



Industry Experiences

SETAC LATARAP, 10th October 2012

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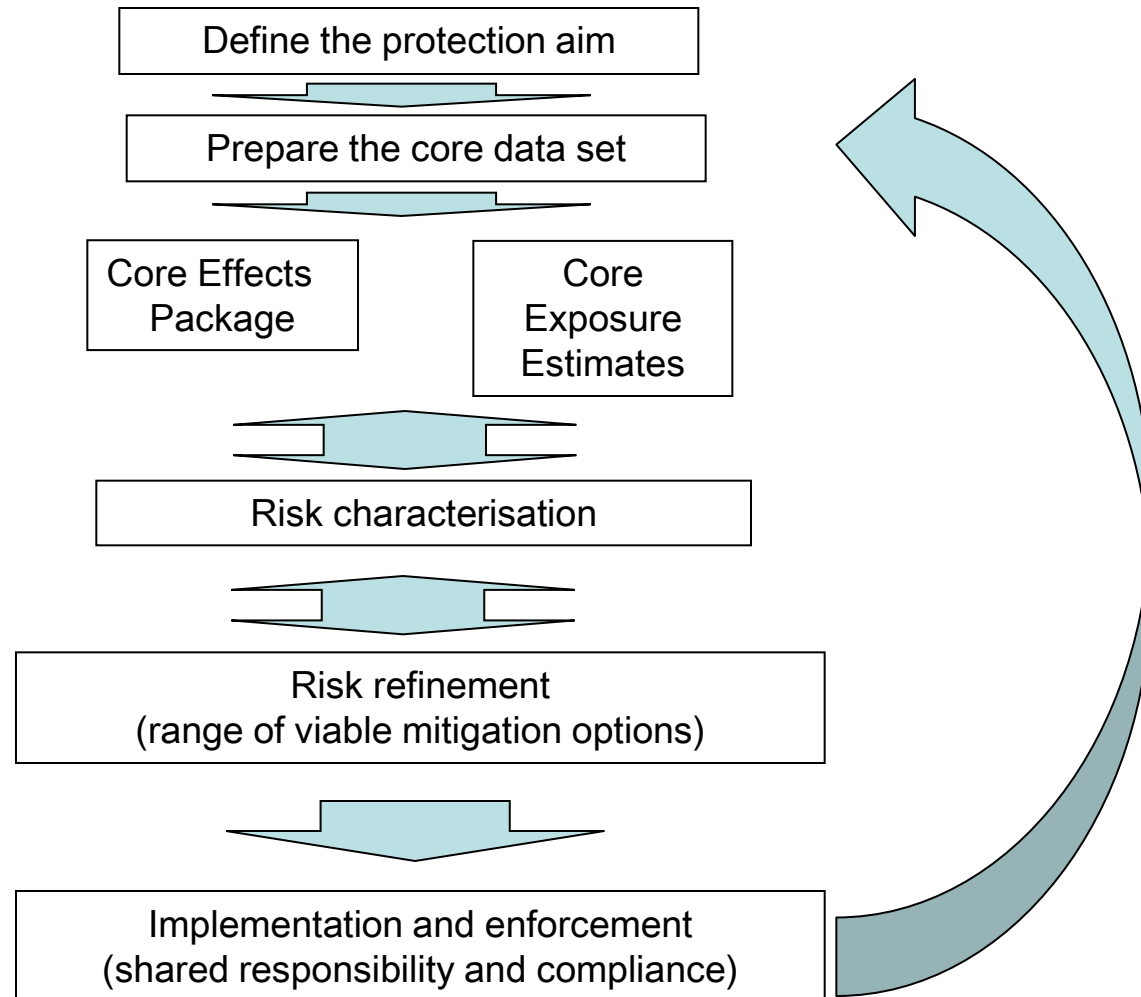


Crop Life approach to aquatic risk assessment

- Aquatic risk assessment approaches should
 - ensure products can be used safely
 - protect aquatic environments from unintended effects whilst securing the benefits of crop protection to support increasing demand for food production
 - be science-based (not hazard cutoffs)
- Crop Life has reviewed the various approaches taken to aquatic risk assessment around the world and synthesized these into a framework

