Project no. 022704 (SSP)

FOOTPRINT

Functional Tools for Pesticide Risk Assessment and Management

Specific Targeted Research Project

Thematic Priority: Policy-orientated research

Deliverable DL3

State-of-the-art review on approaches to environmental risk assessment for pesticides

Due date of deliverable: July 2006
Actual submission date: July 2006

Start date of project: 1 January 2006 **Duration: 36 months**

Organisation name of lead contractor for this deliverable: ICPS

Revision: N/A

Project co-funded by the European Commission within the Sixth Framework Programme (2002-2006)		
Dissemination Level		
PU	Public	X
PP	Restricted to other programme participants (including the Commission Services)	
RE	Restricted to a group specified by the consortium (including the Commission Services)	
CO	Confidential, only for members of the consortium (including the Commission Services)	

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Foreword

The present literature review was prepared within the context of the work package WP1 ('Integrated knowledge reviews') of the FOOTPRINT project.

The preferred reference to the present document is as follows:

Azimonti G. (2006). State-of-the-art review on approaches to environmental risk assessment for pesticides. Report DL3 of the FP6 EU-funded FOOTPRINT project [www.eu-footprint.org], 45p.

1 INTRODUCTION

Risk assessment is a data driven process for determining the likelihood of an event(s) happening. A more detailed definition, provided by OECD (2003), defines risk assessment as a process intended to calculate or estimate the risk to a given target organism, system or (sub)population, including the identification of attendant uncertainties, following exposure to a particular agent, taking into account the inherent characteristics of the agent of concern as well as the characteristics of the specific target system. The risk assessment process, which is the first component in a risk analysis process, includes four steps: i) hazard identification, ii) dose-response assessment, iii) exposure assessment, and, iv) risk characterisation.

Hazard identification is defined as the identification of the type and nature of adverse effects that an agent has as inherent capacity to cause in an organism, system or (sub) population.

The dose-response assessment, which is the second steps in risk assessment, is the analysis of the relationship between the total amount of an agent administered to, taken up or absorbed by an organism, system or (sub)population and the changes developed in that organism, system or (sub)population in reaction to that agent, and inferences derived from such an analysis with respect to the entire population.

The third step in the process of risk assessment is the evaluation of the exposure of an organism, system or (sub) population to an agent and its derivatives, the so-called exposure assessment

Finally, the risk characterization is the qualitative and, wherever possible, quantitative determination, including attendant uncertainties, of the probability of occurrence of known and potential adverse effects of an agent in a given organism, system or (sub)population, under defined exposure conditions (OECD 2003).

The risk assessment fundaments and paradigms initially focused exclusively on human health protection. In the late 80s and during the 90s, the possibilities for extrapolating the scientific basis of risk assessment to the environmental protection concentrated the efforts of ecotoxicology and environmental fate science. The activities of the US EPA, EU, OECD, SETAC and other organisations are considered among the main drivers in this process.

The publication in 1998 of the US EPA Guideline on Ecological Risk Assessment, a revision of the previous Guideline of 1992, is assumed as the inflexion point leading to a new paradigm for ecological risk assessment (SSC 2003a). Within Europe, this period was characterised by development of environmental risk assessment protocols as scientifically based tools for supporting regulatory needs. The first drafts of the Technical Guidance Document describing the risk assessment of industrial chemicals (1993-1994), and the first Guidance Documents on the environmental risk assessment of pesticides, including the publication of the technical annex of Directive 91/414/EC (1996), represent some European milestones.

According US-EPA (1998) the ecological/environmental risk assessment process is based on two major elements: characterisation of effects and characterization of exposure. These provide the focus for conducting risk assessment which can be reclassified in three phases:

- problem formulation,
- analysis,
- risk characterization.

The overall ecological risk assessment process, according US-EPA, is shown in Figure 1.

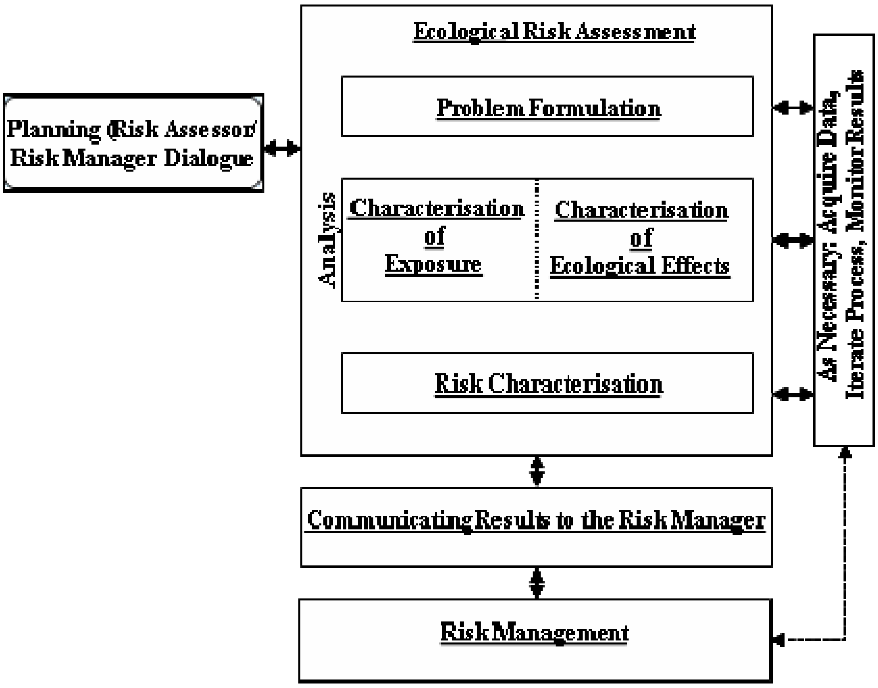

Figure 1 : The framework for ecological risk assessment (from U.S. EPA, 1998).

In problem formulation, the purpose for the assessment is articulated, the problem is defined, and a plan for analysing and characterising risk is determined. Initial work in problem formulation includes the integration of available information on sources, stressors, effects, and ecosystem and receptor characteristics. From this information two products are generated: assessment endpoints and conceptual models. Both products are needed to complete an analysis plan, the final product of problem formulation.

Analysis is guided by the results of problem formulation. In the analysis phase, data are evaluated to determine the likelihood of exposure to stressors and the potential and type of ecological effects that can be expected from this exposure (characterization of ecological effects). The first step, then, is the determination of the strengths and limitations of data on

exposure, effects, and ecosystem and receptor characteristics. Analysis of data has to characterise the nature of potential or actual exposure and the ecological responses under the circumstances defined in the conceptual model(s). During risk characterization the profiles for exposure and for stressor response, derived from these analyses are integrated through the risk estimation process. Risk characterization includes a summary of assumptions, scientific uncertainties, and strengths and limitations of the analyses. The final product is a risk description in which the results of the integration are presented, including an interpretation of ecological/environmental adversity and descriptions of uncertainty and lines of evidence.
Problem formulation, analysis, and risk characterization have been presented sequentially; nevertheless, ecological/environmental risk assessments are frequently iterative: what is learned during analysis or risk characterisation can lead to a re-evaluation of problem formulation or new data collection and analysis (US EPA, 1998)

Although environmental risk is defined as the probability of observing/producing adverse environmental/ecological effects, European legislation of environmental risk assessments includes in all cases a low tier assessment based on a deterministic approach: when the predicted exposure is clearly below the toxic concentrations determined in laboratory studies, the environmental risk is supposed to be acceptable. Generally, legislation for chemicals sets specific methods for risk characterisation but in the deterministic approach the whole assessment is reduced to the acceptability of certain ratios between the expected exposure and the observed toxicity, plus a set of adjustment factors. Low risk is assumed when the exposure level is sufficiently lower than the laboratory toxicity endpoints. The “distance”, or ratio between both values, to accept low risk should cover the uncertainty in the assessment, and is defined by an adjustment factor, fixed for low tier assessments through different procedures, such as the use of application factors for deriving ecotoxicological thresholds or setting fixed triggers for the Toxicity Exposure Ratios. From a conceptual point of view these adjustment factors are equivalent to the “margins of safety” employed in the human health risk assessment; however, it is generally considered that the factors are expressions of risk, not expressions of safety (Forbes and Calow, 2002 cited in SSC, 2003b).

2 ENVIRONMENTAL RISK ASSESSMENT FOR PESTICIDES IN THE FRAMEWORK OF DIRECTIVE 91/414/EEC

In Directive 91/414/EEC, the European Union started with the harmonisation of risk assessment methods for pesticide registration legislation. Part of this harmonisation process was the development of the so-called “Uniform Principles” (Annex VI of Directive

91/414/EEC), which provides the detailed evaluation and decision making criteria, to decide about the acceptability for EU registration of a pesticide. This Annex may be considered as a structured guidance for risk and benefit analyses of plant protection products (PPP). Additional technical guidance is presented in Guidance Documents developed in the last ten years to address the risk assessment in the major environmental compartments: soil, water, surface water and air.

A common evaluation principle is that all normal conditions under which a given PPP may be used, as well as the consequences of its use, must be taken into account. The evaluation in the first step is based on the best available data but in a second step also takes account of potential uncertainties in the data and the range of use conditions that are likely to occur (realistic worst case approach), to determine whether the results could differ significantly.

With respect to distribution and unwanted impacts of the active substance on water resources, the Directive defines clearly when authorization of a PPP for the evaluated conditions of use can be granted; in particular, for groundwater and surface water, the main target of the FOOTPRINT project, the conditions are reported below:

1) No authorization shall be granted if the concentration of the active substance or of relevant metabolites, degradation or reaction products in *groundwater*, may be expected to exceed, as a result of use of the plant protection product under the proposed conditions of use, the lower of the following limit values:

- the maximum permissible concentration laid down by Council Directive 80/778/EEC (1) of 15 July 1980 relating to the quality of water intended for human consumption, or
- the maximum concentration laid down by the Commission when including the active substance in Annex I, on the basis of appropriate data, in particular toxicological data, or, where that concentration has not been laid down, the concentration corresponding to one tenth of the ADI laid down when the active substance was included in Annex I unless it is scientifically demonstrated that under relevant field conditions the lower concentration is not exceeded.

2) No authorization shall be granted if the concentration of the active substance or of relevant metabolites, breakdown or reaction products to be expected after use of the plant protection product under the proposed conditions of use in *surface water*:

- exceeds, where the surface water in or from the area of envisaged use is intended for the abstraction of drinking water, the values fixed by Council Directive 75/440/EEC of 16 June 1975 concerning the quality required of surface water intended for the abstraction of drinking water in the Member States (2), or
- has an impact deemed unacceptable on non-target species, including animals.

The proposed instructions for use of the plant protection product, including procedures for cleaning application equipment, must be such that the likelihood of accidental contamination of surface water is reduced to a minimum.

