Ecotox Expert Working Group

Chairperson: Joe A. Robinson (AHI)

Paris, June 2010

Introduction

The Expert Working Group (EWG) on ecotox was established by the VICH Steering Committee (SC) as one of the first five topics selected for harmonization in 1996. The mandate for this working group was defined by the SC as follows: "to elaborate tripartite guidelines on the design of studies and the evaluation of the environmental impact assessment of veterinary medicinal products (VMPs). It is suggested to follow a tiered approach based on the principle of risk analysis. Categories of products to be covered by the different tiers of the guideline should be specified. Existing or draft guidelines in the EU, the US and Japan should be taken into account."

EWG composition*

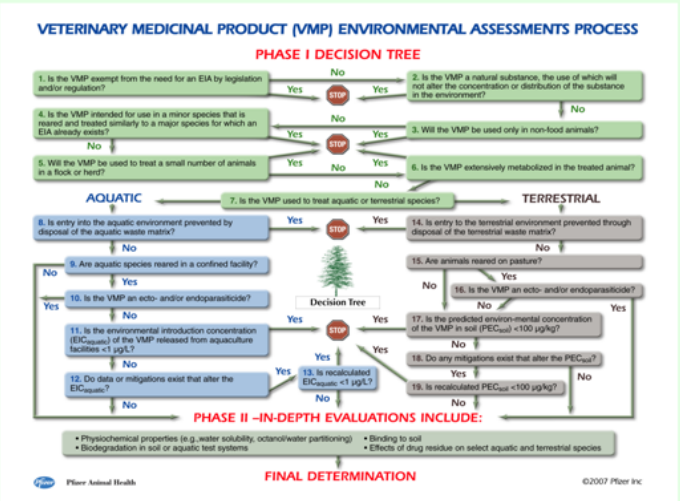
Takeshi Fujii (JVPA, i), Yuuko Endoh (JMAFF, g), Neil Tolson (HC, g), Jean Szkotnicki (CAHI, i), Joop de Knecht (EMEA, g), Joe Robinson (AHI, i), Christian Corsing (IFAH-Europe, i), Charles Eirkson (CVM,g), Jack Holland (APVMA,g), Jan Koschorreck (EMEA, g).

Industry (i), Government (g)

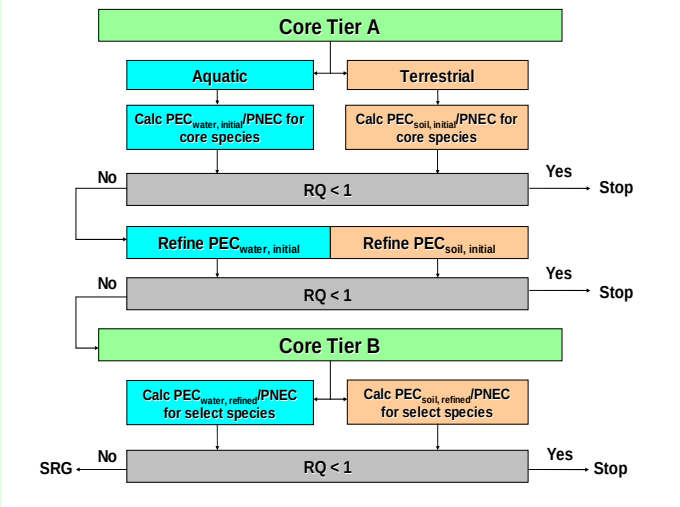
* Final EWG composition; others participated over the years

Guidelines adopted

Phase I: http://www.vichsec.org/pdf/2000/GI06_st7.pdf



Phase II: http://www.vichsec.org/pdf/10_2004/GL38_st7.pdf



Key scientific issues resolved

Resolution of the following key scientific issues and development of the Phase I and II guidelines required nine meetings held across a seven-year time span (1997-2004).

- VMPs for which a full impact assessment is not required (Phase I only);
- VMPs for which a full impact assessment is required (Phase II);
- Development of a tiered testing approach (Phase II Tier A and B);
- Testing requirements for Phase II Tier A and B (examples below):
  - Physical/Chemical properties (water solubility, Kow, Koc)
  - Environmental fate (soil biodegradation)
  - Aquatic effects (algae, daphnid, fish)
  - Terrestrial effects (microbes, plants, earthworms)
  - Dung fauna (beetles and flies) for ecto- and/or endo-parasiticides;
- Guidelines to be used for testing (OECD, ISO);
- Ecotox endpoints (EC50, LC50, NOEC);
- Safety factors to be applied to the ecotox endpoints (10, 100, 1000);
- Use of the predicted no-effect concentration (PNEC) for comparison against a worst-case prediction and refinements of environmental exposure (predicted environmental concentration or PEC);
- Use of the risk quotient approach (PEC/PNEC) for determining Tier B testing.

Intended key benefits of the harmonised guidelines

- Consistent approach among regions that have adopted and implemented the guidelines for evaluating the potential environmental risks of VMPs for use by regulatory authorities and industry.
- Increased predictability of regulatory requirements for industry in contrast to the situation that existed in 1997.
- Reduction in the need for duplicative testing among the regions that have used the guidelines as adopted by the VICH SC.

Guidelines under development

No new ecotox testing guidelines have been identified under VICH that require development.