Work of a SETAC Group to Develop the Scientific Basis for Guidance for Regulatory Ground Water Monitoring: Study Designs

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SETAC EMAG-PEST GW

Richard Allen

- This presentation was chosen by the conference organizers for inclusion in the special session honoring Richard Allen because this type of collaborative work is an example of the kind of projects he was involved with over his career. A number of the people on this SETAC group have worked with Richard in the past.

Richard Allen

- Richard brought the following to research projects
  - Clear definition of the objectives
  - Good insights on the best approaches to achieving these objectives
  - Establishment of an atmosphere of true collaboration among participants
  - A sense of humor

Outline

- Introduction to SETAC EMAG-Pest GW
- Types of Ground Water Studies
- Role of Protection Goals
- Study Designs
- Other Topics
- Future Actions

Introduction

- Over the past few years, ground water monitoring has become increasingly important in the EU registration process
  - There is no detailed EU guidance on monitoring studies, only some general information in the FOCUS Ground Water Report
- Several EU regulators worked with SETAC to set up a group to establish scientific recommendations for conducting such studies

SETAC EMAG-Pest GW

- Current Structure
  - Chaired by Anne Louise Gimsing with an informal steering committee of regulators
  - Full committee which meets once or twice a year
  - Subgroups which meet by phone more frequently, currently there are two subgroups
    - Document subgroup-prepare the document providing the scientific recommendations on study design
    - Vulnerability subgroup-prepare the section on assessing relative vulnerability of potential monitoring sites

SETAC EMAG-Pest GW

- Presentations at the York, U.K. Conference
  - Poster by Anne Louise Gimsing providing general information on SETAC EMAG-Pest GW
  - Poster by Ben Miles on vulnerability assessments
  - Oral presentation on study design (this presentation)

Types of Ground Water Studies

- What is a ground water monitoring study?
  - Often used to denote any field study in which ground water is sampled and analyzed
  - In the EU a distinction is made between a field leaching study (FOCUS Tier 3) and a ground water monitoring study (FOCUS Tier 4)
    - A field leaching study is usually intensive sampling of residues in soil and ground water following an application at one or a limited number of sites
    - A monitoring study is usually less intensive sampling at many sites

Types of Ground Water Studies

- Geographical Scale
  - In-Field and Edge of Field
    - Focuses on residues resulting from a single field
  - Catchment and Aquifer
    - Focuses on residues in ground water over a larger area

Types of Ground Water Studies

- Timing with regards to applications
  - Prospective ground water study
    - Make an application and follow the movement
    - Often includes soil sampling as well as ground water sampling (usually extensive activity at each site)
  - Retrospective ground water study
    - Monitor residues from previous applications
    - Usually does not involve soil sampling
  - Some studies are both retrospective and prospective
    - Monitor residues from previous applications and then make a new application and follow residues

Factors Affecting Study Design

- Ground Water Protection Goals
- Study Objectives
- Parent and Metabolite Properties
- Site Characteristics

Objectives and Study Design

- Study designs should be tailored to the specific study objectives and properties of the active substance and its metabolites
  - Study objectives are often dependent on the protection goal
  - Designs for studies with similar objectives and protection goals are usually similar
- Sampling schedules and site selection should consider the properties of the active substance and its metabolites as well as site characteristics

Ground Water Protection Goals

- Key aspects in the design of ground water monitoring studies include what is considered to be ground water and what ground water needs to be protected.
  - For example, is tile drainage considered ground water?
  - At what depth are above-guideline concentrations a problem? Any depth, > 1 m, > 10 m
  - Temporal considerations – single time point versus average concentrations
  - Most Member States have not formally adopted protection goals for ground water

Ground Water Protection Goals

- The SETAC EMAG-Pest GW has addressed the uncertainty in protection goals by showing how study design might be varied for a range of protection goals.
  - The group is not recommending a specific protection goal

Study Objectives and Study Design

- Objectives of ground water studies can vary
  - Usually includes determining the potential to move to ground or drinking water and the magnitude of residues present
  - May also include:
    - Measuring degradation rates in soil and ground water
    - Efficacy of mitigation measures
    - Confirmation of more detailed studies on a wider range of sites

Effect of Compound Properties on Study Design

- Soil degradation rates and mobility
  - Affect frequency and duration of soil sampling (if part of the study) as well as ground water sampling
- Degradation rates in ground water
  - Studies can be quite short when degradation rates are quite rapid (determining degradation rates may require monthly or more frequent sampling)
  - Studies following the residue plume with slower degrading compounds can take a number of years

Effect of Site Characteristics on Study Design

- Soil type, pH, organic matter
  - Affects the degradation rate and sorption to soil for the active substance and its metabolites, thus affecting the time and amount moving to ground water
- Depth to ground water, temperature, rainfall, crops, and agricultural practices
  - Also affects the time and amount of the active substance and its metabolites moving to ground water

Development of Study Designs

- The need to tailor study designs to objectives, protection goals, compound properties, and site characteristics complicates the development of standardized study designs.
  - Typical designs have been included with a range of number of wells and sampling frequency
  - Guidance has been provided on assessing vulnerability to guide in site selection

Variability of Study Designs

- The variability of study designs is illustrated by the advice provided for in-field study designs.
  - Number of sites: a few to greater than 100
  - Number of wells per site: usually 1-10
  - Sampling frequency: usually quarterly or monthly, may be a single sample
  - Study duration: usually multiple years, but can be significantly less in some situations

Key Points to Be Addressed in Study Design

- Vulnerability of sites
- Product use before and during the study
  - Adequate time for active substance and metabolites to move to ground water
- Connectivity of ground water to treated fields
  - Demonstrating connectivity is more challenging for catchment or aquifer modeling compared to shallow wells installed as part of in-field or edge of field study designs

Other Critical Aspects

- Avoiding contamination during sampling or analysis
  - Very challenging!
- Avoiding influencing residue movement as a result of purging during sampling
- Proper study documentation (GLP and/or quality criteria)

Procedures Covered

- Site Selection
  - New wells
  - Existing wells
- Installation of monitoring wells
- Sample collection
- Analysis of samples

Other Topics

- Use of publically available monitoring data
- Further site hydrogeological characterization
  - Ground water apparent age dating
  - Tracers
  - Geophysics
- Outliers
  - Ground water concentrations not the result of normal leaching through soil
- Study reporting

Status and Future Steps

- The draft of the document providing recommendations on ground water monitoring is largely complete and is currently being reviewed by group members.
- A meeting will be held in November to address remaining points of discussion with the intention of finalizing the document soon afterwards.