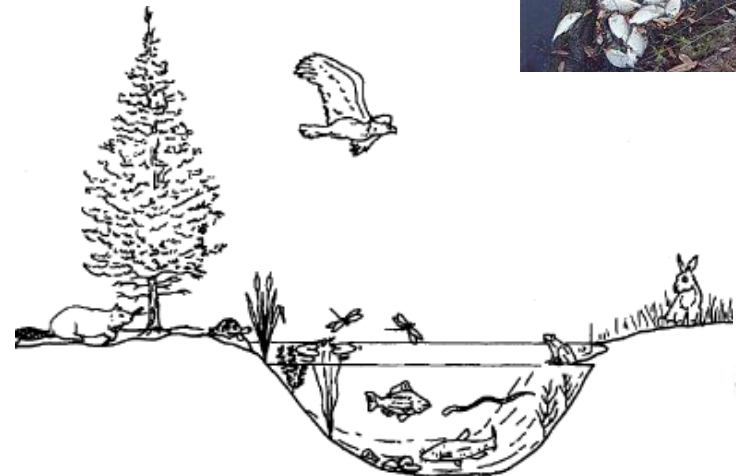


Universal framework for assessing safety of use



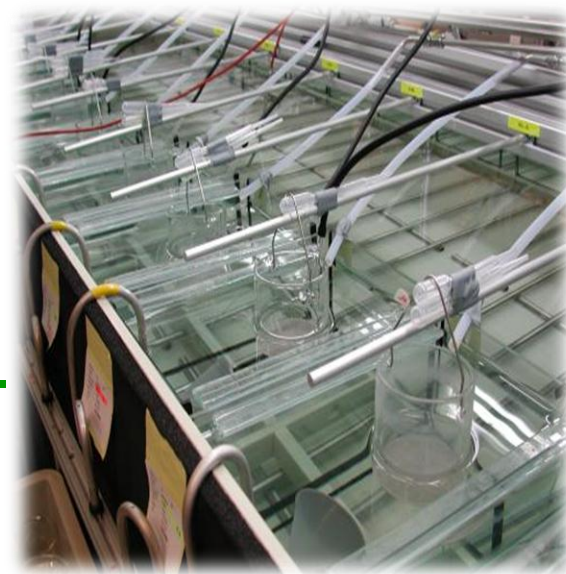
Protection aims

- To protect aquatic ecosystems, prevent visible/significant acute events and ensure no long term effects at the population level



Aquatic effects testing

- Testing procedures for aquatic organisms are now well-established with many globally agreed guidelines (OECD)
- Generally for a modern pesticide developed for worldwide registration, several members of key groups (fish, invertebrates, plants) are tested,
- Some additional tests are triggered depending on compound properties (e.g. sediment, macrophytes)
- Acute and chronic endpoints are developed
- Uncertainty factors used to derive predicted no effect concentration (PNEC)



Fish, aquatic invertebrates, aquatic plants (range of indicator species)



Regenbogen Forelle (*Oncorhynchus mykiss*)
Rainbow trout



Sonnenfisch (*Lepomis macrochirus*)
Bluegill sunfish



Amerikanische Elritze (*Lepomis macrochirus*)
Fathead minnow



Karpfen (*Cyprinus carpio*)
Carp



Wasserfloh (*Daphnia magna*)
Waterflea



Süßwassergarnele (*Hyalella azteca*)
Freshwater shrimp



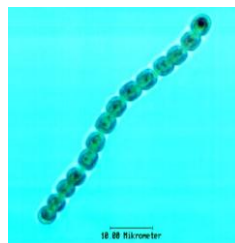
Mücken Larven (*Chironomus riparius*)
Midge larvae



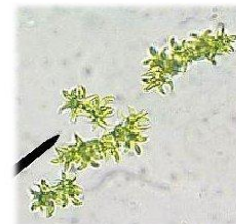
Schwebegarnele (*Americamysis bahia*)
Mysid shrimp



Wasserlinse (*Lemna gibba*)
Duckweed



Blualge (*Anabaena flos aquae*)
Bluegreen algae



Grünalge (*Pseudokirchneriella*)
Green algae



Tausendblatt (*Myriophyllum*)
Water milfoil



Key requirements for standardized ecotoxicity testing – the 5 R's

■ Reliable

- test organisms should be readily available (ideally globally), using internationally available “surrogate” species of uniform quality and performance.