As regards impact on non-target species, where there is a possibility of aquatic organisms being exposed, **no** authorisation shall be granted if the toxicity/exposure ratio (TER) should be less than the trigger values reported in Table 1.

Species	Short-term TER Based on acute toxicity data	Long-term TER Based on chronic data
Aquatic organisms		
Fish	100	10
Daphnia	100	10
Algae	10	-

Table 1 : trigger values for aquatic risk assessment

A lot of effort has been put in the last ten years on the development of methods for pesticide risk assessment in surface and groundwater. Models and criteria for exposure assessment have been described for these two environmental compartments which quite often require specific higher tier evaluation during the registration process: in the review reports, which is the final product of the European evaluation of an active substance and the basic document for the decision, protection of groundwater and/or surface water are, generally, conditions to be taken into account by member states at time of authorisation of products after Annex I inclusion of an active ingredient. From an analysis of recommendations in 125 review reports (from http://ec.europa.eu/food/plant/protection/evaluation) of substances included in Annex I (72 existing active ingredients and 53 new substances), 32% of the total recommendations (66 a.i.) is related to aquatic organisms, 26% (53 a.i.) to groundwater, 14% (28 a.i.) to operators and consumers, 12% (24 a.i.) to arthropods, 6% (13 a.i.) to birds and mammals, 3% to earthworms and bees (6 and 7 a.i. respectively), 2% (4 a.i.) to terrestrial plants and 1% to soil, air and sewage treatment (2 a.i.)

This implies that member states should implement a strategy to handle the described condition and mitigation.

2.1 Groundwater

2.1.1 State of the art in groundwater risk assessment for EU registration process

A common approach, to risk assessment on groundwater, is a tiered one comprising modelling, laboratory studies, lysimeter studies and – if needed – field testing. This approach, which is also the Directive’s one, proceeds from one tier to another and is triggered by fixed concentrations.

In 1993, the FOCUS workgroup (acronym for the FOrum for the Co-ordination of pesticide fate models and their USe) was formed. The remit of FOCUS was to develop consensus amongst the Member States, the European Commission, and industry on the role of modelling in the EU review process of active substances. Guidance was firstly developed for leaching to groundwater (FOCUS 1995, FOCUS 2000). The guidance developed by the workgroup included a description of relevant models and their strengths and weaknesses. However, of the nine models initially investigated (PRZM, PRZM-2, PELMO, GLEAMS, PESTLA, VARLEACH, LEACHM, MACRO, PLM), only four models in updated versions (MACRO, PEARL, successor of PESTLA, PELMO, PRZM) are currently in use at EU level, as recommended in the FOCUS guidance document. These models must also be applied to the same data sets in order to achieve harmonisation of the risk assessments throughout Europe; hence, standard scenarios with regard to soil, weather and cropping data were needed to increase the consistency of the regulatory evaluation process by minimising the subjective influence of model user. Standard scenarios also make interpretation much easier, and enable the adoption of a consistent scientific process for a Tier 1 evaluation of the leaching potential of substances at the EU level. Therefore the FOCUS Workgroup for Groundwater Scenarios was charged in 1997 with developing a set of standard scenarios which could be used to assess potential movement of active substances and metabolites of plant protection products to groundwater as part of the EU process for placing active substances on Annex I. Since this process proceeds at the community level, the standard scenarios had to apply to the whole EU. The FOCUS Groundwater Scenarios Workgroup (FOCUS 1999, 2000) developed nine realistic worst case scenarios (Table 2) and appropriate data input files for the models PELMO, PEARL, and PRZM. For MACRO, only the Châteaudun scenario has been parameterised by FOCUS, as at that time there were no reliable pedotransfer functions available (MACRO DB2 was not released yet).

Location	Mean Annual T (°C)	Annual Rainfall (mm)	Texture	OM (%)
Châteaudun	11.4	648 + I	silty clay loam	2.4
Hamburg	9.2	786	sandy loam	2.6
Jokioinen	4.3	638	loamy sand	7.0
Kremsmünster	8.8	900	loam/silt loam	3.6
Okehampton	10.4	1038	loam	3.8
Piacenza	13.3	857 + I	loam	1.7
Porto	14.8	1150	loam	6.6
Sevilla	18.1	493 + I	silt loam	1.6
Thiva	16.2	500 + I	loam	1.3

Table 2 : Overview of the characteristics of the nine leaching scenarios (Soil texture is based on FAO, 1977, and USDA, 1975; I indicates rainfall supplemented by irrigation.) (from FOCUS, 2000)**.**

According to the new FOCUS Workgroup on groundwater, established in 2003, in considering the interactions between EU and national assessment schemes, the issue of the regulatory significance of preferential flow should be specifically addressed. The best known model to address an aspect of preferential flow is MACRO, which simulates macropore flow through consideration of soil aggregate size. Newer versions of other models, such as PEARL, now also incorporate mathematical routines to address various preferential flow mechanisms (FOCUS, 2005).

The purpose of the standard scenarios is to assist in establishing if “safe” scenarios exist for the supported uses of a substance. Since they are used in a tier 1 of the assessment, they have been defined to represent a realistic worst case. From this first tier assessment there are three possible outcomes:

1. The critical model output for a substance may exceed 0.1 µg/L for all relevant scenarios;
2. It may be less than 0.1 µg/L for all relevant scenarios;
3. It may exceed 0.1µg/L for some relevant scenarios and be less than 0.1µg/l for others

When a substance exceeds 0.1µg/L for all relevant scenarios, then Annex I inclusion would not be possible unless convincing higher tier assessments results demonstrate acceptable use. The higher tier assessment comprises both the use of specific scenarios/site specific data and data from lysimeter studies or field testing as model input.

When a substance occurs at less than 0.1µg/l for all relevant scenarios, this means that there can be confidence that the substance is unlikely to cause harm in the great majority of situations in the EU. This does not exclude the possibility of leaching in highly vulnerable local situations within specific Member States, but such situations can be assessed at Member State level.

Finally, when a substance occurs at less than 0.1µg/L for at least one but not for all relevant scenarios, then in principle the substance can be included in Annex I with respect to leaching to groundwater. As the scenarios represent major agricultural areas of the EU, this would indicate that uses unlikely to cause harm have been identified, which are significant in terms of agriculture in the EU. The scenarios which gave results less than 0.1µg/L, along with the results of any higher tier studies which already exist, help to indicate the extent of the acceptable uses which exist for the substance. “The results of the entire leaching assessment at the EU level could then be used to guide local assessments of leaching at the Member State level” (FOCUS, 2000).

All relevant scenarios (but not all models) are to be run by the notifier for every active substance as a standardised tier 1 assessment of leaching potential. Member states may repeat the assessment with another of the four models.

While consistency among models is esteemed to be high, it is recognised that the models may give different results, especially for concentrations below 1 µg/L, characteristics which may have an impact on the final risk assessment. Recently, the Panel on plant protection products and their residues (PPR Panel) of the European Food Safety Authority (EFSA) was asked for an opinion (PPR, 2004) on the comparability of the three simulation models which have been parameterised for all nine scenarios in groundwater risk assessment: PEARL, PELMO and PRZM.

The PPR Panel concluded that, given the complexity of the models, the FOCUS workgroup has already achieved a remarkable degree of comparability between the models. Crucial differences remain, however, especially at concentrations near the regulatory trigger value (0.1 µg/L). As the main causes of those remaining differences, the PPR Panel identified the different concepts for describing water flow and the lack of agreement on the appropriate value(s) for the dispersion length:

- PRZM and PELMO are capacity models. PEARL uses the Richard's equation.
- PRZM and PELMO predict higher runoff, and runoff occurrence in far more situations than PEARL.
- PRZM and PELMO use an effective dispersion length of 2.5 cm; PEARL uses 5 cm.

As a consequence, PEARL predicts higher annual average leachate concentrations in 1m depth than the other two models in most cases. From comparisons between PELMO and PEARL, the PPR Panel concluded that remaining differences can be reduced significantly when the same effective dispersion length is used. The PPR Panel welcomes ongoing efforts (within the new FOCUS groundwater workgroup) to harmonise the dispersion length, as well as the concepts for water flow, and recommends that the overall degree of protectiveness of the models should be reviewed at the same time (PPR, 2004). For registration purposes the PPR panel recommends that the risk assessment should be based on two models, PEARL and either PELMO or PRZM (i.e., one representative for each concept), rather than on a single model. When the results from both models are on the same side of the trigger values, the risk assessment could be finalised at that step. When the results from the two models give values either side of the trigger value, higher tier assessments would be necessary.

Recently, the consideration of metabolites (or degradation, transformation and breakdown products) created discussion and concern within the framework of Directive 91/414/EEC. A specific guidance document (DG SANCO/221/2000– rev. 10) was prepared to address the relevance of metabolites in ground water. Particular attention was given to the definition of "relevant metabolites" since the Directive clearly states that their trigger for ground water should be 0.1 µg/L. The documents defines also "metabolites of no concern" for which a further evaluation is not considered and "non-relevant" metabolites whose trigger might exceed concentrations of 0.75 µg/L (the so called threshold of no-concern) up to 10 µg/L. The guidance document recommends a formal extension of the need to consider, for groundwater, the relevance of metabolites that are detected at more than >5% of the applied dose at two successive sampling times / intervals during degradation studies on the active substance as well as those for which "the maximum of formation is not yet reached" at the end of the study. The guidance document also recommends that all metabolites exceeding 0.1 µg/L annual average in the leachate in lysimeter studies should also be subject to further assessment.

2.1.2 Future development in pesticide risk assessment in groundwater for EU registration process

The new FOCUS ground water work group was established in 2003 with the remit to provide guidance on higher tier leaching assessment and on harmonisation of risk assessment procedures at national level. Therefore, the Work Group made first an overview on to what extent and how the FOCUS guideline of the first tier assessment is currently used within member states of the European Union and how the countries solve the ground water risk assessment on a member state level (FOCUS, 2005d). From this overview, where sixteen out of 25 member states provided information, it results that all Member States (MS), except for one that is about to implement an assessment scheme, assess risk to ground water on a national level. FOCUS guidance is considered fully satisfactory by seven countries, while the remaining raised some concerns about scenarios, because scenarios are not representing of the national environment and, in some cases, the scenarios are not sufficiently protective (including responses that specific models are needed for consideration of macropore flow in structured soils).

The main trigger for a specific national assessment varies in different MS: national trigger may be the outcome from lysimeter and other field studies, indications of leachability (i.e. leachate concentrations higher than 0.1µg/L) in FOCUS scenarios from the assessment on the EU-level, positive findings from monitoring, experience from earlier national assessments, divergence of the GAP from the intended use on which the inclusion on Annex I is based, and the recommendation for groundwater protection in review report. It seems that each country has its own specific methods for higher tier assessment, but often countries use similar approaches. At the EU level, there is actually no guidance regarding the relative importance of the different approaches in decision-making, therefore the FOCUS group considered that a standard generic approach to the process (i.e. relative importance of modelling data, field experiments, monitoring data etc) would be helpful. The aim of the group, therefore, is to develop a generic assessment scheme that can be used at both the EU and national level in order to provide a clearer decision-making scheme for pesticide registration.

