not necessarily lead to

standards for contaminants They can also result in, for example, guidelines for so called "living" layers, layers on clean top soil needed for a given land use

4 2 STANDARDS FOR PARTICULAR USES

4.2.1 Critical values for specific uses when building on polluted ground

Recently, the Association of Netherlands Municipalities (VNG) published a brochure presenting an approach to soil pollution related to land use (Moet, 1995) The aim of the brochure is to act as a guideline when granting planning permission where there is soil pollution In addition, this approach constitutes a building block for the operationalisation of the 'active soil management' which the municipalities are expected to implement and which is directed towards the prevention of the spread of contaminated soil and the limitation of risks for users

By contrast with the functional properties of the soil (which can be brought together under the denominator of 'multi-functionality', VROM, 1986), what is involved here is the assignation of user functions to the soil The soil function (generally speaking, only one function is assigned at a time) is the way society uses it, for example as a business location/infrastructure element, urban or rural residential area, agricultural area, recreational/nature area (VNG, 1992)

The VNG has already proposed that soil cleaning should be based more on the current use of a site (VNG 1992) It was also suggested that the historically diffuse pollution in urban areas should be taken into account when determining the urgency of cleaning and the objective of cleaning. It was proposed that necessity, urgency and objectives should be assessed on the basis of standards differentiated according to the type of land and the use of the site. In this approach, cleaning is based on the current use of the site. Any change in that use should result in reconsideration of further cleaning (VNG, 1992)

In the VNG brochure, people as users of soil occupy a central position This is inherent in the nature of the brochure which, as was pointed out above, is used in the assessment of whether planning permission can still be granted given a particular type of soil contamination As the intensity of human use decreases, with a corresponding decrease in exposure to the soil pollution, the tolerable contaminant levels stated in the VNG brochure increase (see table 6). The calculations for this table are based on the CSOIL model which describes a general relationship between levels of soil contamination and human exposure

Table 6. Critical values for specific uses in mg/kg D.M for substances in a soil with 10% organic matter (source: Moet, 1995)

Substance name	Soil use			
	residential with vegetable garden	residential with garden	residential without garden, traffic, social/-cultural work	recreation, green amenitie
arsenic	150	680	6700	1400
barium	620	4300	64000	13000
cadmium	4.2	35	3200	660
chromium (III)	620	2200	16000	3300
chromium (VI)	0.09	0 31	2.2	0 46
cobalt	100	450	4500	920
copper	2600	16000	100000	92000
mercury	44	200	2000	400
lead	330	1500	12000	2400
molybdenum	110	910	32000	6600
nickel	1100	6600	100000	33000
tin	100000	100000	100000	100000
zinc	-100	56000	100000	100000
cyanide complex	0.56	4 4	42000	8600
thiocyanates	0.48	3 -	35000	-200
anthracene	21000	29000	100000	31000
benzo(a)anthracene	6600	11000	47000	12000
benzo(k)fluoranthene	510	7600	47000	12000
benzo(a)pyrene	630	1100	4700	1200
chrysene	46	420	4700	1200
phenanthrene	133	660	44000	11000
fluoranthene	228	1070	47000	12000
indeno(1#2#3cd)pyrene	9300	12000	47000	12000
benzo(ghi)perylene	10000	12000	47000	12000
pyrene	330	6600	47000	12000
pentachlorophenol	16	80	17000	5600
DDT	-200	11000	47000	12000
DDE	285	7800	47000	12000
aldrin	3 36	13 8	230	61
dieldrin	1 16	5.4	210	60
endrin	0 9	4.36	220	59
butylbenzylphthalate	154	780	54000	14000
di(2-ethyihexyl)phthalate	251	4600	58000	15000

Tables of this kind are extremely appealing because of their lack of ambiguity and simplicity of use. In addition, it is very easy to miss the fact that soil, in addition to being used by people to a greater or lesser extent, also has other functions For example, when the exposure route through vegetables from people's own gardens is disregarded, levels are derived for a number of metals which are toxic to plants The permissible levels in soil stated in Table 6 are, indeed, not harmful for humans in

residential conditions 'with garden' but it would be very difficult, if not impossible to grow anything in the garden This is a feature of the CSOIL model· plant death as a result of the uptake of contaminants is not included in the model as the model was not developed for that purpose.

4.2.2 LAC values

For the purposes of problems occurring with agricultural soil functions on contaminated sites, trigger values were formulated in 1986 on instructions from the Agricultural Advisory Committee on Environmental Contaminants (LAC) for a number of substances (LAC, 1986, 1991) These trigger values indicate the levels at which problems for agriculture can be observed in terms of reductions in crops, animal disease or an undesirable level of contamination in products (according to the Commodities Act, Pesticides Act and Marketing Board Regulations) Trigger values for selected substances are based on the most sensitive criteria and the most sensitive product The values apply 'at optimal alkalinity and fertilization conditions' Furthermore, a differentiated system is assumed for each environmentally-critical substance, a breakdown was made according to type of soil (sand/reclaimed land, clay/peat land) and according to the agricultural use of the land (meadow land for cattle or sheep, arable farming for cattle feed, other arable crops and market gardening, and ornamental plant cultivation)

4.2.2 Plant trigger levels

On the basis of studies of the cadmium and lead content of both soil and plants in allotments where a certain degree of contamination with these metals was expected on the basis of the location or of the location's history, it was concluded that soil levels as well as levels in certain leafy vegetables were clearly higher (Van Lune, 1986, 1987). In another area of the Netherlands (de Kempen), an increased cadmium level in the soil emerged in vegetables (Lexmond, 1989). The Centre for Environmental Studies of Leiden University has linked the risk to humans associated with the TDI as a result of the consumption of vegetables with raised metal levels to soil concentrations in allotments (Wegener et al., 1993). By analogy with the LAC trigger values for agricultural ground, this study describes plant trigger levels for lead, cadmium and mercury for a number of plants which, on the basis of the uptake pattern for these metals, were considered to be suitable for plant studies The plant trigger level for a substance indicates the concentration of that substance in a study plant above which measures for the protection of public health are desirable The figures are not standards as in the Commodities Act. When

calculating the plant trigger values, the dietary habits and age categories of allotment-holders have been taken into account, with consumption patterns of children aged between 1 and 3 and vegetarians being weighted heavily

4.2.4 Limitations for the differentiated setting of standards

Standards do not tell the whole story

The TCB has pointed out the limitations of soil standards objectives in assessing the risks of soil pollution (TCB, 1990b, 1991, 1992, 1993). The integral Dutch Intervention values developed by the National Institute of Public Health and Environmental Protection (Van den Berg and Roels, 1995) have been adjusted as well as possible to take account of certain human toxicological and ecotoxicological criteria and they constitute a practical and simple tool when appraising the need for clean-up Nevertheless, they cannot be used for any health-based risk assessment, nor can any statement be made about the risk of effects in food chains (secondary poisoning) or of the spread of substances to other environmental compartments or biota These limitations apply all the more to a system of soil standards differentiated according to soil use given the fact that it is still unclear to what extent demands which the various types of use make on the soil can be translated into genuinely different use-specific critical values and clean-up objectives.

An assessment of soil pollution related to land use can, however, also take place without a differentiated system of standards set beforehand for soil Human exposure (and, *mutatis mutandis*, ecosystem exposure also) can then be estimated using data from exploratory and detailed soil surveys. The need to clean polluted soil can then be determined on the basis of a specific study of current exposure and effects, for example by means of a study of plants or bioassays of soil fauna

Permanence of soil functions

There is a fundamental distinction between the uses to which soil can be put on a scale which is determined by spatial planning, and the functional properties of soils which can, in certain cases, be seen as permanent Permanent soil functions include the ecological function and the drinking water reservoir function[9] . Assigning a

[9] The permanence of the soil function "reservoir for the drinking water supply" follows on simply from the fact that groundwater is present everywhere and is always in movement In sand sub-strata in particular, horizontal movement can amount to some tens of metres a year The permanence of the ecological function follows from the recognition of a general ecological function (TK, 1983, TCB, 1993) which soil fulfils as a part of ecological cycles in the biosphere. The additional specific ecological function of soil as a home for soil organisms is less permanent in nature

single use function to soil does not therefore exclude the same soil from fulfilling several functions at the same time. The differentiation of standards according to types of soil use on the basis of soil functions is therefore complicated by the fact that soil use can seldom be classified into mutually exclusive categories, barring exceptions such as inaccessible natural areas or buildings on ICM landfills An additional problem is that the effect on various use functions by soil pollution depends specifically on a large number of other soil properties The description of these relationships has barely begun.

4.2.5 Possibilities for setting differentiated standards?

It hardly needs emphasizing here that diversity in ecosystems is determined to a very large extent by abiotic conditions, with the condition of the soil being a crucial factor This means - once again, the point does not need emphasizing - that the type and extent of ecological risks for ecosystems of human activities in general and of soil pollution in particular depend on those abiotic conditions In policy terms, it is not particularly relevant to say that the use of soil (or of the environment in general) by society is detrimental to biodiversity and other ecological values. On the other hand, it is much more meaningful to point out that people and society benefit from a minimum level of natural and environmental quality Here, for example, one might consider life in the soil in connection with the fertility of soil for the purposes of providing the basic necessities of life (food) or as a precondition for public green spaces and plant growth in people's gardens This approach throws up specific questions relating to the use of polluted ground. An emphatic distinction is made here between soil functions as they are stated under the banner of 'multifunctionality' and specific uses in human society.