■ Reproducible

- the same test should give similar results (*within experimental limits*) irrespective of where or when the test is conducted
- variation (biological and environmental) within the test system should be minimised by using well-defined, “ring-tested” methods (e.g. OECD Guidelines)



■ Robust

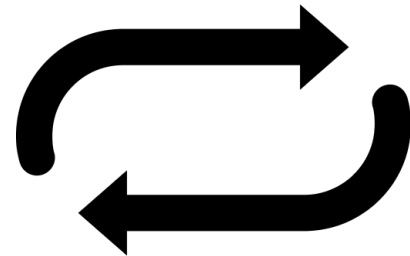
- procedures, observations and interpretation should not be too demanding for new laboratories or for evaluators to interpret
- well-defined, easily transferable and interpretable test methods (e.g. OECD Guidelines).



Key requirements for standardized ecotoxicity testing – the 5 R's

■ Repeatable

- endpoints are sensitive and discernible over and above background variability (biological and environmental)
- using test organisms of uniform quality (e.g. age, condition) with well understood life-history and low variability (i.e. normal survival, growth and reproduction is well defined)

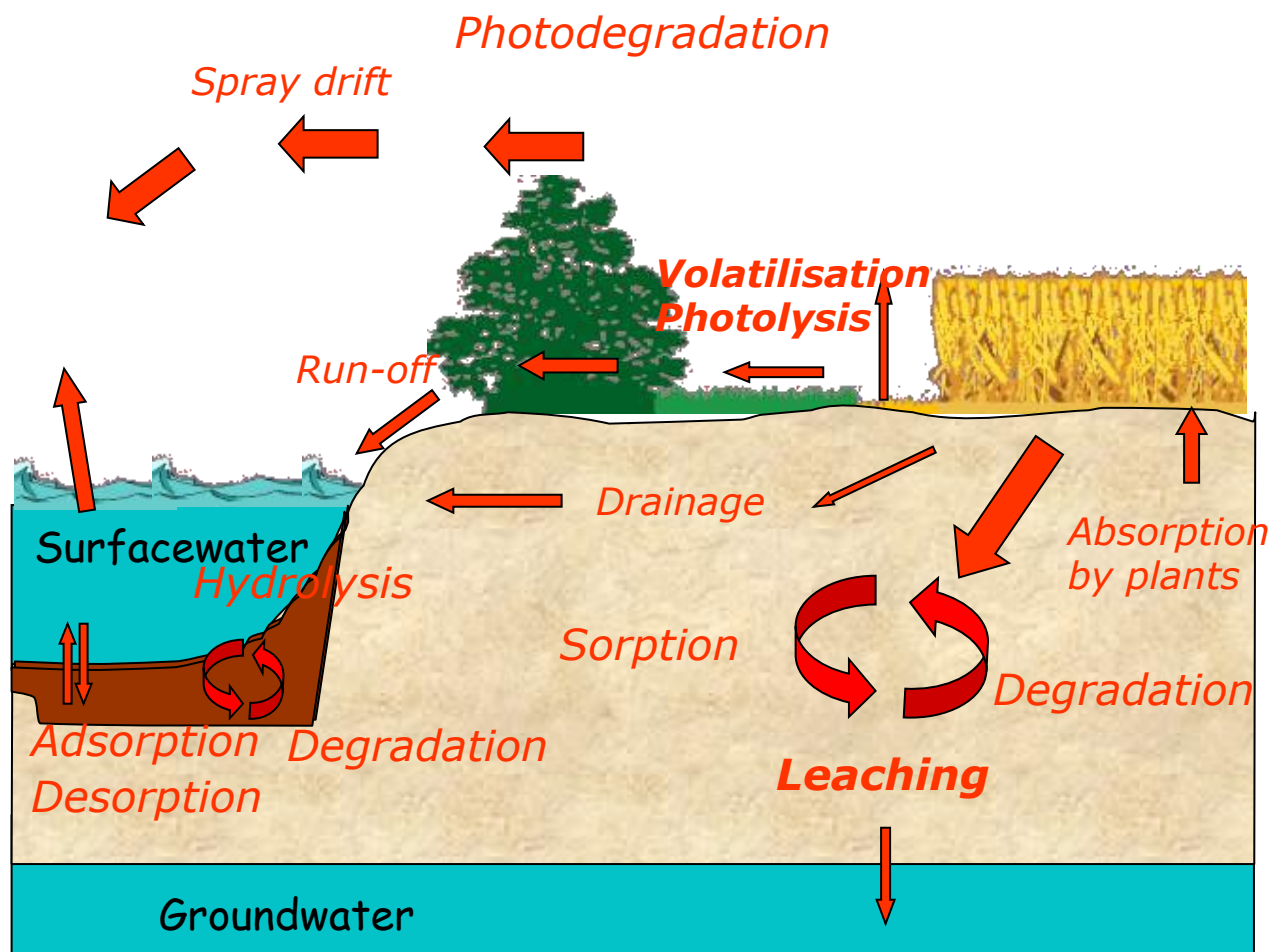


■ Relevant

- tests should be ecologically relevant
- effects observed should signal adverse changes in the ecological system we wish to protect
- achieved by conducting tests that evaluate safe exposure levels for ecologically-relevant surrogate end-points (survival, growth and reproduction of individual organisms)



Fate and behaviour of pesticides in the environment

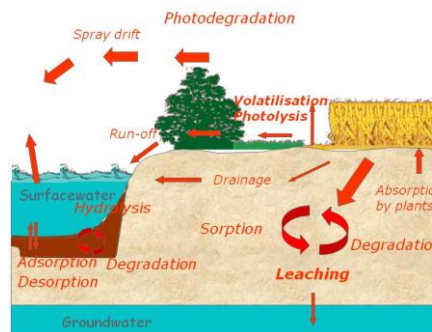


Environmental exposure calculations

Use pattern

- Application method