Following consideration of the types of data that are available for determining the PEC_{gw}, the group categorised risk assessment approaches into four tiers based on the availability of information, as reported in Figure 2.

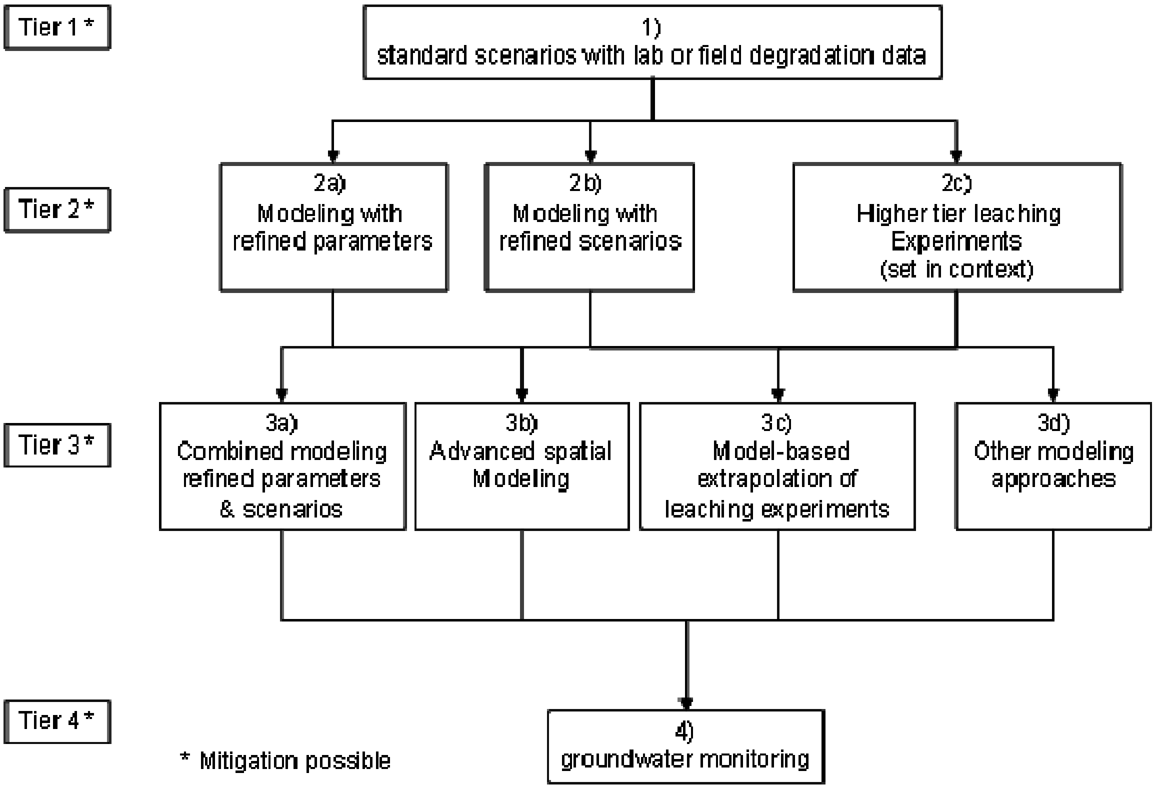

Figure 2 : FOCUS proposal for generic tiered assessment scheme for ground water
(Gottesbüren, 2005)

All PEC_{gw} modelling assessments based on data according to the requirements in 91/414/EEC in combination with standard FOCUS (2000) scenarios or the standard national groundwater scenarios, are classified as Tier 1.

Higher tier (more refined) modelling or experimental approaches are classified as Tier 2, and supersede assessments at Tier 1. These approaches can be categorized as:

(a) parameter refinements for modelling (e.g. long term sorption measurements, field dissipation). The refined pesticide input values are to be used with the modelling scenarios from tier 1 (EU-FOCUS or the national scenarios). The results can be used e.g. to define mitigation with regard to the use area based on soil and compound properties;

(b) scenario refinements (e.g. GIS data, hydrogeological data; characterisation of vulnerable situations or 'risk areas' to enable more targeted simulations for specific crops). The scenario refinement must be shown to be an improvement with respect to realistic representation of the specific soil, weather, and agronomic conditions, considering the objective of the protection goals. The tools for scenario refinements can also be used to define mitigation measures to ensure that uses of the pesticide do not violate the protection goals;

(c) higher tier leaching experiments directly measuring the concentrations (instantaneous, averaged over time etc.) leached under field or lysimeter conditions constitute a different approach to addressing potential leaching issues. However, as with any field derived data they may only be relevant to the climatic and agronomic (crop, timing, application rate etc.) conditions in which the studies were conducted.

Combinations of the modelling, refined parameters, and experimental approaches from Tier 2, as well as advanced spatial modelling and "other higher tier modelling approaches" (e.g., 3 D aquifer modelling) are classified as Tier 3, and supersede assessments at Tier 1 and 2.

For Tier 3, two alternatives exist. First, a combination of strategies proposed in Tier 2 can be followed. Second, advanced modelling approaches can be suggested. Following this latter strategy, the one-dimensional flow and transport modelling concept is replaced by more advanced modelling approaches. In the higher tier, spatial variation of the leaching event may be introduced. According to a first draft proposal of the group (FOCUS, 2006), two different approaches may be distinguished: in a first approach the spatial variation of the underlying properties (soil, crop, climate, agricultural) driving the leaching event is considered as a basis for the selection of a more appropriate scenario. This scenario is next combined with a leaching model to assess the percentile of the leaching event.

In a second approach, the spatial variation of the underlying properties driving the leaching event is also considered (Tiktak *et al.*, 2004).

Monitoring of groundwater (with appropriate reality checking) is considered as the highest tier (Tier 4) and supersedes assessments on Tier 1, Tier 2, and Tier 3. The FOCUS Workgroup, within the context of the draft guidance document (FOCUS, 2005d and 2006) defines monitoring studies are as: "Studies in which ground water is sampled from a large number of locations in a region or country and is subsequently analysed to determine the concentration of the pesticide of interest. Experimentally determining the reason for the presence or absence of the compound is not necessarily an intrinsic part of these studies, although the weight which is placed on the findings will depend on the appropriate selection of the sites to sample". Groundwater monitoring data is considered, by the Workgroup, as the highest tier of assessment since the actual concentrations in groundwater are directly measured rather than being estimated by modelling approaches or approximated from small scale field studies.

Certain member states such as the UK, the Netherlands and Germany have already published guidance on the use of monitoring data in pesticide registration (Mackay *et al.*, 2004 Cornelese *et al.*, 2003; Aden *et al.*, 2002 as reported in FOCUS 2006).

Monitoring data will be only available for consideration at the Annex I level for existing active substances. The FOCUS proposal is that where such data are available, whether generated by the notifier or other organisations, they can be used for decision-making subject to certain quality checks (FOCUS 2006).

According to the FOCUS tier proposal, not yet finalised, mitigation will play a role at all decision tiers at the EU and at the national level to identify if approval can be given according to the respective protection goals. On EU level only general recommendations for risk mitigation measures can be given based on the evaluation of the properties of the active ingredient(s) and the risk assessment made for the representative formulation in relation to the EU scenarios

Detailed risk mitigation measures with regard to the protection of ground water require detailed knowledge of local environmental conditions; therefore, they are mainly allocated to the authorisation procedure on the member state level and, in most of the cases, risk mitigation measures will be related to restrictions imposed in the registration process of a plant protection product. The FOCUS Wokgroup identified four major types of mitigation:

- Dose related risk mitigation. A lowering of the applied dose may be achieved by mixing the assessed active substance with other active substance/s, or lowering the number of applications or applying the pesticide at a later growth stage. All these techniques may be only considered on the member state level. In certain cases the restriction of the application to every other year or even longer intervals may be a more promising approach
- Pesticide properties in correlation to soil properties. In this case the combined consideration of substance properties and environmental properties (such as soil pH) may result in risk mitigation by excluding the use in certain defined areas, where a risk for leaching is identified. This risk mitigation step can consist of excluding use in either specific geographical areas or soil types.
- Hydrogeological properties. Using GIS data (when the necessary data are available) will give information on geographical areas with environmental properties that may lead to a risk for ground water contamination of a specific compound. If there were indications from potential risk for ground water contamination, vulnerable areas have to be identified on the member state level.
- Mitigation related to timing. Depending on environmental conditions, mitigation may also include timing in which applications can be made, e.g. spring application vs. fall application.

Some of these possible mitigation measures have already been taken into account by Commission Directive 2003/82/EC of 11 September 2003 amending Council Directive 91/414/EEC as regards standard phrases for special risks and safety precautions for plant-protection products. The Annex IV of this Directive defines the general attribution criteria for standard phrases for specific safety precautions, to be applied, when necessary, to plant-protection products labels. Among the safety precautions phrases related to the environment (SPe), SPe1 and Spe2, reported below, already incorporate the possibility to indicate specific mitigation options for groundwater.

- SPe1, To protect groundwater/soil organisms do not apply this or any other product containing (identify active substance or class of substances, as appropriate) more than (time period or frequency to be specified,
- SPe2 To protect groundwater/effects on aquatic organisms do not apply to (soil type or situation to be specified) soils

The Directive establishes also the general application criteria for these phrases. In particular, the criterion for SPe2, is exactly in the logic of *pesticide properties in correlation to soil properties*: "the phrase may be assigned as a risk-mitigation measure to avoid any potential contamination of groundwater or surface water under vulnerable conditions (e.g. associated to soil type, topography or for drained soils), if an evaluation according to UP shows for one or more of the labelled uses that risk-mitigation measures are necessary to avoid unacceptable effects".

2.2 Surface water

2.2.1 State of the art in pesticide risk assessment in surface water for EU registration process

Also pesticide risk assessment on surface water is performed using a tiered approach. Depending on the results of the initial risk assessment, more detailed data relating to environmental exposure or hazard may be required to clarify the environmental risk. Such data are generated from an increasingly comprehensive series of studies (higher tiered studies). At each tier a comparison has to take place between the estimated exposure and the estimated hazard; therefore, two separate tiers for both exposure and effects estimation are necessary. This means fate modelling and laboratory fate studies, from the exposure assessment side, as well as laboratory acute and chronic testing on non target species, from the effects assessment side. Ecological/environmental monitoring is a further promising tool for risk assessment of existing plant protection products. In July 1994, the FOCUS Steering Committee installed the Working Group on Surface Water to analyse the role of mathematical models applied to surface waters and their role in the registration process (FOCUS, 1997). In 1996, a further FOCUS Working Group on Surface Water Scenarios was established, to develop a series of standard agriculturally relevant scenarios for the European Union, that can be used with the models identified to fulfil the requirements for calculating PEC_{sw}, and to establish a procedure for the estimation of the concentration of the active substance of a PPP, to be used in the registration process in the EU according to Directive 91/414/EEC. The procedure developed by $FOCUS_{sw}$ Workgroup (FOCUS, 2002) consists of four steps, as illustrated in Figure 3, whereby the first one represents a very simple and extreme worst case scenario using first order kinetics and assuming a loading equivalent to a maximum annual application.