However, it is not only *ecological* quality requirements relating to plant growth which can be formulated for soil when it is used in different ways Minimum requirements are also imposed on the levels of heavy metals and pesticides in garden refuse from, for example, allotments, parks and road verges Although the extent of the annual arising of landscape refuse, as well as the possibilities for processing, have still not been mapped out satisfactorily (Projectgroep Groenafval, 1996), there are clear regulations relating to the use of compost. Statutory regulations pertaining to the quality and use of compost and black turf soil pursuant to the 'Order concerning the application of other organic fertilizers' are based on the Fertilizers Act and the Soil Protection Act. One therefore sees composting companies being selective in their approach to the landscape refuse which is supplied because of the possible presence of chemical contaminants When landscape refuse is

submitted as cattle feed (the possibility is being studied of processing the material mown from road verges) maximum standards are observed for contaminants by the Marketing Board for Animal Feed (see WVC, 1992). On the one hand, then, minimum requirements are already in place in practice for the quality of landscape refuse although not yet with respect to all the alternative processing options On the other hand, it is still unclear to what extent the various constituents of landscape refuse are released in certain types of soil use and in particular what the relationship is in those cases between quality and the quality of the soil It would therefore be sensible to map this out and to combine the exploratory study with an exploration of any future problems when setting use-specific standards for soil

4.3 ECOLOGICAL FUNCTIONS IN RELATION TO SOIL USE

When an ecological justification is requested for an appraisal of soil quality in relation to land use, it should first be established which ecological functions (with the exception of the permanent functions referred to above) can be expected under normal conditions with a particular type of use An attempt can then be made to indicate the extent to which ecological parameters should be met if the particular type of soil use is to achieve at least an acceptable level in general and ecological terms Finally, such specific ecological quality requirements must be compared to those which apply to the general ecological function of the soil

4.3.1 Nature is everywhere

In urban - and even industrial - surroundings, one finds a surprisingly wide range of species (Melchers and Timmermans, 1991, Huizinga, 1987a, b; Vogelwerkkgroep Avifauna West-Nederland, 1981) which can only be attributed in part to 'birds of passage'. Many species are dependent (if not for the whole year, at least for particular seasons) on good environmental quality in the urban setting. Examples are the pigeons in city squares or winter guests in urban settings such as robins and redwings. The biological carrying capacity of areas outside the national ecological network of protected areas (EHS) determines in part the chances of survival of flora and fauna within the EHS The food supply outside the EHS is vital for species which forage there but which pass the remainder of their existence within the boundaries of the EHS (purple heron) The possibilities of interchanges between metapopulations in separate habitats increase the size of the area and therefore the chances of survival and individual richness of the species (Verboom, 1996). A larger population constitutes a buffer against fluctuations in numbers under the influence of natural or non-natural factors In addition, the island theory suggests

that the number of species in place increases as the habitat becomes larger (MacArthur and Wilson, 1967) These considerations mean that not only the 'white areas' are important but also the urban and even industrial environments.

Often, but not always by any means, there are species in urban/industrial areas which are more or less synanthropic in the narrow sense of the term In this group, one can distinguish species which are strictly dependent on the human living environment/habitat and which are not even found any more in the wild or which have undergone a clear adaptation ('domestication') as a population This results in a distinction being made between different (but not always mutually exclusive) forms of synanthropy (Klausnitzer, 1989).

a) Obligatory synanthropy (eusynanthropy), the species in question occurs only in human settlements and only reproduces there (Table 7) Many of these species are cosmopolitan
b) Optional synanthropy (hemisynanthropy, oligosynanthropy), species which have the best chances of survival within the human living environment There are also populations outside this environment which may act as a base for immigration.
c) Permanent synanthropy, species which pass through their entire developmental cycle in the human living environment.
d) Temporary synanthropy (xenanthropy), species which are found within the human living environment at certain times (for example, wintering) or in certain circumstances. No independent populations are established here Figure 18 presents a picture of seasonal variation for a number of bird taxa in the degree to which they are tied to urban areas
e) Partial synanthropy, the species lives in an urban setting during a particular phase of its life-cycle (possibly even on a daily basis)

As a supplement to Table 7, a very large number of species of insects can be listed from a range of groups (Klausnitzer, 1989): cockroaches, wood lice, animal lice and plant lice, ants, bees and wasps A complete list of species of this kind would take up too much space and, as an illustration, go beyond the aim of this study.

Among a variety of taxa, there is also an observable trend towards 'urbanization', i e the adaptation of certain species to life in an urban setting This is a familiar phenomenon, notably among birds, with examples being blackbirds, oxeyes, blue tits, black redstarts, turtle doves, kestrels, peregrine falcons, blue herons, black-headed gulls and magpies These adaptations involve extensions of foraging and breeding

biotopes associated with changes in behaviour Urbanization of this kind is also found in other groups of animals (Klausnitzer, 1989, Adams, 1994) The adaptation would also seem to be expressed among urban populations of invertebrates as morphological, physiological or genetic differentiation. Examples of this are industrial melanism in the peppered moth (*Biston betularia*) (Kettlewell, 1973) or lead regulation in the common garden-snail (*Helix aspersa*) (Beeby and Richmond, 1987)

Species located by chance in towns sometimes lack the capacity to spread to other towns, especially when there are large distances between them. The interjacent rural biotopes present too great an obstacle Populations of this kind therefore run a relatively high risk of dying out again when conditions worsen These are generally populations of species which have been introduced or have turned wild such as the rose-ringed parakeet in Amsterdam, Arnhem, Bonn and Wiesbaden

Table 7. Examples of species of animals which are tied exclusively to the human living environment (eusynanthropy). The species lists are not necessarily found in the Netherlands. Species which are only found in hothouses or botanical gardens have been omitted

Animal group/species	Notes
Earthworm species?	under paving ('hypolithion') (Tichler 1966)
Pot worms *Fridericia* species	Warsaw city centre (Kasprzak, 1981)
Mites *Dermatophagioides* sp , various orders	house dust, 15 *de novo species* exclusively in the centre of Warsaw (Niedbala *et al* , 1982)
Pseudo-scorpions *Allochernes powelli, Cheiridium museorum, Dinocheires panzeri*	Hamburg (Weidner, 1954)
Harvest-men. *Opilio parietinus, Phalangium opilio*	Warsaw (Czechowski *et al* , 1981)
Web spiders *Amaurobius ferox, Oonops domesticus, Pholcus phalangioides, Physocyclus simoni, Scytodes thoracica, Sevestria florentina, Sosticus loricatus, Steatoda grossa, S notabilis, S triangulosa, Tegenaria domestica, Zygiella x-notata, etc*	majority of species found in or on buildings, some species are Southern European and only live eusynanthropically on the northern edge of their area (Sacher, 1983; oral communication S.P Hopkin)
Wood lice: *Armadillidium vulgare, Haplophthalmus dancus, Cylisticus convexus, Armadillidium depressum, A nasatum, Porcellio dilatatus, P laevis, P spinicornis, Pocellionides pruinosus*	Mediterranean or Pontic varieties with increasing level of synanthropy at the northern edge of their area (Klausnitzer, 1989), *A d* in gardens in Bristol (oral communication S P Hopkin), *P s* and *P p* in houses (information from M.P. Berg)
Centipedes: *Cryptops anomalans, C parisi, Lithobius pilicornis, Scutigera coleoptrata*	oral communication S P Hopkin, *L p* in centre of Amsterdam, *S c* , Mediterranean variety, in houses (information from M P Berg)
Millipedes *Melogona voigti, Blaniulus guttulatus, Choneiulus plamatus, Cylindroiulus appeninorum, C vulnerarius*	eusynanthropic in Northern Germany (Tischler 1980), parks and ruderal sites (information from M P Berg)
Springtails and silverfish. *Seira domestica, Lepisma saccharina*	in houses, originally Mediterranean (Klausnitzer, 1989)
Ground beetles· *Bembidion quinquestriatum, Prisonychus terricola, Sphrodus leucophthalmus, Tachys bisulcatus*	cellars (Klausnitzer, 1989), gardens, walls (Barndt 1981)
Birds· swifts, house-martins, swallows, feral pigeons, collared turtle-doves, jackdaws, house sparrows	Saemann, 1970; Klausnitzer, 1989
Mammals. house mouse, brown rat, black rat, house shrew, stone marten, common pipistrelle, Nathusius' Pipistrelle, serotine bat, pond bat	Klausnitzer, 1989; Lange *et al* ,1986; oral communication from B. Verboom