- Application rate
- Application timing

Fate studies



Computer models



Predicted environmental concentration

PEC soil
PEC surface water
PEC groundwater
PEC sediment
PEC air



Surface water exposure estimates

■ Tier I

- Scenario 10 Ha field draining into a 1 Ha pond
- No degradation or sorbtion
- Fixed spray drift inputs
 - 5% (arable), 20% (trees), 100% (aerial)

■ Tier II

- US-EPA GENEEC model
- Includes water solubility, soil sorption, soil degradation, hydrolysis, aqueous photolysis



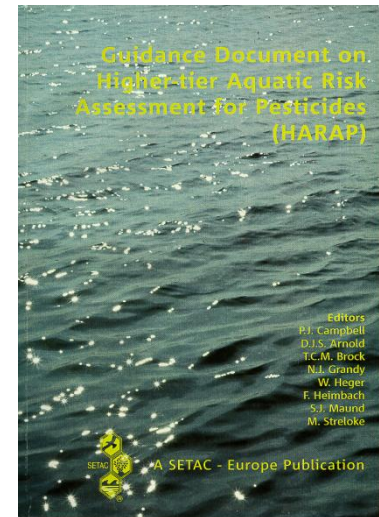
Surface water risk assessment

- Compare effects endpoints to predicted exposure concentrations
- Uncertainty factor of 10 for acute endpoints (LC/EC₅₀) for representative species (fish, Daphnia, algae)
- No uncertainty factor for chronic endpoints
 - Endpoint is no observed effect concentration
- Data on the active ingredient are adequate for assessments
 - Formulation testing should not generally be required



Risk refinement and mitigation

- Higher-tier studies or assessments to evaluate effects under more realistic/field conditions (lab assessments typically conservative)
 - Range of options depending on the potential risk identified (see e.g. SETAC HARAP)
- Mitigation measures targeted on potential risk identified
 - Lower rates/fewer applications
 - Buffer zones
 - Low spray drift nozzles
 - Vegetative filter strips



Example of Tier I risk assessment



Microsoft Excel
Macro-Enabled Worksheet