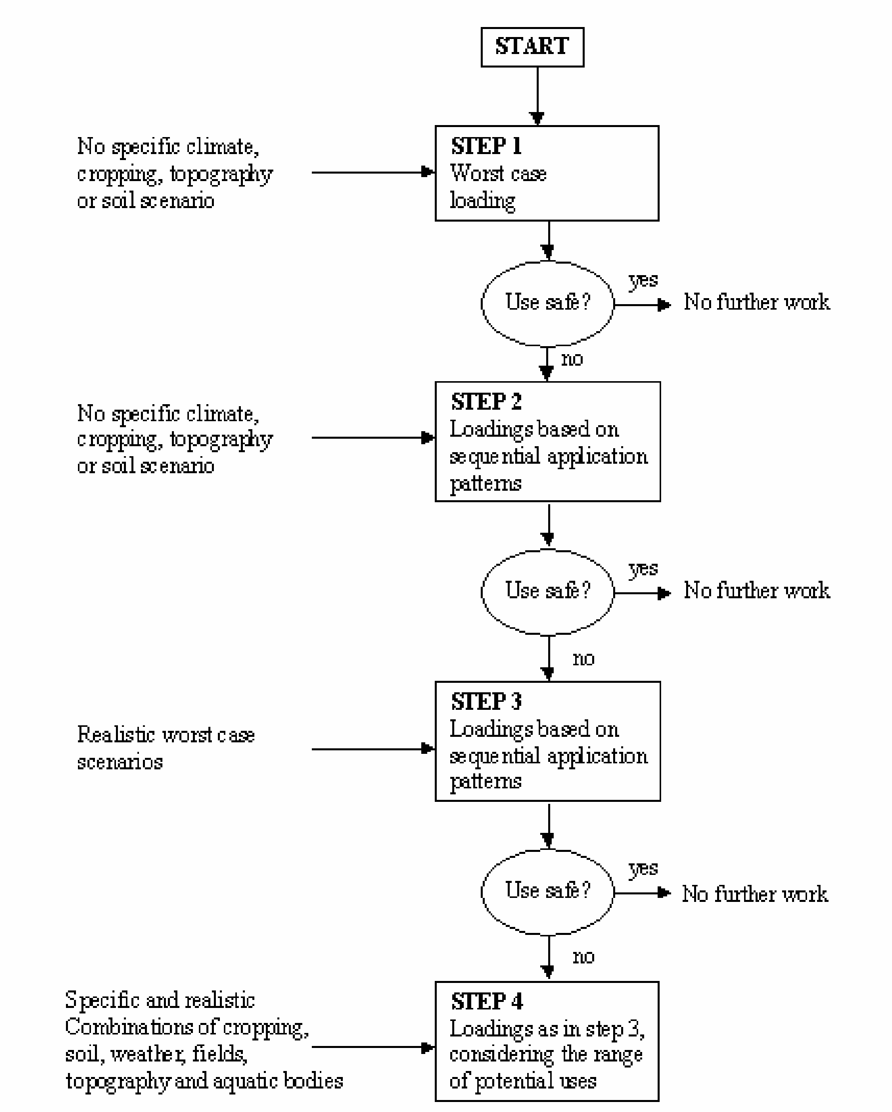

Figure 3. The Tiered Approach in Exposure assessment of Plant Protection Products
(from FOCUS 2001)

Tier 2 assumes surface water loading based on sequential application patterns, taking into account the degradation of the substance between successive applications. Again the PEC_{sw} are calculated and may be compared to the same and/or different toxicity levels for aquatic organisms. As with Tier 1, if the use is considered acceptable at this stage, no further risk assessment is required whereas an unacceptable assessment necessitates further work using a Tier 3 calculation.

The third step focuses on more sophisticated modelling taking into account realistic "worst case" amounts entering surface water *via* relevant routes like runoff, spray drift, drainage. $FOCUS_{sw}$ considers spray drift, run-off and drainage as routes of entry but does not take into account aspects such as atmospheric deposition, dry deposition, colloid transport, discharge of waste water, ground water and accidents. $FOCUS_{sw}$ includes both runoff of pesticide in water and pesticide sorbed to soil particles; the pesticide in the water goes to the water layer and the pesticide sorbed to soil particles is added to the sediment.

For step 3, $FOCUS_{sw}$ workgroup defined 10 realistic worst-case scenarios, which collectively represents agriculture in the EU for the purposes of an assessment of the Predicted Environmental Concentration (PEC) in surface water (FOCUS, 2002). Realistic worst case concentrations are calculated in three identified types of small water bodies across the EU: ditch, stream, and pond. The major characteristics of the ten scenarios are reported in Table 3.

Name	Mean annual T (°C)	Annual rainfall (mm)	Topsoil	Organic matter (%)	Slope (%)	Water bodies	Weather station
D1	6.1	556	Silty clay	2.0	0 – 0.5	Ditch, stream	Lanna
D2	9.7	642	Clay	3.3	0.5 – 2	Ditch, stream	Brimstone
D3	9.9	747	Sand	2.3	0 – 0.5	Ditch	Vreedepeel
D4	8.2	659	Loam	1.4	0.5 – 2	Pond, Stream	Skousbo
D5	11.8	651	Loam	2.1	2 – 4	Pond, stream	La Jailliere
D6	16.7	683	Clay loam	1.2	0 – 0.5	Ditch	Thiva
R1	10.0	744	Silt loam	1.2	3	Pond, stream	Weiherbach
R2	14.8	1402	Sandy loam	4	20*	Stream	Porto
R3	13.6	682	Clay loam	1	10*	Stream	Bologna
R4	14.0	756	Sandy clay loam	0.6	5	Stream	Roujan

Table 3 : Overview of the ten scenarios defined by $FOCUS_{sw}$ (from FOCUS, 2002).

Six scenarios are called D scenarios (drainage), because after release of the pesticide, it may enter the neighbouring water body via spray drift deposition and water flow through drainage pipes. In the four R scenarios (runoff) pesticide may enter the water body via spray drift deposition and runoff plus erosion.

The models chosen in $FOCUS_{sw}$ for estimating the different routes of entry are MACRO for estimating the contribution of drainage, PRZM for the contribution of runoff and erosion, and TOXSWA for the estimation of the final PEC in surface waters. An additional loading is defined as spray drift input. The calculation of the contribution of the spray drift is incorporated in the Graphical User Interface (GUI) for the surface water scenarios called SWASH (Surface WAter Scenario Help). This is a general software shell developed to ensure that the relevant FOCUS scenarios and input are defined consistently for all models.

The $FOCUS_{sw}$ Workgroup distinguished five different application types: downward ground spray,air blast (for orchards), aerial application, soil incorporation and granular application (FOCUS, 2002). Recently, the PPR Panel (PPR, 2004) identified dust drift as a source of contamination of surface water that should be considered for assessing non-spray applications (NSA). A survey among the EU-member States indicated that no separate assessment is currently made for dust particles that may arise from these products in the course of application. Therefore the PPR Panel has developed procedures to estimate dust drift deposition of NSAs onto surface water. The PPR Panel agreed with the FOCUS surface water WG that runoff and drainage are important entry routes for NSAs, but proposed an improved parameterization of runoff and drainage scenarios for NSA applications.

At Step 3, the calculated PEC_{sw} for each scenario are compared with relevant toxicity data and a decision made as to whether it is necessary to proceed to Step 4 exposure estimation. An overview of the relation occurring among the three steps and the actual range of exposure is reported in Figure 4.

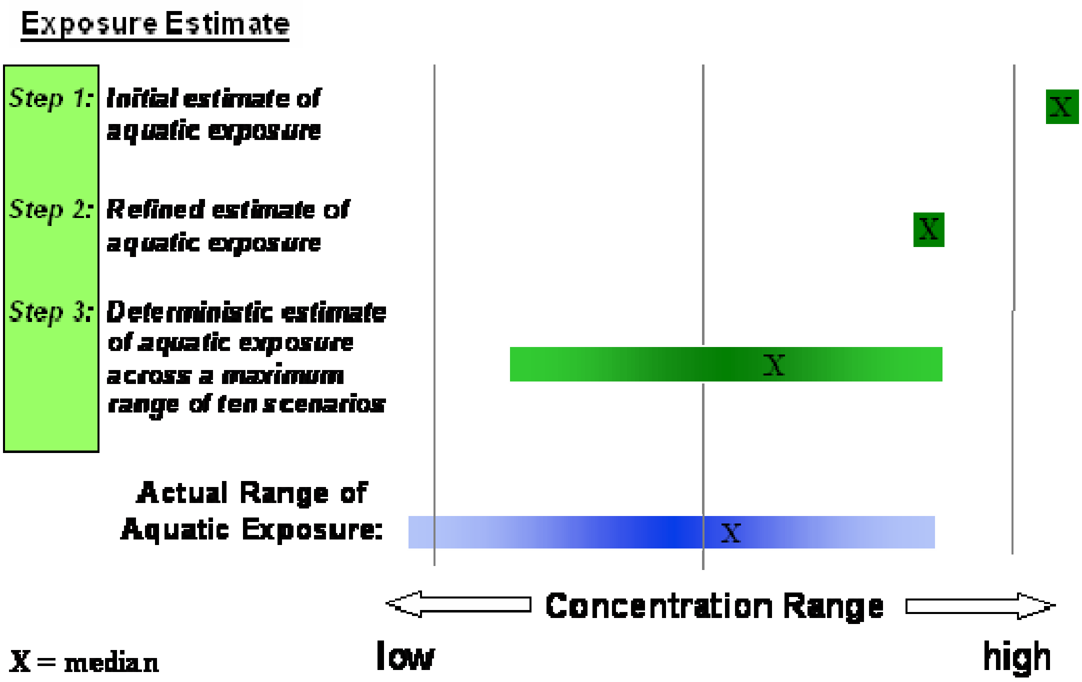

Figure 4 : Conceptual relationship between the desired Predicted Environmental Concentrations at Steps 1, 2 and 3 and the Actual range of exposure (from FOCUS, 2002)

The last (4th) step considers substance loadings as foreseen in step 3 but it also takes into account the range of possible uses. The uses are therefore related to the specific and realistic combinations of cropping, soil, weather, field typography and aquatic bodies adjacent to fields. By its nature, Step 4 will be a 'case-by-case' process, depending on the properties of the compound, its use pattern, and the areas of potential concern identified in the lower tier assessments.