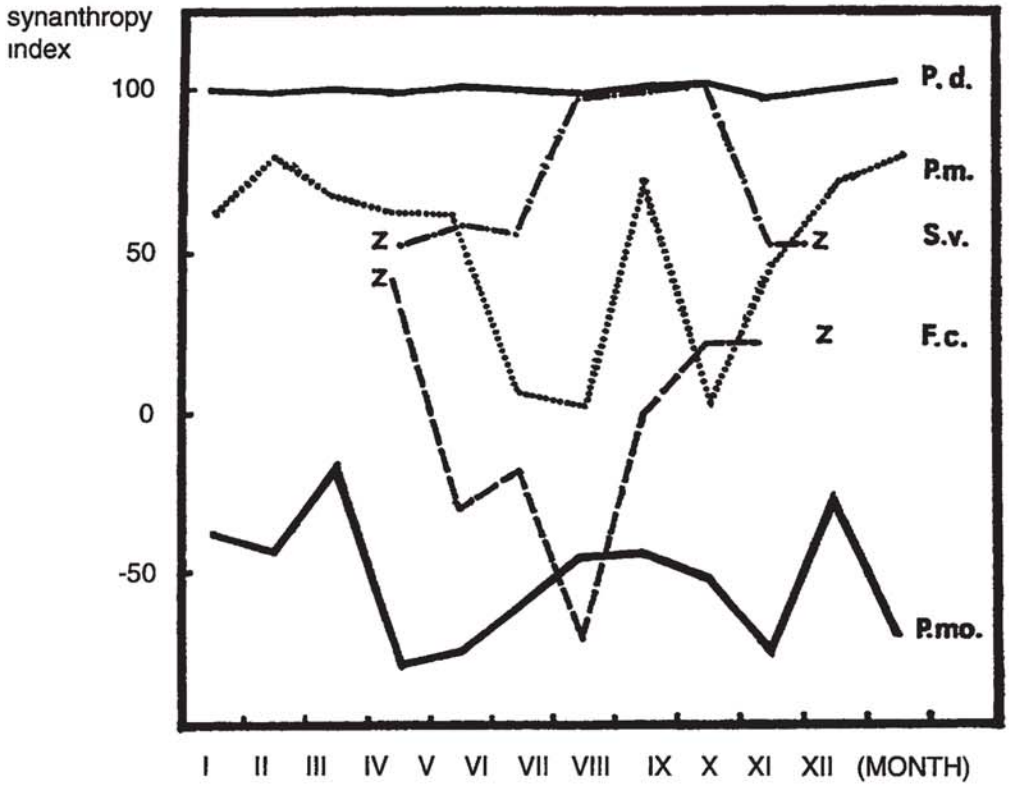

Figure 18. Monthly fluctuations in the degree to which some species of birds are tied to the urban environment (synanthropy index) The synanthropy index can vary between 100 (only found in human living environment) and -100 (not found in human living environment) Legend **Z** = migrating season, **P.d.** = house sparrow, **S.v.** = starling, **F.c.** = finch, **P.m.** = great tit, **P.mo.** = tree sparrow (after Nuoteva, 1971)

In most animal groups, a variety of species have been described with an optional synanthropic pattern, notably among the ground beetles, rove beetles, sawflies, and plant lice. 349 species of sawfly were found, for example, in Leibzig, many of which were decidedly more numerous in the city than outside it (Reichert 1933) It is clear that the urban setting provides species of this kind with optimal chances of survival, on the one hand as a result of the presence of a number of specific habitats (walls, cavities and niches, as well as specific host plants such as climbers) and on the other hand because of very moderate and relatively warm micro climates Optional synanthropic species are often cosmopolitan or dependent on man-made environments Examples are the slater (*Porcellio scaber*) and the honey bee (*Apis mellifera*), known to ecotoxicologists as standard experimental animals (Van Straalen and Van Gestel, 1993, OEPP/EPPO, 1991) and indicators of environmental quality (Dallinger *et al*, 1992; Hoffel and Muller, 1983) One might also mention

other protected taxa such as the mole cricket (*Gryllotalpa gryllotalpa*) (Odé, 1996) and the hunting wasp (*Philanthus triangulum*) (SBA, 1992)

It can be said of 'urban' communities that food webs are generally fairly simple with short food chains (Falk, 1976, Owen, 1978) A characteristic of these webs would appear to be a relatively large proportion of parasitic types, both species and individuals (Klausnitzer, 1989) Particularly on the level of secondary parasitism, there can be extremely complex trophic relationships (Klausnitzer, 1983). Nevertheless, top predators are once again very under-represented, even though this will be more the result of human intervention that the unsuitability of the environment, as is illustrated by the story of the peregrine falcon which is increasingly starting to brood in American and British cities (Cade and Bird, 1990). However, there are also taxa which actually do poorly in the urban environment. Butterflies are limited to nomadic types which can survive in an non-specific, dynamic and unstable setting (Bink, 1992) Nevertheless, the Brown Hairstreak (*Thecla betulae*), which is included on the Red List, has been seen mainly in towns and villages (Veling, 1996) Snails are also only moderately represented in urban environments Only a limited number of species are found regularly in high densities These are species with a broad ecological capacity for adaptation which find optimal conditions in specific habitats (see Klausnitzer, 1989). Furthermore, the - small - group of reptiles and amphibians would also appear to be poorly represented in the urban setting The rare natterjack toad is one of the few species which appears to benefit from this dynamic environment and it is common in, for example, allotments in the vicinity of Amsterdam (SBA, 1992). The wall lizard is also a characteristic inhabitant of the 'urban biotope' (NBP, 1990)

4.3.2 Ecological parameters

Table 8 lists the specific ecological parameters which are involved for a limited number of types of use of soil Here, following the VNG brochure (Moet, 1995), attention will be paid to dwellings with vegetable gardens/gardens and the combined forms of use of recreation and green facilities and dwellings without gardens, traffic and social/cultural work. In addition, a distinction will be made on the basis of the primary functions of agriculture and nature

For the time being, it is not possible and perhaps also undesirable to implement specific ecological parameters on a normative basis. Further research and the integration of research data is needed for this purpose and it would be advisable to try to establish links during that process with initiatives aimed at developing a soil biology indicator system for assessing soil *life support* systems On the basis of

the Strategic Action Plan for Biological Diversity (notably the action point 'Biological diversity in policies for nature conservation, the environment, spatial planning and water management') an indicator system was recently worked out for the functional ecological value of soil organisms in terms of soil *life support* functions (Schouten *et al*, 1997) In addition, the same action items also aim to make biodiversity objectives concrete in terms of their functional value for economic activities

Table 8. Qualitative ecological parameters for various forms of soil use. The degree to which they should be met can vary according to the type of use

Use	Ecological parameters
nature	all species, interactions and processes
agriculture	most sensitive production crops and cattle, self-cleaning capacity of soil
recreation, green facilities	non-sensitive plant species, nutrient cycles, avifauna etc
dwelling with vegetable garden, allotments	most sensitive production species, nutrient cycles, self-cleaning capacity of soil, pets, eusynanthropic flora and fauna
dwelling with garden	plant growth (ornamental varieties), nutrient cycles, self-cleaning capacity of soil, pets, eusynanthropic flora and fauna
dwelling without garden, traffic, social/cultural work	greenery and verge vegetation, self-cleaning capacity of soil, eusynanthropic flora and fauna

At present, normative implementation is only possible for the nature and agricultural functions by, respectively setting generic standards for overall environmental quality and trigger levels for environmentally-critical substances in soil used for agricultural purposes However, the trigger values are only determined in a few cases by ecological parameters, an example being the LAC trigger value for copper in meadows on sandy ground in connection with toxicity for sheep

The plant trigger values are based on a line of reasoning and a method which, ideally, should also be part of a user-based ecotoxicological risk assessment. This would mean, for example, a listing of the species which can be supposed to be present given a certain use of the soil. The principal route of exposure would have to be indicated for these species -or at least for clusters of them - combined with an effect prognosis After the inevitable alterations, existing model structures could be used for this purpose Examples of this approach might be group-based species and functional models for secondary poisoning (Traas and Aldenberg, 1992 and later

versions of CATS, Jongbloed *et al.*, 1994; Romijn *et al.*, 1994, Gorree *et al*, 1995) or even individual-based and dynamic population models (Klok and De Roos, 1996; Baveco and De Roos, 1996). A recent development in model-building and other extrapolation methods is directed towards risk assessment relating to secondary poisoning among target species and other species of special concern in nature policy (Posthuma *et al*, 1995, NKV, 1997)

4 4 DISCUSSION

It is clear that the call for a use-specific approach in the appraisal of soil quality is primarily linked to demands in society at large in the areas of accommodation, infrastructure and industry For other uses such as agriculture, recreation and nature, there are fewer reasons to introduce differentiated standards On the contrary, 'nature is everywhere' and the ecological values of soil (both specific and general) and the quality of drinking water actually benefit from a single, generally-applicable, soil quality standard There is therefore a fundamental conflict here.

As a result of this conflict, social costs are inevitable and policy choices are required Either time-consuming procedures and cleaning result in high economic costs for house-building and businesses, or the costs are borne by drinking water extraction (present and future) and nature. Whatever the situation, soil pollution costs money.

With uses of soil in which consumptive exposure is negligible - notably in the case of non-volatile compounds - differentiation in soil standards based on human toxicological risks soon results in very high tolerable soil concentrations On the other hand, ecological arguments for differentiation allow for less room to manoeuvre with respect to standards because general and use-specific ecological parameters impose relatively stringent requirements on soil quality for all uses (as discussed in this report).

Given the ecological specificity of nature and the environment in urban areas, general environmental standards should, in principle (from the ecological point of view at least) be followed here also. An ecological justification of differentiation in standard setting based on soil use should at least provide guarantees for the relevant ecological parameters. This not only applies to all sorts of ecological processes but also, in particular, to the continued existence of Dutch populations of eusynanthropic species

The policy of the national government with respect to nature in the cities is not very explicit and mainly contains recommendations for the maintenance and development of ecological values on the municipal level *"Attention needs to be paid to the conservation and development of specific 'urban biotopes' which are of major significance for the continued existence of a number of native plant and animal species which are tied to a large extent to the urban environment "* (NBP, 1990) Policy objectives with respect to nature in the city are, however, not worked out in any further detail. The national ecological policy concentrates mainly on the conservation and development of nature in the national ecological network of protected areas. The policy for urban ecology in towns, on the other hand, is, in principle, formulated in much greater detail in municipal green structure plans. On this policy level, there is a meeting of policy and management with respect to ecology and the environment However, in the interests of consistent protection for urban ecology, the authorities involved should implement differentiation in standards for environmental quality jointly on the national level in order to prevent lower levels of government from introducing highly varied priorities in user demands.

When a policy choice is being considered on cost grounds which may involve adverse consequences for ecological parameters, it may only relate to general parameters which are not use-specific since the specific parameters guarantee that the soil functions correctly in economic terms in that respect Sites which do not meet these conditions can affect the use function or may constitute a social risk in other ways. Growing vegetables in a vegetable garden on polluted ground can, for example be rendered more difficult when the soil contains concentrations of substances at which phytotoxicity can occur. Alternatively, risks for consumer health may result

In accordance with the risk philosophy on which the environmental protection policy is based, consideration may be given to carrying out a risk analysis for specific ecological conditions in order to arrive at an ecological justification of use-specific standards Given current knowledge, however, the use of the HC5 method is not a solution here since a limitation in the set of toxicological data relating to organisms specific for types of soil use or soil processes in general will result in lower risk limits than a generically-derived MTR. This is not so much a result of a possibly higher mean sensitivity of the organisms in question as it is the result of a larger margin of uncertainty in the derivation method since the data which can be used are less specific. It is possible that, for a few heavy metals for which relatively large

amounts of data are available (cadmium and zinc), this method opens up reasonable possibilities.

An alternative approach to the problem which may be considered is the identification for each type of use of one or more organisms or processes which belong to the necessary ecological conditions (characteristic species). A specific critical value could then be estimated for characteristic species and processes of this kind on the basis of known ecotoxicological data. This approach is currently being used by the National Institute of Public Health and Environmental Protection to calculate ADI-like exposure limits for target species in nature policy To that end, data about the toxicological sensitivity of entire categories of animals (birds, mammals) is being processed in an HC5 procedure and combined with data/suppositions about exposure via various food sources (Luttik *et al.*, 1997) As an alternative, the American approach of adopting the lowest sensitivity of a comparable species could be followed, based on the best studies described in the literature

Finally, as has already been pointed out elsewhere in this report, it generally makes little sense, if one wishes to obtain a sound estimate of ecological risks, to limit the risk estimate to the use of toxicological threshold values in accordance with the HC5 approach (or the fraction which may potentially be affected) with, where appropriate, an approximation of 'the' biological availability. It is essential for the arsenal of ecotoxicological methods and techniques to be extended considerably To bring this about, further research is required in which it is essential for there to be funding aimed at encouraging policy-oriented activities In addition, the use of generic methods will not always be appropriate for specific soil pollution situations when particular uses are involved. Room should be left for *expert judgement* when estimating the ecological risks of soil pollution, notably for current risks of exposure (route and duration) for the organisms and soil processes in question. Given the current scientific situation, the possibilities for an ecological basis for use-specific differentiation of soil standards would appear to be limited for the present

5 ACKNOWLEDGEMENTS

Chapter 2 and the Appendix were written with assistance from Trudie Crommentuijn and Wim Mennes (both from RIVM/CSR) who kindly allowed their expertise to be exploited. Thanks are also owing to Sim Broekhuizen and Ben Verboom (IBN-DLO), Steve Hopkin (Division of Zoology, University of Reading) and Matty Berg (Free University Amsterdam) for information about eusynanthropic fauna We are indebted to Joop Vegter (TCB) for his inspiration and his role as a 'sounding board' in this project. Joke van Wensem (TCB) took the editing of the draft report in hand and brought the apparently separate chapters together into a coherent whole

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ANNEX

CONTENTS

1 METHODS FOR DOSE-EFFECT ASSESSMENT

For toxic substances, dose-response relationships can be used to establish an acceptable exposure Here, a fundamental distinction is made between genotoxic and non-genotoxic substances on the basis of the toxicological action As a rule, it is supposed that a single molecule of a genotoxic substance is sufficient in principle to cause a carcinogenic or teratogenic mutation. In the case of non-genotoxic substances, on the other hand, a threshold value is assumed below which no effect will occur. On the basis of this distinction, different models must be used in order to derive a safe dose assessment from experimental dose-effect data

1.1 Non-genotoxic substances

With non-genotoxic substances, the safe dose is smaller than or equal to the threshold value, in other words the dose at which there is no effect There are various methods for estimating a threshold value, the most generally-used of which is the *no observed effect level* However, this is not a measure without its critics This traditional method and more recent alternatives developed within human toxicology or in ecotoxicology are described below and are compared to each other on the basis of Kramer *et al*, (1995) and Zeilmaker *et al* (1995)

No observed effect level (NOEL)[1)]

The NOEL is the highest experimental dose which does not induce any effect which differs significantly in statistical terms from the control group. When it is used to derive a human toxicological limit value such as the *acceptable daily intake* (ADI), the NOEL should be determined in chronic and semi-chronic studies

Advantage

The NOEL can be determined even on the basis of limited dose-response data A simple statistical evaluation of the differences between trial and control groups is adequate.

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1) Another measure which is used is the 'no observed *adverse* effect level (NOAEL) in order to distinguish minor stimulation at low doses (hormesis) Since certain substances can have a substantial effect on, for example, reproduction (oestrogenic effect), without it being clear whether this has implications on the fitness of offspring, the term 'adverse is not always meaningful An adverse effect is considered to be an effect "*leading to functional impairment and/or the induction of pathological lesions which may affect the performance of the whole organism, or which reduce an organisms ability to respond adequately to additional challenge*" (EPA, 1980) As a rule, this report uses the term 'NOEL

Disadvantages

The NOEL is very dependent on the doses selected and the number of replications in the experiment A high degree of variation in the observations soon leads to a high NOEL but without a guarantee that there is no toxicity (Hoekstra, 1993)[2]. In addition, the NOEL does not provide any information about the dose-response relationship so that toxicity is not quantified when the threshold value is exceeded.

Benchmark dose, Gaylor's linear extrapolation, bounded effect dose

The *benchmark dose* (BM) is the lower limit of the statistical confidence interval for the dose which corresponds to the threshold value at which an effect occurs (Crump, 1984) The BM is estimated on the basis of the dose-effect curve (see figure 1) by reading off the corresponding dose for an accepted effect limit (NOEL<NEL<LOEL), and then calculating the confidence interval on the basis of the experimental error

Linear extrapolation using the Gaylor method results in the lowest dose (LED_{10}) at which a 10% effect occurs within a certain confidence interval (figure 2) This is obtained by linear interpolation of the upper limit of the statistical confidence interval for the ED_{10} , the dose at which a 10% effect occurs (Gaylor, 1988). On the basis of the LED_{10}, a linear extrapolation can be made to zero in order to establish a conservative safe dose

The *bounded effect dose* (BED) is the highest experimental dose for which a confidence interval does not exceed a 25% effect (Hoekstra and Van Ewijk, 1993). A safe dose is obtained here by linear extrapolation to zero from the upper limit of the statistical confidence interval for this dose (figure 3).

The 25% effect level is considered to be relatively high compared to both of the other methods but it is claimed to be a reflection of the fact that the method is developed for ecotoxicological data (Kramer *et al* , 1995).

2) In order to meet this objection, the introduction of the 'quasi-NOEL(qNOEL) has been proposed (Calabrese and Baldwin, 1993) This qNOEL, which is located between the 'real NOEL and the LOEL, is the highest concentration which is not different from the control but also not different from the LOEL The qNOEL can, depending on the statistical analysis, be approximated using an uncertainty factor. However, this concept results in a large degree of dependence on the analytical power of the statistical technique used

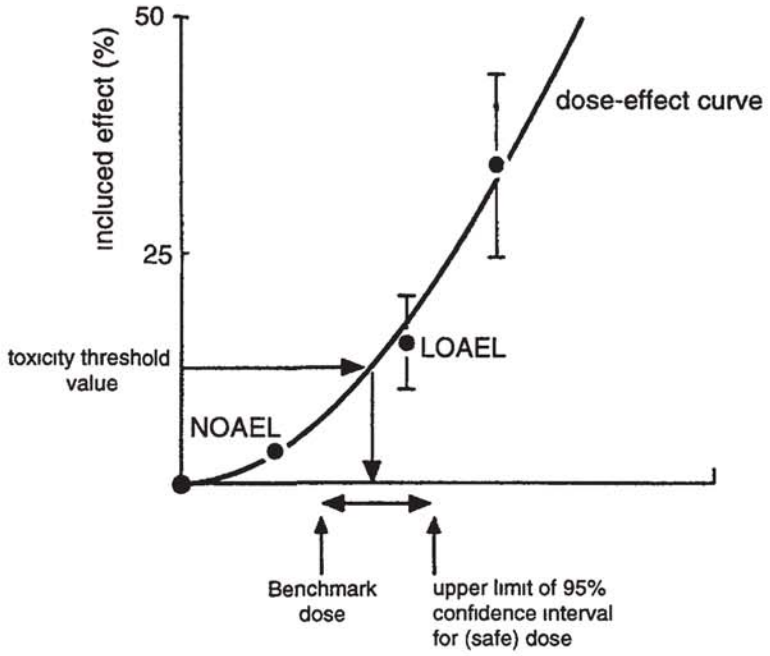

Figure 1. Graphical presentation of Crump's *benchmark dose* The graph shows the proportion of laboratory animals (%) in which an effect was observed in relation to the dose to which the animals were exposed.