As with exposure assessment, the current approach to effects assessment under 91/414/EEC follows a tiered approach (DG-SANCO, 2002). The starting point for analysis of potential aquatic effects is a set of standard acute and chronic toxicity tests with well known species. Such studies, which are routinely conducted by registrants early in the development of an active ingredient, are essential for establishing a basic toxicity profile, determining which types of organisms (fish, invertebrates, or aquatic plants) are sensitive, and inferring the range of exposure concentrations that might cause toxic effects.

At the lower tiers, acute and chronic toxicity parameters are determined for the active substance and a representative formulated product, and are then compared to exposure concentrations from FOCUS Steps 1, 2 and 3 in an iterative process (Figure 5).

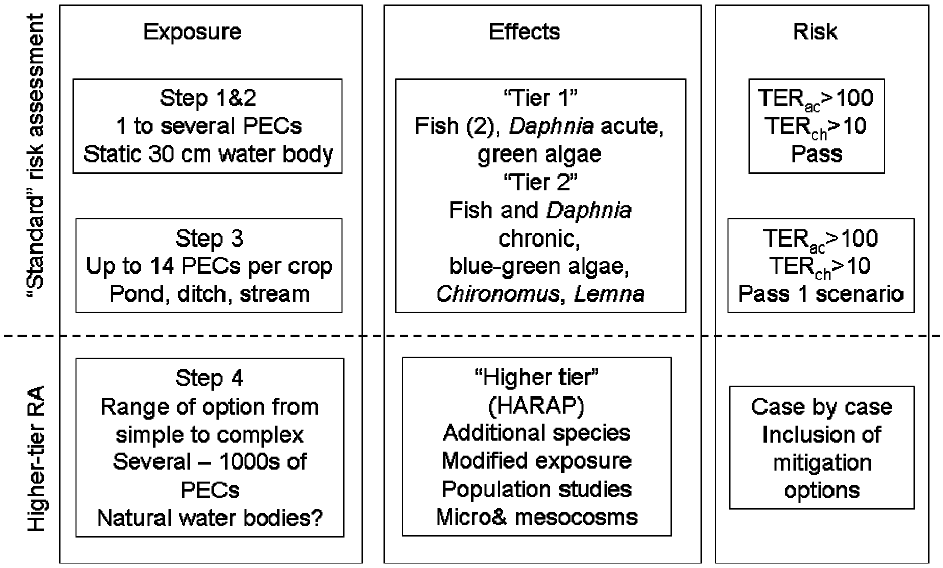

Figure 5 : Overview of the aquatic risk assessment process (from FOCUS, 2005a)

Depending on the results of this initial analysis, refinement of the effects assessment may require further investigation of:

- responses of organisms under exposure conditions that more closely reflect actual pesticide use, which requires an understanding of exposure patterns under different scenarios of interest;
- the toxicity of the pesticide to other species; and
- the ecological significance of expected effects.

For higher tier evaluation, laboratory studies incorporating more realistic exposure regimes can be undertaken. The testing of more species from taxonomic groups identified as being of potential concern, reduces the uncertainty of the risk assessment attributable to inter-species differences in sensitivity and allows a reduction of the uncertainty factor that is applied to the lower-tier data. These may include time varying exposure followed by pesticide dissipation, repeated exposures, or testing in the presence of sediment to allow sediment-water partitioning to take place (with organisms exposed in either the sediment or the water, or both). To enable an evaluation of the ecological significance of effects, techniques for population analysis can be applied to extrapolate from effects on individuals (such as are measured in laboratory toxicity tests) to effects on the abundance and persistence of populations (ECOFRAM, 1999). Species sensitivity distribution (SSD) approaches are also gaining wider acceptance as a method of refining the effect endpoint. A variety of laboratory and field experimental designs (including microcosms and mesocosms) are also available to measure the effects of pesticides on populations and communities. The term “microcosm” can be used for small-scale studies, while mesocosm generally refers to larger outdoor tests. Microcosm studies can be considered a compromise between standard laboratory tests and mesocosm studies. Mesocosm studies can examine effects of pesticides on communities of organisms under simulated field conditions.

Interpretation of these studies focuses on responses of dominant populations, community level effects, potential indirect effects and the recovery of aquatic populations and communities. Micro/mesocosm tests can measure the environmental relevance of certain fate processes, and to evaluate environmentally realistic exposure conditions. The general relationship between data from standard laboratory tests and micro- and mesocosm studies for herbicides and insecticides has been widely described by Brock *et al*. (2000 a, b).

Results from lower-tier effects assessments could be compared to either Step 3 or Step 4 exposure calculations and similarly results from higher tier effects assessments could be compared to either Step 3 or Step 4 exposure calculations. The FOCUS surface waters scenarios group recommended that at higher tiers, all of the options for effects and exposure refinement along with mitigation options should be considered in order to select the most appropriate path for further risk refinement at Step 4.

2.2.2 Future development in pesticide risk assessment in surface water for EU registration process

The framework for assessing the effects aspects of aquatic ecological risk assessment has become increasingly harmonized over recent years, and higher-tier effects approaches are now well-established, via HARAP (1999) e CLASSIC (1999) and the EU Aquatic Guidance Document, 2002. Some general guidance concerning higher-tier aquatic exposure assessment is included in the FOCUS surface water report (FOCUS, 2001). However, there is a need to further refine the tiered approach to exposure assessment by developing harmonized approaches to include landscape-level and mitigation factors.

A number of activities have begun at Member State level to evaluate the potential uses of landscape and mitigation factors in pesticide risk assessment (Reichenberger *et al*., 2006), but the development of harmonized guidance (at least as far as the scientific principles are concerned) in this area is a strong need. At the highest tier, risk assessment and mitigation should go together because measures that are used to refine potential exposure assessments can also be used to define appropriate mitigation strategies. For this reason, a FOCUS working group on Landscape and Mitigation Factors in Ecological Risk Assessment was established in June 2002, to investigate options and feasibilities of including landscape and mitigation factors in higher-tier exposure assessments, and to produce a review of the state of the art in landscape and mitigation factors in exposure assessment, as well as to make recommendations for future FOCUS groups to develop this area further. The group provided two reports (FOCUS, 2005a, b), which are now waiting for the opinion of the PPR panel before being considered officially in EU registration process. In the two-year activity, the group made extensive reviews in four sub-topic areas, namely:

- Development of harmonized approaches to mitigation measures;
- Incorporating modelling refinements and mitigation into exposure assessment at Step 4;
- Methods and data for describing agricultural landscapes;
- Ecological considerations in landscape assessments.

The group recommends landscape-level risk assessment for Step 4 through the definition of the influence of the surrounding landscape on the edge-of-field exposure of surface water by considering the structure of the area of landscape (e.g. land use, soil types, proximity of crop and water) surrounding the water body of concern.

A second possible way for conducting landscape risk assessment has been identified as the assessment for an entire landscape incorporating the spatial relationship between water bodies over a large area such as a catchment. The group considers this last approach not suitable at present for registration purposes, because tools for spatially-distributed assessment of pesticide exposure and effects at the catchment level are not sufficiently developed.

Moreover, the precedent of the current review process has generally focused assessments on single active ingredients whereas catchment assessments require the consideration of multiple stressors both pesticidal and other. Finally, the group considers that point source inputs of active ingredients, which are outside the actual framework of risk assessment according to Good Agricultural Practice, are a confounding factor at the catchment level.

From the review of mitigation measures currently used in MS and a collation of the approaches available in the scientific literature (FOCUS 2005b), the FOCUS group indicated that there are a number of suitable approaches currently available for mitigating the exposure of surface water from plant protection products. According to the FOCUS Workgroup (2005a), lots of approaches are available to spray drift mitigation (buffer zones, application technology and windbreaks) up to a reduction of 99% in exposure. Techniques are also available, although less developed, for immediate use for mitigating runoff exposure where needed by up to 90% (through the use of filter strips and application restrictions). Mitigation of drainage inputs is least-developed; application restrictions, based on soil type and season, could be used to essentially eliminate drainage inputs on vulnerable soils. It has to be said that these high efficiencies have been observed under controlled and easy-to-measure experimental conditions. In reality, there may be other influencing factors which could lead to much lower efficiencies (Reichenberg *et al*., 2006). There is a need to harmonize methods for producing spray drift data and to develop harmonized spray drift models, and an urgent need for more work on drainage and runoff, and issues such as simulating irrigation patterns in specialist crops.

Another point developed by the group was the possibility for incorporating modelling refinements and mitigation into exposure assessment at Step 4, which was classified in three main refinement options. Firstly, relatively simple changes can be made to the existing FOCUS Step 3 scenarios by refining input parameters for the chemical or scenario to make them more precisely reflect the potential risks being assessed. Secondly, mitigation measures can be incorporated into Step 3 scenarios (resulting in a Step 4 calculation). Thirdly, more specific scenarios could be developed to more precisely reflect the environmental and agronomic conditions for use of a plant protection product at a local or regional scale. The location of such new scenarios should follow the procedures adopted by the FOCUS surface water scenarios group.

A wide range of methods and data is available for describing agricultural landscapes, which could be employed to develop refined exposure assessments at Step 4. The use of geographical information systems (GIS) allow a quantitative description of the agro-ecosystem landscape, enabling relationships between cropped land and areas containing non-target organisms to be explored. In FOCUS reports (2005a,b) a number of technical recommendations have been developed to deal with questions of scale of analysis, site selection, data availability, and setting landscape assessments in a broader regional or even EU context. Currently, in the EU registration process, landscape analyses are provided by notifier as higher tier studies for aquatic risk assessment. Typical landscape analyses are based on the use of satellite imagery and aerial photographs to assess the proximity between sources of contamination and the surface water bodies. The percentage of water bodies really receiving an exposure as derived from $FOCUS_{sw}$-Step 3 is then provided as to tool for pesticide risk assessment. A number of substances were evaluated at higher tier level with this approach; an example of this kind of evaluation, performed on an insecticide to be used on citrus fruit, have been discussed in the appendix A4 of the FOCUS report (2005a) as well as in scientific paper and conferences (Padovani *et al.*, 2004, Carter & Capri, 2004).

As part of the remit of the Work Group, a subgroup was established to discuss whether there were further possibilities for incorporating ecological considerations into Step 4 assessments.