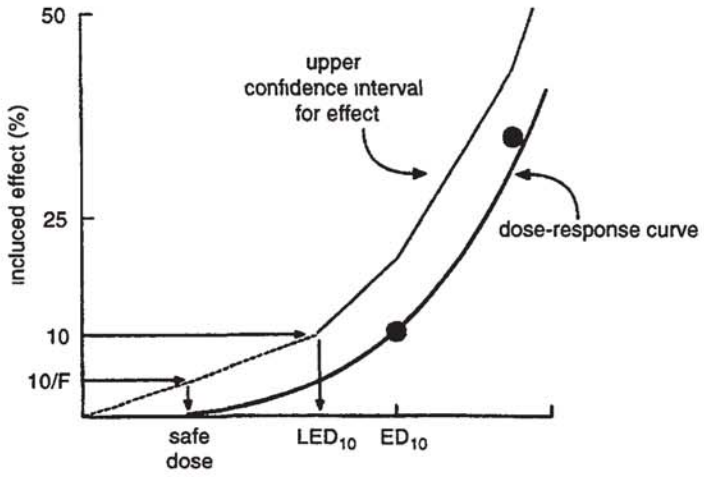

Figure 2. Graphical presentation of Gaylor's calculation of a safe exposure level. The graph shows the proportion of laboratory animals (%) in which an effect was observed in relation to the dose to which the animals were exposed ED_{10}, the dose at which 10% of the effect is induced. LED_{10}, the dose associated with the upper limit for the 95% confidence interval for the effect level of the ED_{10} F, safety factor for toxicity (in laboratory animals), the level of which depends on the severity of the effect.

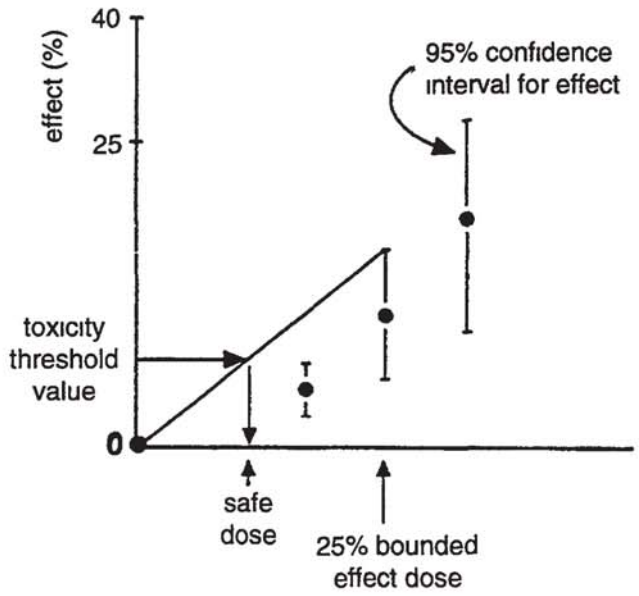

Figure 3. Graphical representation of Hoekstra's method for determining a safe dose on the basis of the 25% 'bounded effect dose'

Advantages.

These three methods all have the same advantage over the NOEL concept in that they use confidence intervals for the threshold value or the safe dose In addition, they assume a dose which produces an effect in order to determine the safe dose or threshold.

The methods of Crump and Gaylor can be used to determine a safe dose which is relatively independent of the experimental doses When a BM, LED_{10} or safe dose is exceeded, this method can be used to assess toxicity However, this application is limited to situation in which the BM or LED_{10} are exceeded for periods which are comparable to the experimental exposure time on which the dose-effect relationship is based. In addition, it is supposed that there are no inter-species variations.

The BED is not derived using a dose-effect model so that this technique can be used in situations in which insufficient dose-effect data is available to determine a safe dose in any other way.

Disadvantages

Crump's *benchmark dose* method cannot be used if only two or three experimental doses have been assessed since this makes it impossible to establish a sufficiently reliable dose-effect curve. Nor can the BM be much lower than the lowest

experimental dose because of the unreliability of extrapolation on the basis of fitted regression models This objection applies primarily when low threshold values are used

When the methods of Crump and, in particular, Gaylor are used, the choice of model (sigmoidal or logistical) for the description of the dose-effect relationship determines the safe dose which is ultimately calculated when the latter is based on the low-dose section of the curve This is because, in this section, the degree to which models are appropriate for experimental data is highly variable In other words, the choice of the effect percentage for determining the BM or LED can be a determinant element in the basis for the calculation of a safe dose
The BED results in a rather conservative (low) estimate for a safe dose In addition, the BED is clearly dependent on the choice of experimental doses

In summary The choice of the method to be used should be independent of the quality of the available data (in other words is it reasonable to state a dose-effect relationship?) and of the *effect level* to be accepted (is the corresponding dose within the range of experimental observations since extrapolation outside this range results in a rapidly increasing level of unreliability)

No Effect Level

The actual threshold value for an effect, the *no effect level* (NEL) can be assessed using a *split-line* model developed by traditional ecology A model of this kind can be postulated for ecological data in which a dependent variable y has a linear relationship with an independent variable x, up to a point where there is a sudden change in the relationship, after which another linear relationship comes into effect (figure 4) Although these model parameters can vary in independence from conditions (experimental or real) or between species, it is possible that the data will be studied in a single analysis The techniques for the associated regression analyses (Hudson, 1966) and evaluation of several data sets and models for point estimates (γ, ∂) (Perry, 1982) are nevertheless not yet used in ecotoxicological dose-effect research

Advantages

Possibility of analysis of numerous studies conducted in different conditions or analysis of multi-species data.

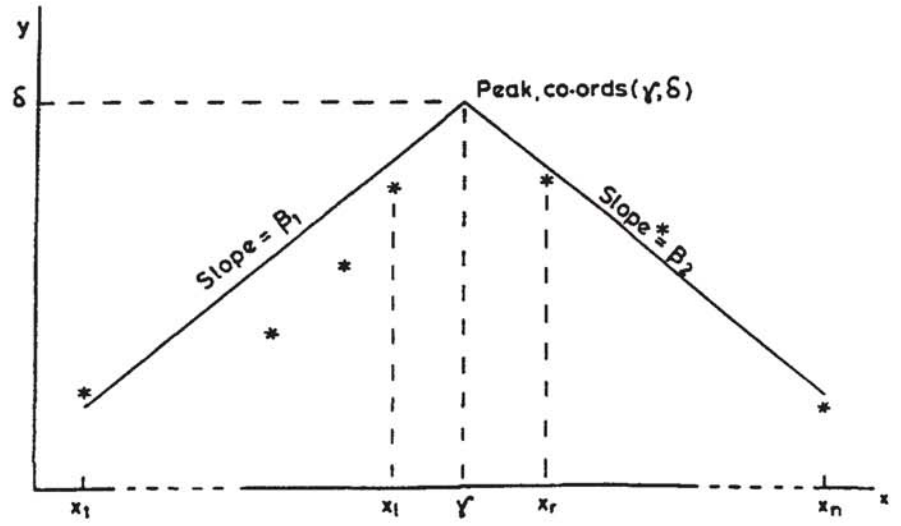

Figure 4. A *split line* with parameters β_1, β_2, γ and ∂ These four parameters are estimated using the measurement data (*) The amount of data (x_1, y_1) . (x_n, y_n) is n The x values (to be read as doses) are found in increasing order from x_1 to x_n. The threshold value NEL (γ, ∂) is located between x_1 and x_r, which correspond to the NOEL and LOEL respectively.

Disadvantages:

The method requires several observations on either side of the threshold value since a bent line can otherwise be interpreted as a straight one Multi-species data can then produce results which are at variance with conclusions on the basis of data for single species (Taylor, 1963)

Dose-severity diagrams

Whereas the methods discussed above were directed towards the evaluation of the most sensitive toxicological parameter, the severity of the adverse effect plays less of a role in the method of *dose-severity diagrams* which has been developed by the EPA to assess the human *chronic reference dose*. The total of available dose-effect data is shown in graph form in a *dose-severity diagram* To do this, effects are classified according to intensity. NOEL-NOAEL-LOAEL-FEL[3)] (DeRosa *et al*, 1985, EPA, 1987) or a *rating value for effects* (Stara *et al.*, 1986; Hartung and Durkin, 1986, quoted in McColl, 1990). The doses can also be classified The data is then shown in a scatter diagram (figure 5) and a straight line can then be drawn to the right of the scattered points. The point of intersection of this line (the *apparent severity slope*) with the dose axis results in the *overall* NOEL.

3) FEL = Frank Effect Level

Advantages:

All available toxicity data is used and, when the ADI is exceeded, one has an indication of the toxicological impact of the substance in question

Disadvantages:

The classification of effects is difficult since criteria are not clearly defined Effects are described in ordinal terms and stated in intervals and it is unclear whether all the intervals are equally large. Given the lack of objective methods, the determination of the *apparent severity slope* depends for the time being on a simple visual appraisal Any quantitative analysis of effects is therefore open to question Finally, it would appear that the final result which is obtained is, as a rule, hardly any different from the very lowest NOEL (for the most sensitive toxicological parameters and the most sensitive species)

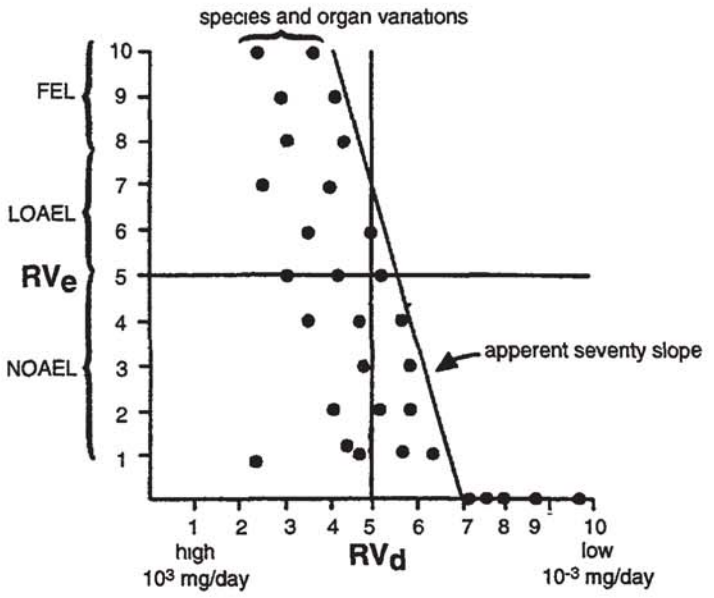

Figure 5. Example of a *dose-severity plot*· effects are classified according to EPA criteria and displayed as a graph using the logarithm for the associated dose. The *x* intercept of the *apparent severity slope* corresponds to the *overall* NOEL.

1.2 Genotoxic substances

Whereas non-genotoxic substances are characterized by a threshold value for the occurrence of an effect, the supposition with genotoxic substances is, as a rule, that there is no threshold value The possibility of determining the risk in excess of the background level for the occurrence of carcinogenicity given life-long exposure depends, however, very much on the number of experimental animals so that, in

practice, risks of less than 5-10% cannot be isolated[4] Human exposure and the resulting doses are, for most carcinogens in the environment, many times smaller than the doses used in research with laboratory animals. This therefore requires not only extrapolation for specific differences between animals and humans but also for risks which are several orders of magnitude below the range of available dose-effect data Establishing the dose-effect curve for genotoxic substances therefore requires models which are fundamentally different Although a considerable number of mathematical models have been developed for this purpose (see table 1), which are brought together in figure 6, no single concept is considered to be pre-eminently suited for the assessment of carcinogenicity at low doses. The results vary considerably a particular dose for humans resulting from environmental exposure (e g dose B in figure 6) could, on the basis of threshold models, be interpreted as 'no additional risk or precisely as 'additional risk_ but with a potential difference in interpretation of one order of magnitude, depending on whether linear or sub-linear models are used

Table 1. Overview of the most quoted mathematical models for the description of the relationship between administered dose, time and tumour incidence (source: Kramer *et al* , 1995)

Tolerance distribution models	Mechanistic models	
Logit	One-hit	Moolgavkar (MVK)
Probit	Miltihit	Cohen and Ellwein
Mantel Bryan	Weibull (Pike)	
Weibull	Multistage (Armitage-Doll)	
Gamma-Multihit	Linearised Multistage	

Of the large range of models, the mechanistic ones are the best choice, preferably those with a biological basis (as compared to *hit models*) (Kramer *et al* , 1995) Biologically-based models, the MVK model for example (Moolgavkar and Luebeck, 1990), predict the outcome of toxicological experiments using quantitative equations for the specifically mechanistic stages in the toxic action of genotoxic substances (Andersen *et al* , 1992) This provides an opportunity to assess risks in all exposure conditions rather than in experimental conditions only. In other words. it is possible to extrapolate for doses, exposure duration and exposure route In addition, it is certainly just as important for extrapolation to low doses to be based on a mechanistic understanding of carcinogenicity The model parameters can

4) Data for carcinogenicity at low doses cannot be obtained directly from experimental studies because the statistical sensitivity and the number of experimental animals are too small Extrapolation outside the range of testable - i e high - concentrations is therefore required

be interpreted biologically and they are therefore, in principle, measurable. This type of model could also be used to construct models for carcinogenesis resulting from cytotoxic, non-genotoxic substances

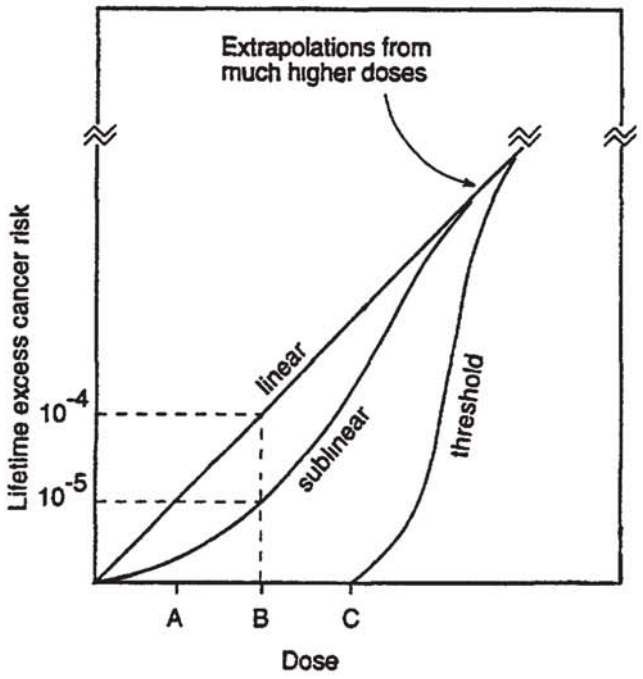

Figure 6. Hypothetical dose-response curves for experimentally-induced cases of cancer at low doses of genotoxic substances

1.3 Evaluation methods for dose-effect assessments

Although the alternatives stated in section 1.1 meet the objections made against the NOEL, they are certainly not in widespread use. This is primarily attributable to the fact that the alternatives involve a new problem, namely that an effect level has to be stated which can be seen as negligible or acceptable Whereas the qualitative question previously was which toxicological testing parameter was adverse, the much more difficult to quantitative question now arises of the level at which an effect is adverse for a particular parameter. At present, no objective answer to this question is possible.

This means that both the NOEL approach and the alternatives depend on a certain level of subjectivity. However, the difference is that, with the derived benchmark dose, effects of a certain size can be excluded so that the subjectivity is explicit and controlled by the person making the risk assessment, whereas this is not the case with the NOEL since the latter is determined on the basis of *expert*

judgement without it being possible to exclude effects of *un*determined size It would therefore be mistaken to reject the proposed alternatives for this reason.

An entirely different alternative is the use of regression analysis for models with a direct threshold value and the determination of the associated confidence interval. Existing methods in this area, the *hockey-stick* model for example, generally suffer from very wide confidence intervals in the area of the threshold value In this respect, considerable improvements may be expected (see Kooijman and Bedaux, 1994, 1996)

Table 2. Overview of toxicological criteria as alternatives for the NOEL, broken down according to the discipline which developed them

Human toxicology	Ecotoxicology
- Crump's 'Benchmark dose'	- Hoekstra's 'Bounded effect dose'
- Gaylor's linear extrapolation	- Kooijman and Bedaux's threshold value model
- EPA 'Dose-severity diagram'	
- Hockey-stick model	

When the proposed alternatives (summary in table 2) are compared for the derivation of effect limits, it emerges that all the methods are, in principle, preferable to the NOEL which is traditionally used Each of the methods offer specific advantages but the decision about which of them to use is primarily determined by the available experimental data. Furthermore, although methods developed by human toxicology have already been available for about a decade, they are - mistakenly - hardly used at all by ecotoxicologists. This can only be partially explained by the limited size of ecotoxicological experiments and the amounts of data which they have produced It is the case that there is little individual variation in stocks of laboratory animals used in human toxicological experiments whereas ecotoxicologists must, as a rule, take considerable biological variation into account (Baird *et al*, 1990) This could easily exclude the use of a number of alternative criteria but not the BED recently developed by Hoekstra.

In conclusion, it can be stated that, on the level of the dose-response approach for non-genotoxic substances, the possibilities and reliability of the derivation methods for research data are comparable in human toxicology and ecotoxicology However, this does not apply to genotoxic substances. In this area, strikingly little work is being done by ecotoxicologists, whereas human toxicologists have already developed numerous models (Moolgavkar and Luebeck, 1990, Health Council, 1994; see also Kramer *et al*, 1995)

2 EXTRAPOLATION METHODS

After safe doses have been assessed in test species, they should be converted for humans (human toxicology) or for related species or the entire habitat (ecotoxicology) There are numerous methods for general extrapolations of this kind (see, for example, Kramer *et al*, 1995) which are generally specifically adapted to one of the two disciplines. In addition to the general extrapolations, methods have also been developed for specific areas such as exposure duration or exposure route In what follows, the discussion will cover a few widely used methods.