During the course of its discussions, the Ecology Subgroup identified a number of key areas where ecological and ecotoxicological considerations could provide opportunities for refined risk assessment at Step 4. One important development in this area would be the definition of the ecological characteristics (biotic and abiotic) of the FOCUS surface water scenarios. Information of this sort could be used in the future to refine both the exposure and effects assessment. One of the challenges confronting risk assessors in light of the FOCUS surface water scenario developments is the time-varying exposure profile of concentration produced at Step 3, which can be at odds with the maintained exposure conditions in standard toxicity tests. Furthermore, moving to the landscape level provides opportunities for considering recovery potential, both internally (from within the water body of concern) and externally (from neighbouring waters).

3 FURTHER DEVELOPMENTS IN PESTICIDE RISK ASSESSMENT

“We need to rediscover how to do basic scientific research on leaching models completely independently of regulatory considerations” (Travis, 2000). This comment, which is valid not just for leaching models, should be taken into account when addressing the future for pesticide risk assessment. A lot of effort in the last decade was focussed on methods for improving pesticide risk assessment in the regulatory framework.

Even if this has been a strong engine for revision strategies and development of tools, methodology and guidance documents, the registration process is limited by its intrinsic administrative character.

Evidence from monitoring studies demonstrates that contamination of surface waters by pesticides arising from point sources (e.g. via sewage treatment works, spills, farmyard washoff) can often be a significant proportion of the total loading at the catchment scale. Point source contamination often arises from accidental spillage or handling/disposal activities and current regulatory exposure models do not include the effects of point source loading. From the recent review on mitigation strategies to reduce pesticide inputs into water bodies, Reichenberger *et al*. (2006) concluded that point-source inputs can be relatively easily mitigated by increasing awareness of the farmers with regard to pesticide handling and application, and encouraging them to implement loss-reducing measures of “best management practice”. Information and advisory campaigns and trainings were successful and effective in most study catchments, but continuous effort is necessary to prevent backsliding.

In some catchments which are dominated by diffuse inputs at least in some years, mitigation of point-source inputs alone is not sufficient to reduce pesticide loads/ concentrations in water bodies to an acceptable level.

The exposure conditions relevant for the pesticide risk assessment at edge of a field scenario are not necessarily the conditions in water bodies draining an agricultural area as active substances may be used in different preparations / crop types with application patterns which may vary depending on preparation and crop type. Moreover, factors like local weather conditions or growth stages of plants on individual fields, time schedule of farmers etc. may influence pesticide contamination. Moreover, flow regimes of tributaries may be different and hence the transport velocity of pesticide-loaded water coming from different areas of the basin. Therefore, the “edge of a field” exposure-scenario used in the pesticide risk assessment might not in all instances be the worst-case scenario (Lepper, 2006).

The assumption of a static water body, in fact, often yields higher dilution than the assumption of a flowing headwater body.

3.1 Model improvement

A lot of research has been conducted in the last 30 years to describe and simulate the transport of pesticides in soil (FOCUS, 1995; FOCUS, 2000; Vanclooster *et al.,* 2000). A number of mathematical tools of varying complexity have been developed (Carsel *et al.,* 1985; Rao *et al.,* 1985; Jury *et al.*, 1986; Jarvis *et al.,* 1991; Hutson & Wagenet, 1992; Knisel *et al.,* 1992; RZWQM team, 1992; Grochulska & Kladivko, 1994; Tiktak *et al.*, 2000).

Almost all the evaluation of pesticide leaching is performed at 1-m depth under the assumption that groundwater is unlikely to be affected by pesticides at concentrations exceeding 0.1 µg/L if those concentrations are not encountered at a shallow depth. Little research has been conducted on the fate and behaviour of pesticides once they have leached through the soil and below the root zone.

Water flow and contaminant transport in groundwater are difficult to study and investigations on pesticide fate at the aquifer scale are scarce. The tendency has been to isolate the various processes which control the fate of pesticides and to investigate them separately.

Studies on pesticide fate at the scale of the aquifer which have been reported in the literature referred generally to monitor of seasonal variations of pesticide concentrations in the groundwater (Hill *et al*., 1996; Barbash *et al*., 2001; Cerejeira *et al*., 2003;) or in the unsaturated and saturated zones (Johnson *et al*.,2001).

Recently, a research project funded by the European Union within the 5th Framework Programme, PEGASE, developed mechanistic or semi-empirical tools for the modelling of pesticide contamination in groundwater at various spatial scales. Approaches investigated included the refinement of a screening tool (PESTGW) and 1D root zone models (MACRO and ANSWERS), the addition of pesticide fate and crop subroutines in integrated models (thereby allowing the prediction of pesticide fate in the soil-unsaturated zone-saturated zone continuum; MARTHE, TRACE and POWER) and the coupling of different models (TRACE+3DLEWASTE, MACRO+FRAC3DVS, MACRO+MODFLOW, ANSWERS+ MODFLOW). The numerics of the models were upgraded within the framework of the project, which allows the future deployment of advanced modelling activities, such as automated calibration against field data or sensitivity and uncertainty analyses (PEGASE, 2004).

The FOCUS surface water scenarios represent an agricultural field using a single combination of soil, weather and boundary conditions. The simulated area is assumed to have a single crop grown on it and all spraying takes place simultaneously. The upper catchment of the stream is assumed to be hydrologically equal to the column modelled, but 80 % of the upstream catchment is assumed to be unsprayed. In reality, the conditions within a catchment differ spatially, especially as larger scales are considered: different soil types are present, surface flow is influenced by topographic variation, pesticide applications can occur at various times and the exposure of the stream can vary due to surrounding vegetation. To take into account all this variability a catchment model is required. FOCUS workgroup on Landscape and Mitigation, referring to a review of White *et al*. (2003), divided catchment modelling into three groups: one dimensional leaching models, which lack the capability of simulating surface processes, field-scale models which simulate runoff but have limited capabilities of simulating flow routing or spatial heterogeneity and finally, various types of catchment models which simulate both surface processes as well as spatial heterogeneity.

As a general consideration, in catchment modelling the FOCUS Workgroup suggests that the appropriate level of complexity should be a balance between precision in predicting concentrations and resource constraints (time, money, data, and technology). More sophisticated simulations require more extensive and higher quality datasets. Therefore, attention should be paid to assessing the primary issue of concern (potential for exceeding of an exposure threshold, duration of exposure etc…) and should be also directed to represent the most sensitive and relevant governing factors.

Catchment modelling approaches are expected to become a higher profile tool within regulatory risk assessments required under the Water Framework Directive.

3.2 Incorporation of spatial variability of parameters

There is great variability and uncertainty in field parameters that influence the accuracy of pesticide fate modelling. Spatial variation in pesticide/soil interactions (sorption, transport, degradation, ageing, formation of bound residues) is determined by several factors, many of which remain unexplored. There have been several previous studies on the spatial variation of pesticide/soil interactions (Walker and Brown, 1983; Rao and Wagenet, 1985; Wood *et al.*, 1987; Parkin and Shelton, 1992; Novak *et al.* 1997; Zander *et al.* 1999; Walker *et al.* 2001; Wood *et al.* 2002). These studies focused on quantifying the variation in the sorption (Lennartz 1999) and degradation of pesticides (Walker and Brown 1983; Walker *et al.* 2001; and Wood *et al.* 2002). Walker and Brown (1983) examined spatial variation associated with simazine and metribuzin degradation. They showed that small scale variation was an important component of the total variation, by a comparison of the coefficients of variation at different separation distances. Rao and Wagenet (1985) suggested the use of geostatistics to analyse the variation in properties such as sorption and degradation of pesticides. However its application has been limited and few studies have used geostatistics to quantify the variation in pesticide sorption (Wood *et al.* 1987; Novak *et al.* 1997) or degradation (Parkin and Shelton, 1992; Zander *et al.* 1999). This could be due to the large sample size required to compute a reliable variogram. Studies that have applied geostatistics to pesticide/soil interactions have generally been based on small data sets making the computed variograms highly unreliable, e.g. Zander *et al*., (1999); Parkin and Shelton (1992) as reported in Price (2003).

In studies conducted in Hawaii by Loague et al. (1990), as reported in FOCUS (2005b), it was demonstrated that variability in organic carbon content in five soil types was characterised by coefficients of variation in the range of 25-55%. Therefore geostatistically robust representations of run-off potential are not straightforward and representativity issues have to be dealt with great care.

Rao and Waganet (1985) suggested the need to separate the intrinsic factors from the extrinsic ones to understand the spatial variation in pesticide persistence better. An example of an extrinsic factor is the uniformity of pesticide application. Vischetti et al. (1997) studied the variability in pesticide application rate and found little structure in its variation, suggesting either that pesticide application was done uniformly or that the variation was locally erratic.

3.3 Incorporation of uncertainty in the modelling

It is never possible to quantify all sources of uncertainty and variability in an assessment (Dubus et al., 2003), but quantifying a few may be sufficient to reach a regulatory decision (EUFRAM, 2005).

However, the quantitative output of an assessment should always be accompanied by a list of unquantified sources of variability, uncertainty and dependency, and a qualitative assessment of their potential influence on the assessment endpoint.

Parameter uncertainty represents a lack of knowledge about specific factors or parameters that characterise the physical system that is being modelled. Parameter uncertainty can lead to inaccurate or biased estimates and can be reduced through further measurements with for instance a larger sample size, or an unbiased sample design. The use of more sophisticated modelling and analysis tools can also reduce uncertainty. The use of field measurements is an option in all frameworks.

The uncertainty analysis becomes the key issue in higher tier risk assessment. Although several workshops have been organised (EUPRA, 2001; EUFRAM, 2005), the final conclusions still indicates the need for a case-by-case assessment. Two aspects require special attention within the uncertainty analysis: uncertainty on the ecological relevance of the observed effects (realism), and uncertainty on the capability of the studies to cover all relevant European conditions (representativity). Some proposals for addressing these issues are available. Several proposals for evaluating the uncertainty in risk assessment are available (e.g. Helton and Davis, 2002; Pate-Cornell, 2002; Aldenberg and Jaworska 2000) which obviously may also be suitable for risk associated to environmental issues (von Stackelberg, 2002; Johnston, 2002). The adoption of procedures for expressing the uncertainty in the risk assessment is strongly recommended, and the efforts for harmonizing the evaluation and expression of the uncertainty developed by others (Taylor and Kuyatt, 1994) might be highly valuable (SSC 2003c), although they are not directly intended for environmental risks. In this framework, the EUFRAM project is developing a draft framework on basic guidance for risk assessors, addressing, among the other topics the methods of uncertainty analysis (EUFRAM, 2004a).

This guidance, which aims to link together the methods that have been proposed and demonstrate how they can be used, summarises current idea of the members of the project, on methodology for uncertainty analysis. In Table 4 is reported an overview of approaches for dealing with uncertainty in risk assessment, selected by the group, with comment on how to use these methods together with the pros and cons.