2.1 Non-genotoxic and non-immunotoxic substances

In what follows, a few methods will be explained which are used in the extrapolation of toxicity data for non-genotoxic substances Advantages and disadvantages will again be stated on the basis of Kramer *et al.*, 1995

Safety factor method[5)]

This method is used in the extrapolation of effect limits (usually the NOEL and solely for non-genotoxic substances) from animal studies to establish a human toxicity standard. With a complete package of experimental toxicological data, a factor of 100 is usually involved which consists of inter-species variations when converting from animals to humans (factor 10) and inter-individual variations in order to take heterogeneous sensitivity in the human population into account (factor 10). When the results of human epidemiological research are used to determine recommended exposure limits, the share of inter-species variation is eliminated from the safety factor. In effect, an extrapolation is conducted with the factor for inter-individual variation from the biological organization level of the individual to that of the population. The factor 100 also covers the possible error in the extrapolation method on the basis of body weight which would be eliminated in the case of extrapolation on a caloric basis. A further appraisal of the constituents of the safety factor 100 can be found elsewhere (Health Council, 1995) With a less comprehensive package of toxicological data, several extrapolations can be carried out, for example for exposure duration or exposure route or for effect doses as basis for further work This means that variation resulting from the complex of environmental influences and observation errors (the error complex) can be accounted for in an extra safety factor. Each stage then has its own safety factor up to a maximum of 10 with the potential total reaching a

5) Also known as uncertainty factor

factor of 10,000. The application of a safety factor to toxicity data results in an ADI or TDI.

Advantages

A simple method which can always be used if the dose-effect data is suitable In addition, uncertainties relating to various extrapolations are covered. Practical use has proven the practicality of the factor 100 in use with food additives and pesticides

Disadvantages

A factor 10 does not, of course, exactly represent the difference between human and animal responses. It is a conservative limit which has been arbitrarily chosen

Renwick's safety factor method

This is a refinement of the safety factor method in which generalized and specific information about intra-species and inter-species variations in toxicodynamics and toxicokinetics is included (Renwick, 1993) Without specific information, the safety factor is given a fixed numeric value (figure 7) As a rule, specific information results in a lower total safety factor.

	Toxicodynamics	Toxicokinetics
Inter-species variation	2 5	4
Intra-species variation	2 5	4

Figure 7. Refinement of a safety factor 100 (Renwick, 1993).

Advantage.

Specific distinction between inter-species and intra-species variations in kinetics and dynamics

Disadvantages

It is difficult to establish factors for toxicodynamics because the required data is usually lacking on both levels It is also unclear how to select kinetic factors. In addition, Renwick bases his calculations on the administered dose and not the internal dose Ultimately, the continuing assumption is a safety factor of 100

Allometric scaling method

Concentrations of substances in organisms can sometimes be explained on the basis of body weight, particularly in the case of animals (Fagerstrom *et al.*, 1975;

Griesbach *et al.*, 1982) This is linked to the fact that absorption takes places through surfaces and that the ratio surface area content depends on body size The extrapolation can be conducted on the basis of the body weight, the body surface and the caloric requirement (see Health Council, 1995) In allometrics, specific physiological characteristics are linked empirically to body weight, for example 'log-oxygen consumption' versus 'log-body weight' (figure 8) When, on the basis of generalizations of this kind, toxicological data are converted from one animal species to another (including humans), the term used is 'allometric scaling'. The generalizations produced by this technique must be based on sound interpretations and correlations between various test species before they can be used in human toxicology in the extrapolation from animals to humans The technique is particularly appropriate for inter-species comparisons relating to internal doses given the same external exposure In principle, the elimination rate in small animals is higher than in larger species, including humans.

Disadvantages

Problems occur when the species compared are different in physiological terms and the substance being studied is eliminated or stored as different metabolites (Van Straalen and Van Wensem, 1986, Van Hattum *et al*, 1991, Janssen *et al.*, 1991) Specific differences in the internal distribution of the substance over tissues under the influence of protein complexes can make comparisons between species awkward. In addition, this technique cannot (yet) take into account specific variations in adsorption or biological availability If factors of this kind were understood, a more refined type of allometric scaling would become possible At present, the technique is seldom used in human toxicology (Rauws and Groen, 1994), nor is it used extensively in ecotoxicology, with uses appearing to be confined mainly to aquatic fauna or intra-species comparisons.

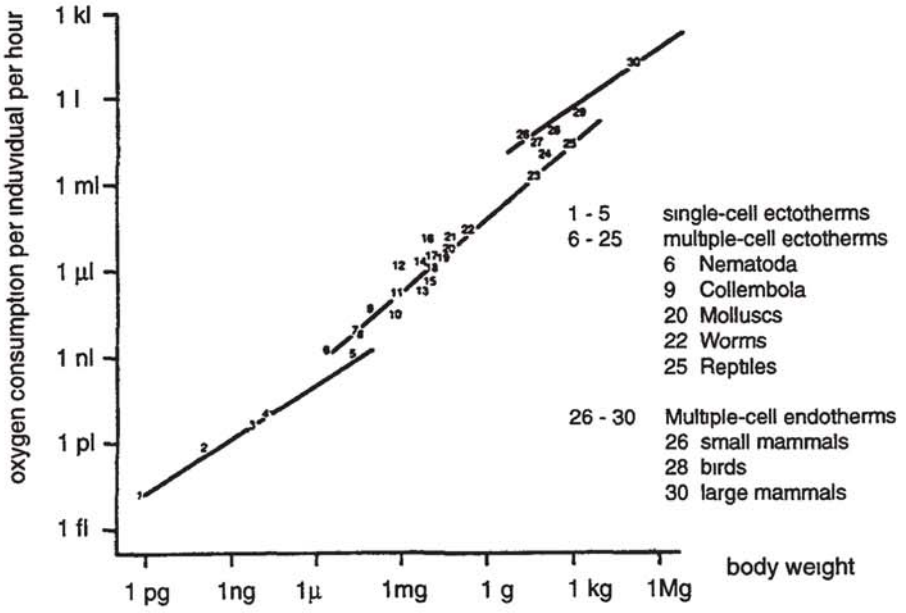

Figure 8. Relationship between oxygen consumption and body weight in various taxa (source Van Straalen and Verkleij, 1991).

Exposure duration and effect the Haber rule

The Haber rule is used for the extrapolation of exposure duration (Calabrese and Kenyon, 1991)· the product of the administered dose (C) and the exposure time duration (T) until the effect occurs is a constant K: C*T = K It follows from this that

$$\log C = \log K - \log T$$

When the product of exposure time and dose is a constant, this corresponds implicitly with a constant effect level The constant K is therefore dependent on the size of the effect being studied. For example, a series of LC_{50} levels obtained at different exposure periods can be presented in graph form as an effect limit line (figure 9) However, the relationship is not valid if extremely short time intervals are involved or if concentrations are very low Between the first moment of exposure and the occurrence of an effect, there is a minimum reaction time known as the latency time. With chronic exposure, there is a maximum exposure time above which the concentration required to induce a certain effect no longer decreases. The concentration then achieved is known as the 'chronic effect concentration', abbreviated in figure 9 as $LC_{50}(\infty)$ In the section 'between' latency time and chronic effect concentration, the exposure time can be extrapolated using the effect limit line

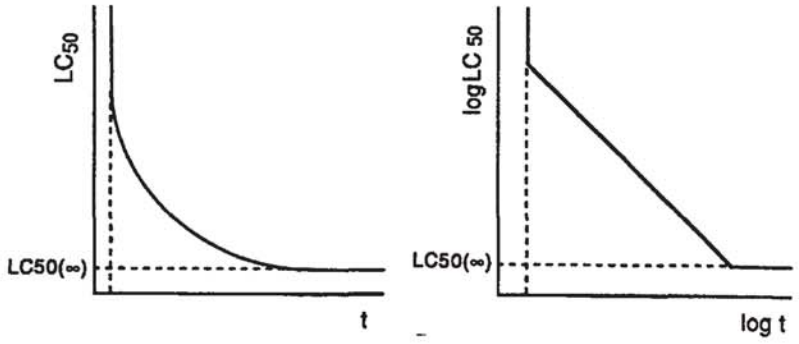

Figure 9. Example of an effect limit line according to the Haber rule The relationship between the concentration at which a particular effect occurs and the associated exposure time is shown on the left on a linear scale and on the right on a logarithmic scale (source: Van Straalen and Verkleij, 1991)

Advantage

A simple method when dose-effect data is available

Disadvantages

In principle, the method is not valid because exposure (biological availability), for example, cannot be treated as a constant When exposure does not result quickly in an effect, for example with carcinogenic substances, relatively more effect is found with long exposure periods so that the slope in the right-hand section of figure 9 is steeper