	HOW?	WHY?	WHY NOT?
Worst case analysis	• estimate assuming the plausible extreme • compare with reference value	• account for uncertainty by being conservative • under ignorance, shift burden of proof	• level of conservatism unquantified and may be too low or too high
Interval analysis	• replace each point estimate with an interval (e.g. [1,2]) • use interval arithmetic to combine the intervals	• natural for scientists and easy to explain to others • works no matter where uncertainty comes from	• paradoxical: can't give exact value but can give exact bounds • ranges can grow very quickly, giving very wide results
Monte Carlo simulation	• replace each point estimate with a probability distribution • repeatedly sample from each, tally answers in a histogram	• simple to implement • fairly simple to explain • summarizes entire distribution of risk • can use information about correlations between variables • user-friendly software on familiar platforms	• requires a lot of empirical information – or assumptions • assumptions can lead to non protective conclusions • only appropriate if uncertainty is statistical • does not separate uncertainty and variability
Second order Monte Carlo	• let parameters of input distributions be distributions too • nest Monte Carlo analyses • summarize with distribution of distributions, or condense into a single distribution	• acknowledges and accounts for uncertainty about distribution parameters • separates variability and uncertainty • can handle model uncertainty in a limited way • user-friendly software on familiar platforms	• can be daunting to specify inputs • requires data or assumptions about distribution shape and dependencies • results are cumbersome to interpret and explain • confounds frequentist and subjectivist interpretations of probability
Probability bounds analysis	• specify what you are sure about • establish bounds on probability distributions • pick dependencies (no assumption, independence, correlated, perfect, etc.)	• handles uncertainty about parameter values, distribution shapes, dependencies, and model form • puts rigorous bounds on Monte Carlo results • bounds get narrower with better empirical information • faithful to frequentist interpretation of probability	• displays must be cumulative • does not yield 2-D probabilities • must truncate infinite tails • lacks theoretical basis for interpreting its treatment of sampling uncertainty • difficulties with repeated variables or complex dependencies

Table 4 : Overview of selected approaches for dealing with uncertainty in risk assessment (from EUFRAM, 2005b).

3.4 Probabilistic Risk Assessment

Under the current Directive 91/414/EC, the principles behind environmental risk assessments are deterministic and are based on single point estimates of toxicity and exposure.

Even if this kind of approach is based on deterministic elements, it cannot be considered wholly deterministic. Almost all assessments under 91/414/EEC, in fact, already incorporate at least some probabilistic elements: assessments for most taxonomic groups use LC_{50}, LD_{50} or EC_{50} measures of toxicity, which are derived from probit curves representing variation in sensitivity between individuals. Similarly, fixed uncertainty or assessment factors used in risk assessment may be derived from quantitative analysis of uncertainties. On the other hand it is practically impossible to quantify absolutely every source of variability and uncertainty affecting an assessment. Therefore, most assessments are neither fully deterministic nor fully probabilistic, but somewhere in between (EUFRAM, 2005).

In real world settings, both exposure and effects are highly variable in space and time due to chemical use patterns, environmental characteristics and biological attributes. So the question is not whether to start doing probabilistic assessments, but whether it may be helpful to include more probabilistic elements than we already do and – if so – when and how to do it.

Probabilistic methods are one of the tools that should be used together with other lines of evidence to improve the understanding of exposure, toxicity and resulting risk. As a generic technique, in the framework of Directive 91/414/EEC probabilistic methods will have application in refined exposure assessment for surface water and groundwater: major discussion will be on $FOCUS_{sw}$ Step 3 scenarios and in assessments outside of the $FOCUS_{sw}$ and $FOCUS_{gw}$ scenarios. Moreover, also landscape analysis may have a role in assessing potential spatial variability in exposure concentrations during validation of probabilistic calculations. Progression to a more probabilistic means of describing exposure and expressing the risks is proposed also by Scientific Steering Committee (SSC, 2003b). Even though the deterministic approach that involves the definition of a threshold has served the needs of risk managers well in the past, it provides an apparent (often unrealistic) sharp distinction between the levels where there is an effect and that where no effect will occur.

This may be a poor basis in some cases for risk management decisions and may result in confusion among the public (SSC, 2003b). It is recognised that the introduction of probabilistic approaches also may produce difficulties in understanding. According to the Scientific Steering Committee, one of the challenges when interpreting probabilistic results is the lack of established criteria for using them in decision-making.

A phased approach to the use of probabilistic approaches for risk assessment purposes is therefore necessary (SSC, 2003b). Various options for the refined, higher tier risk assessments are identified in existing EU Guidance Documents, including probabilistic approaches.

Current EU Guidance Documents for both aquatic and terrestrial ecotoxicology (DG SANCO 2002 a,b) state that traditional deterministic assessment methods have limitations that could be overcome by probabilistic approaches. The Aquatic Guidance Document (DG SANCO, 2002a) states that probabilistic risk assessment is usually a tool for higher-tier assessments and hence its suitability needs to be considered case-by-case. Until now, however, probabilistic approaches have gained only limited acceptance, partly due to a lack of guidance on how to implement and evaluate them. For the foreseeable future, deterministic methods are likely to remain the primary tool for lower tiers of risk assessment.

Nevertheless, the necessity of higher tier for risk assessment refinement, had opened the possibility of using statistical methods for risk assessment being them probabilistic risk assessment in evaluation of exposure (Monte Carlo etc.), of toxicity (mesocosm studies) and in analysis of the territory (landscape analysis, satellite images)

A significant amount of information on the development and use of probabilistic modelling for higher-tier risk assessments as well as recommendations for interpreting and applying the results of probabilistic assessments is available (e.g. ECOFRAM, 1999; EUPRA, 2001, Dubus *et al*. 2002; Dubus *et al*., 2003). EUFRAM project, an EU- funded concerted action involving 29 organisations including regulatory authorities, government research institutes, agrochemical companies, consultancy companies and universities, is preparing a draft document which aims to provide a framework of basic concepts, principles and methods that will help users to conduct, report, evaluate and communicate probabilistic assessments in appropriate ways. The main task of the project is to develop a draft framework on basic guidance, addressing

- the role and outputs of probabilistic assessments
- methods of uncertainty analysis,
- probabilistic methods for small datasets
- methods to report and communicate results
- ways to validate probabilistic methods
- methods to improve access to existing data
- requirements for probabilistic software and databases.

Case studies will be presented, showing how methods can be applied in order to assess impacts of pesticides on terrestrial and aquatic organism.

The project is aimed primarily at risk assessors in government, industry and consultancy companies and is fully addressing the role of probabilistic approaches within risk assessment for pesticides.

EUFRAM does not have a formal status in relation to Directive 91/414/EEC, so documents should not be regarded as formal guidance. The project will be completed at the end of 2006 and details can be found at www.eufram.com.

The results of probabilistic assessments should be considered together with conventional deterministic results and other lines of evidence (e.g. field studies or monitoring), to arrive at overall conclusions. This may include consideration of the wider ecological consequences of predicted impacts (e.g. extrapolation from effects on individual organisms to consequences for the wider population).

3.5 Incorporation of spatial technologies

In order to address the growing use of spatial technologies (GIS, remote sensing) in landscape analysis for risk assessment, several issues should be identified and addressed in future research. Because of the relative newness of these spatial approaches (as compared to other methods in risk assessment), confidence in the scientific, consistent, and ethical application of these technologies may be a concern on the behalf of regulatory agencies (FOCUS, 2005b). In addition, since multiple approaches in the application of spatial technologies to a given problem may yield similar results, interpretation of results requires a moderate level of understanding in spatial processing to assess the relevance and validity of the methods used. While there are several initiatives underway in the EU to generate and distribute spatial information in a consistent and transparent manner, most of these do not address pesticides and surface water as the primary focus. GINIE Geographic Information Network In Europe, is a research project funded by the Information Society Technology Programme of the EU (November 2001- January 2004). Its partners are EUROGI, the European Umbrella Organisation for Geographic Information, the Open GIS Consortium Europe representing the Geographic Information (GI) industry, the Joint Research Centre of the European Commission, and the University of Sheffield (Coordinator). The aim of the project was to develop a deeper understanding of the key issues and actors affecting the wider use of GI in Europe, and articulate a strategy to promote such wider use that is consistent with major policy and technological developments at the European and international level. Close attention has been paid to the role of GI in supporting European policies with a strong spatial impact (agriculture, regional policy, transport, environment), e-government, the re-use of Public Sector Information, and the recent initiative to develop INSPIRE - Infrastructure for Spatial Information in Europe. (Description taken from web site at http://www.ec-gis.org/ginie/)

INSPIRE (Infrastructure for Spatial Information in Europe) is a recent initiative launched by the European Commission and developed in collaboration with Member States of the European Union and accession countries. A key objective of INSPIRE is to make more and better spatial data available for Community policy-making and implementation of Community policies in the Member States at all levels. INSPIRE focuses on environmental policy but is open for use by and future extension to other sectors such as agriculture, transport and energy. The proposal focuses specifically on information needed in order to monitor and improve the state of the environment, including air, water, soil and the natural landscape. (http://inspire.jrc.it/home.html). Also the Agri-Environment Action deals with spatial data; members of the the Agri-Environment Action work on the following issues:

- Integration of spatial information layers at different scales for the estimation of land cover change in rural areas. The work consists of the methodological development of tools for the implementation of a sustainable EU agricultural policy.
- Monitoring and modeling of European landscapes, including the test of selected pressure indicators over European landscapes.
- Further development of a European river and catchment database (CCM) at intermediate scale (1:250,000 to 1:500,000) in support to environmental reporting activities of DG Environment and EEA.
- Making available JRC’s expertise and competence for understanding the linkages between agriculture and environment, with particular emphasis on the spatial component. (Description taken from web site at http://agrienv.jrc.it/activities/)

These initiatives that addressed data gathering and dissemination on the EU level are providing relevant data layers for use in exposure estimation, but generally do not provide any method of interpretation or combination of data into metrics meaningful for pesticide exposure estimation. The proactive development of a set of landscape-level information related to specific crop/climate/exposure regimes, for use by regulatory agencies, academia and research organizations, and the crop protection industry, should be considered for future research efforts (FOCUS, 2005b). The Digital Dataset of European Groundwater Resources - version 1.0 (Hollis et al., 2006), a project was financed as a Company Investment Prospect by the European Crop Protection Association (ECPA), and steered by the ECPA GIS working group, is one of these possible developments.

The goal of these research efforts will be to provide a reasonable level of confidence for the regulatory community, academia and research organizations, and the crop protection industry, that spatial approaches can be consistently, scientifically, verifiably, and ethically applied to ecological risk assessment.

3.6 Risk Communication

Probabilistic assessments are more difficult to communicate than conventional deterministic ones, and this could be a major obstacle to the acceptance of probabilistic approaches by end-users. The immediate audiences for probabilistic assessments are technical specialists (e.g.

peer reviewers, evaluators) and decision-makers or policy staff in government, industry and NGOs (non-governmental organisations). According to EUFRAM (2004b), other interested parties, including the general public, might be of reference in communicating results of probabilistic risk assessment particularly in the context of increased transparency associated with the practice of risk analysis.

Different audiences have different communication needs, which must be considered as part of the process of developing an effective risk communication strategy.

Different individuals within any audience have different preferences; therefore a balanced picture of what is known and what is uncertain is necessary.

Probabilistic methods can only be implemented successfully if they gain the trust and understanding of risk assessors, decision-makers, stakeholders and the public. To this purpose, methods for communicating the inputs, process and outputs of probabilistic assessment are required. These methods should be developed in collaboration with stakeholders, including non-governmental organisations and social scientists, to ensure they are effective (EUPRA, 2001). When the public want information about a risk, they prefer a clear message from technical experts regarding risks and associated uncertainties, and cross-population variabilities, including the nature and extent of disagreements between different experts (EUFRAM 2004b). To communicate this information to the public, decision-makers must themselves be aware of uncertainties and variabilities associated with risk assessments.

There is at the present time increasing societal and political pressure directed towards increased transparency in risk management practices. For this reason, the uncertainties associated with technical risk assessments, upon which risk management decisions are founded, will increasingly be subject to public scrutiny. Decision-making associated with probabilistic risk is assessment apparently not easy for the general public.

In the first conclusion on “Communicating results of probabilistic assessments”, performed by EUFRAM group (EUFRAM, 2005), a substantial part of the difficulty in communicating probabilistic results is considered due to the lack of established criteria for decision-making. The group considers that even if the results address the assessment objectives and are clearly communicated, the lack of decision criteria makes them hard to interpret. It is unlikely that standard criteria will be established soon so, for the time being, results will have to be evaluated case by case. This further increases the importance of providing good interpretative text with results.

4 FOOTPRINT AND PESTICIDE RISK ASSESSMENT

The FOOTPRINT project is aimed at developing a set of computer tools that will allow users to: i) identify the dominant pathways and sources of pesticide contamination in the agricultural landscape; ii) estimate levels of pesticide concentrations in surface water and groundwater; iii) make scientifically-based assessments of how the implementation of risk reduction strategies is likely to reduce pesticide contamination of water resources.

The FOOTPRINT project proposes to develop robust and harmonised procedures for pesticide risk assessment, allowing consistent assessments to be performed from the scale of the farm to that of the EU. Characterisation of all EU agricultural land will be provided by a large number of generic, effectively homogeneous agro-environmental scenarios. Each scenario will represent a unique combination of those agronomic practices, soil and subsoil hydrological characteristics and climatology that determine the fate of agriculturally-applied pesticides within Europe.

This approach will further the current risk assessment procedures for pesticides, which presently rely on a limited number of scenarios to cover the diversity of European agricultural land. Moreover, the same set of scenarios will be used for the three different levels, providing in this way a coherent and integrated solution to pesticide risk assessment.

The general risk assessment philosophy, which will be implemented in the FOOT tools, will be based on current practices in the EU: comparison of leaching concentrations at 1-m depth to the EU legal limit for drinking water of 0.1 µg/L for groundwater; comparison of predicted concentrations vs. ecotoxicological parameters with thresholds established by Directive 91/414/EEC for surface water. The major effort in FOOTPRINT project will be on the pesticide environmental exposure for water resources rather than on ecotoxicological effects side. This approach will not exclude the use of the tools for more advanced and innovative risk assessment approaches, as for instance considerations of groundwater characteristics for assessment of the risk to groundwater and the optimisation of the tools to facilitate the export and subsequent use of predicted concentrations in more complex risk assessments (e.g. combination of predicted concentrations and results from ecotoxicological species sensitivity distributions).

MACRO and the runoff and erosion model PRZM can be run for all the identified European soil scenarios. Meta-models of the simulation model MACRO (v.5), for pesticide leaching to groundwater and for losses to surface water via drainage systems, and of the PRZM model, for surface runoff and erosion, will be developed and will subsequently be incorporated into the risk assessment and risk reduction tools for local-, catchment- and regional/EU scale

applications developed. The user can decide to use the real models, more accurate, with higher-tier options such as kinetic sorption, rather then the faster and simpler meta-models.
All three tools will allow the calculation of edge-of-field PEC; at catchment scale, the so-called FOOT-CRS tool will also allow PEC_{sw} calculation at catchment outlets, a possibility which might be of specific importance for water managers.
Water contamination from point sources will be considered in the development of the tools, especially at catchment scale. In particular, predictions of pesticide concentrations resulting from losses from hard surfaces (e.g. farmyards) will be based on the recently developed HardSPEC pesticide fate model and considerations with regard to the spatial connectivity between hard surfaces and the potential receiving water body.

The application at farm level, FOOT-FS, will be a stand-alone application as well as a web portal which will identify the pathways and areas most contributing to contamination of water resources by pesticides. It will provide site-specific recommendations to limit transfers of pesticides in the local agricultural landscape. The diagnostic approaches for the identification of contamination pathway will be CORPEN (France) coupled with Hydrology Of Soil Types: HOST (UK)
A diagnostic of each field will be performed with the farmer / extension adviser and will suggest changes in agricultural practices where appropriate:

- agronomic practices
- landscape management (buffers, hedges, ditches, tree planting, etc.)
- choice of spraying periods
- choice of pesticides and spraying schedule
- point source mitigation (especially preventing pesticide runoff from farmyards)

Specific attention will be put on user-friendly interface and communication with end users. FOOT-FS will provide scientific based suggestions, but emphasis will be given to using novel techniques for communicating the risk to the farmer/land manager. A suite of decision rules will be developed to aid the interpretation of the model results (fate and ecotoxicology) and graphical techniques, use of icons etc. will be used to highlight high-risk areas on the farm and taxa most threatened.

The application at catchment scale, FOOT CRS, developed in ArcGIS environment, will be used by local authorities, stewardship managers and water managers. The identification of the areas most contributing to the contamination of water resources by pesticides will allow the definition and/or optimisation of action plans at the scale of the catchment.
The diagnostic approaches for the identification of contamination pathways will be Aquavallée (France), a tool for mapping types of pesticide transfers which uses a GIS and a

decision making implementation of CORPEN and HOST.

The potential presence of any intercepting vegetation (e.g. buffer zones) and the distance between the application point and the water body will be accounted for through landscape analysis using aerial photographs and/or satellite imagery. FOOT-CRS will be based on a great number of spatial information layer:

- distribution of agro-environmental scenarios in the catchment (GIS map);
- land use: area of arable land, grassland, special cultures, and the crops of concern;
- proportion of tile- or mole-drained arable land, to account for drainage inputs;
- river network, subcatchments for PEC calculation;
- area-specific discharge, to account for both edge-of-field and catchment/regional scale PEC;
- stream flow velocity (for Gustafson or water quality model);
- surface water network density, for drift evaluation;
- presence, length and structure of bank vegetation, for drift and runoff/erosion evaluation;
- administrative boundaries: districts, municipalities;
- number of farms per sub-catchment, degree of connection to sewage plants, to address the problem of point sources;
- density of field sprayers and sewage plants as a further input in defining point sources contamination.

FOOT-CRS might be considered a higher profile tool within regulatory risk assessments required under the Water Framework Directive. The information provided can be directly used by catchment managers and decision makers without being overly complicated by issues of uncertainty.

The application at National/European scale, FOOT NES, will assess the probability of pesticide concentrations exceeding legal or ecotoxicologically-based thresholds identifying the areas most at risk from pesticide contamination. GIS application will be developed, identifying risks in terms of classes (colours), at 1- m depth and considering drainage density for groundwater. The diagnostic approaches for the identification of contamination pathway will be the Index of hydrological Network Development and Persistence (IDPR), a simplified approach for tendency of a catchment to transfer water to groundwater (infiltration) or to surface water (run off) based on comparison between actual and conceptual (hypothetical) drainage network. It will be up to the user to decide whether to employ the meta-models of MACRO and PRZM or the real-time models themselves.

The statistical distribution of predicted pesticide concentrations provided by FOOT-NES will be tested whether corresponds to that for measured data on exposure at the national level. In common with the evaluation exercise at the catchment scale, maps produced by the FOOT-

NES tool will be compared to a number of member states vulnerability maps produced using other approaches. FOOT-NES will have the potential to be used as a higher-tier tool for the EU pesticide registration process, as it will develop new approaches to identify 'hot spots' for pesticide contamination in the landscape and to convert local leaching and small water body concentrations into concentrations likely to be observed in local groundwater resources and surface water abstraction sources at Europe/National level, providing in this way, a powerful instrument for decision-making to registration authorities and policy makers.

5 CONCLUSIONS

In these last twenty years, environmental pesticide risk assessment has been deeply addressed both from scientific communities and from regulatory organisations. US EPA, EU, OECD, SETAC and other organisations have been the major drivers of this activity. Guidance documents on specific topics of environmental pesticide risk assessment have been prepared, at international level, and have been discussed by several Scientific Committees. Two areas of pesticide environmental risk assessment were mainly discussed: characterisation of effects and characterization of exposure. The current accepted approach, to both the exposure and effect assessment, is a tiered one: from a first tier, very simple and extreme worst case, up to the last tiers characterised by higher tier studies and modelling. The higher tier studies and models are not yet totally defined, and are still open for investigation, regulation, and development.

There is a general agreement that the environmental exposure assessment must be related to the use pattern and possibilities for environmental releases during the life cycle of the substance. Distinctions among intended and non-intended releases are obvious, but not sufficient for a proper assessment of the environmental exposure. The use of real emission/exposure data is crucial for a proper decision.

At European level is presently under discussion the proposal for a Directive of the European Parliament and of the Council establishing a framework for Community action to achieve a sustainable use of pesticide. The purpose of this Directive is to establish a legislative framework which:

- contributes to the reduction of the impact of pesticides on human health and the environment;
- aims at achieving a more sustainable use of pesticides;

- promotes a significant reduction in risks and of the use of pesticides consistent with the necessary crop protection.

FOOTPRINT, with the three tools developed for three different scales and typologies of end-users, can be expected to contribute to this purpose as well as to a large range of existing and future EU policy instruments and directives like the current Council Directive 91/414/EEC and its future revision, the 'Water Framework Directive', WFD (Directive 2000/60/EC), the proposed Groundwater Daughter Directive and, to a lesser extent, the Common Agricultural Policy. As a major improvement over current risk assessment procedures for pesticides, the project will provide a characterisation of all EU agricultural land, using a large number of generic, effectively homogeneous agro-environmental scenarios covering the diversity in European agricultural and environmental conditions.

Finally, the project is expected to become a powerful tool in decision–making for different end-users, as it will develop new approaches to identify 'hot spots' for pesticide contamination in the landscape and to convert local leaching and small water body concentrations into concentrations likely to be observed in local groundwater resources and surface water abstraction sources.

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