The relationship between exposure time and effect was presented using another model by Kooijman (1981) and Neely (1984). In this model, the period of time (t) which elapses before the organism dies was related to the lethal internal dose, also known as the *lethal body burden,* LBB Given accumulation in a single-compartment model, the following equation applies

$$LBB = Q(\infty)(1-e^{-kt}) \quad (a)$$

Here, Q is an internal quantity of the substance (in mg, for example) and k is a rate constant for elimination (in mg mg^{-1} day^{-1}) This equation is valid for all external concentrations, including the LC_{50}. When a balance has been established between external and internal concentrations, the relationship between them indicates the bioconcentration factor (BCF) When the external concentration is equal to the LC_{50}, the following equation applies

$$BCF = Q(\infty) / LC_{50} \quad (b)$$

Equations a and b can now be re-written as:

$$LC_{50} = LBB / BCF(1-e^{-kt}) \quad (c)$$

And since:

$$LBB / BCF = LC_{50}(\infty) \quad (d)$$

equation (c) can be re-written as

$$LC_{50} = LC_{50}(\infty) / (1-e^{-kt}) \quad (e)$$

This relationship is shown in figure 10 Using this model, the elimination constant k can be estimated (and therefore the kinetics of the substance) on the basis of mortality figures Variations in toxicity between substances can, in this way, be explained on the basis of kinetic variations

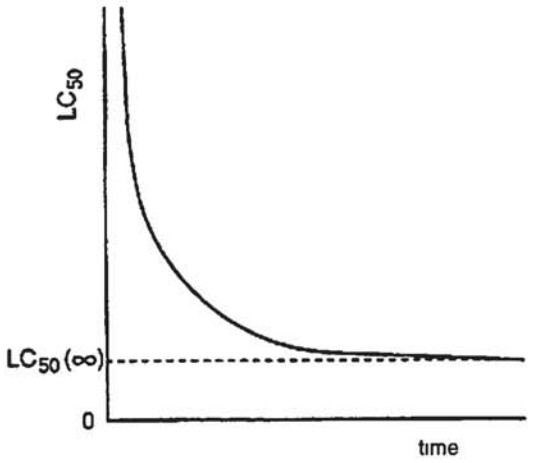

Figure 10. Global form of the curve for formula (e) with which the elimination kinetics of a substance are assessed on the basis of mortality figures (source Van Straalen and Verkleij, 1991)

Advantage:

This model provides a better picture of the mechanism on which the time effect is based

Disadvantages

In studies of mortality resulting from acute exposure, it is not possible to make a simple assumption that there is a kinetic balance. Equation (b) is then no longer valid Furthermore, biological availability cannot be treated as a constant in comparisons of chronic and acute experiments

Route to route extrapolation

In the extrapolation of toxicological data from experimental animals to humans, one can run up against the problem of differences in exposure routes. Route to route extrapolation is then necessary To do this, an availability factor is required so that corrections can be made for variations in concentrations in blood serum which are associated with the exposure route. In this way, oral toxicity data (intra-species) is converted to inhalation data using the equation (van de Meent and Toet, 1992)

$$NOAEL_{oral}*B_{oral}*biomass = NOAEC_{inh}*B_{inh}*IR$$

Here, B_{oral} is the biological availability given oral exposure and B_{inh} availability after inhalation IR is the inhalation rate in m^3 day^{-1} $NOAEL_{oral}$ is expressed in mg kg^{-1} day^{-1} and $NOAEC_{inh}$ in mg $m^3 day^{-1}$

Advantage

A simple method when dose-effect data is available

Disadvantages

The method is impracticable when there are different types of effect dependent on the exposure route In principle, the method is difficult to use since biological availability cannot be treated as a constant

PBPK modelling

All the models discussed above postulate links between external concentrations and the effect However, it is better to work with the dose in the target organ, the internal dose This is a specific reflection of kinetics, physiology and physical-chemical interactions The inter-species comparison of internal doses is thought to explain variations in sensitivity, in part at least. A method for assessing the internal dose is PBPK, *physiologically-based pharmacokinetic modelling* Here, the physiology of an organism is described schematically as a collection of compartments of organs and tissues linked to each other in a realistic configuration by the vascular system The distribution, absorption, biotransformation and elimination of a compound are described as dynamic processes. This means that PBPK models are, at least in part, specific for the species of animal involved or a broader taxonomic unit and the substance in question

Advantages

Using a (validated!) PBPK model, the internal doses in target organs and tissues can be assessed for all types of exposure (Pieters *et al*, 1996) Inter-species comparisons (humans versus animals) of internal doses can allow for the quantification of numerous uncertainties relating to extrapolation, examples being route to route, high to low dose or variations in exposure routes or times

Disadvantage.

PBPK models do not provide a dynamic description of the effect They only assess the internal dose which is associated with an effect In some cases, the formation of toxic metabolites can indeed be described (Andersen *et al*, 1987) but the supposition that the type of effect can be compared between species remains open to dispute. This objection should be met in order to improve risk assessment To do this, PBPK models could be integrated with toxicodynamic models so that specific differences in kinetics as well as specific differences in mechanisms can be assessed

2.2 Genotoxic substances

No extrapolation is carried out for genotoxic substances and inter-species variations between humans and animals (such as a safety factor 10) (W Mennes, oral communication) since it is supposed that the risk to humans of additional carcinogenicity given life-long exposure is virtually non-existent at the level of 10^{-6} (Young, 1987)

2.3 Immunotoxic substances

Immunological effects are hardly studied at all by toxicologists and not at all by ecotoxicologists. A distinction can be made between (1) the direct or indirect effect of the toxic substance on the immune system (immunosuppression, for example) and (2) an immunological response from the host to the substance (allergy) or a host allergen that is modified by the substance (resulting in, for example, auto-immunity) The first reactions can be seen as 'pathological effects for which a NOEL can be established The dose-effect relationships referred to under (2) are not sufficiently understood and, furthermore, variations in sensitivity between animals and humans can be very large (Health Council, 1995). A detailed examination of this category of substances will not be included in this report.

2.4 Evaluation of extrapolation methods

In both human toxicology and ecotoxicology, the standard method is to determine the NOEL in order to state a safe dose for non-genotoxic substances. This approach is beset with a number of limitations which apply less to the alternative methods Whether these methods can also be used more widely - something which is often claimed - could be studied on a comparative basis using a suitable database An important option is also that of using confidence intervals in risk assessments in relation to the probability of effects occurring

For the generalization of threshold values, there are numerous extrapolation methods and models, from simple safety factors to complex PBPK models Here, objectivity increases with complexity but there is also an increase in the efforts required in terms of research and validation. The methods described here are used on varying scales in human toxicology and ecotoxicology (table 3) The use of safety factors in particular is common-place in both disciplines However, in ecotoxicology, extrapolation is on a basic level, namely from effect parameters (LD_{50}, ED_{50}) to NOEL, analogous to the EPA method (Denneman and Van Gestel, 1990) In human toxicology, extrapolation is from a NOEL to a human toxicity standard

Table 3. Overview of the use of various methods in human toxicology and ecotoxicology for the inter-species extrapolation of toxicological data for non-genotoxic substances

Method	Human toxicology	Ecotoxicology
Safety factor	++[1]	++
Renwick's safety factor	+[1]	-
Allometric scaling	-	±
Haber rule	-[2]	-
Route to route extrapolation	±[2]	-
Exposure time and LBB	-	±
PBPK models	±	-

1) Extrapolation from animals to humans on the basis of arbitrarily chosen safety factor

2) Reprehensible method which does not result in any improvement in animal-human extrapolation

The available range of extrapolation methods presents both researchers and policy-makers with a choice The scientific choice is soon determined by the nature of the available data many methods require quantitative data and the more refined methods require a wide dosage range In principle, the most refined models which assume internal doses (PBPK) or biologically-based models (MVK) are preferable. However, in practice, there is generally not enough information The

policy choice is independent of these scientific factors and can be more pragmatic In risk management, for example, the choice of developing a refined model is uninteresting when a small section of the population is exposed to doses of a particular substances at concentrations which are far below the NOEL in animal studies. In this case, the risk can be considered to be very small and the use of a safety factor will be adequate to fix a standard here On the other hand, a PBPK model is thought to be the most suitable for assessing internal doses in humans when there is a danger that the exposure of the population may exceed the protection level The risk can then be assessed on the basis of the (internal) dose-effect relationship The question of when which model is best in terms of the requirements of a 'risk manager' could be answered using a decision system

It becomes clear from the methodological discussion of extrapolation methods above that, with the exception of PBPK models, all other approaches are based on external exposure. This disregards possible variations between species in sensitivity and physiological structure, not to mention variations in biological availability or specific exposure routes PBPK models or similar approaches which concentrate on internal exposure get round this complex problem and therefore have more to offer However, the development of general models - and their calibration and validation - still has a long way to go.

It also emerged that many methods have qualitative or quantitative problems when it comes to availability and exposure In addition, for a quantitative risk assessment, an assessment of the *actual* exposure is required alongside an assessment of dose-effect relationships The integration or combination of both factors is essential here and, once again, the lack of theory and relevant measurement techniques in the area of exposure makes itself felt. This means that this theme plays a vague but crucial role on several levels in risk assessment

In quantitative risk assessment, then, a lot of development work still remains to be done in the area of exposure extrapolation techniques for toxicological criteria, the determination of possible exposure routes (*exposure assessment*) and actual exposure (*risk characterization*) A number of initiatives are in progress in human toxicology such as exposure of humans through consumer goods (Van Veen *et al.*, 1994, Van Veen, 1995), through food (Slob, 1993), through air pollution (Van Scheindelen *et al*, in preparation), through soil pollution (Van den Berg, 1995; Linders, 1990) By comparison, developments in ecotoxicology are lagging behind and this is perhaps the result of the fact that the pluriform nature of organisms

and exposure routes is much larger and that it is more difficult to distinguish between them

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