

SETAC Pharmaceuticals Advisory Group Scope and Purpose

Introduction

The presence and potential hazards of pharmaceuticals in the environment have received increasing international attention in the academic and popular press, as well as within the regulatory community. The increased focus on potential ecological effects from pharmaceuticals largely initiated as a result of a growing number of technical papers published from the late 1990s until the present that reported low levels of pharmaceuticals in WWTP effluent and surface water, and to a more limited extent, groundwater, drinking water, and sediment.

Environmental concerns about pharmaceuticals have consistently been linked to two factors:

- (1) The bioactive property of pharmaceuticals, which is the basis of their therapeutic (pharmacological) activity
- (2) The potential for pharmaceuticals to be routinely present, albeit at low concentrations, from ongoing use

Concerns have been raised about whether the current environmental risk assessment scientific methodology may need to be revised or replaced to appropriately evaluate the potential environmental impact of pharmaceuticals.

The Society of Environmental Toxicology and Chemistry (SETAC) Pharmaceuticals Advisory Group (AG) was established to advance the science and understanding of pharmaceuticals in the environment. It is a formally recognized forum within SETAC and was established by the SETAC World Council (SWC) in October 2005. Membership to the Pharmaceuticals AG is open to all SETAC members, as well as to all professionals interested in the topics addressed by the Pharmaceuticals AG.

Scope

The scope of the SETAC Pharmaceuticals AG is human and veterinary pharmaceuticals. Personal Care Products (PCP) and other emerging contaminants are not included since it is specifically pharmacological bioactivity that has called into question the adequacy of the existing environmental risk assessment science for pharmaceuticals. Scientific coverage of the Pharmaceuticals AG includes all fields pertinent to conducting effective environmental risk assessments for pharmaceuticals, such as transport, fate, exposure, effect, and impact analysis. All environmental compartments, such as aquatic, terrestrial, and biomass are included.

The following are accepted characteristics of a pharmaceutical:

The US Food and Drug Administration definition of a drug includes the following concepts:

- A substance intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease
- A substance (other than food) intended to affect the structure or any function of the body

The EU definition of a medicinal product includes the following concepts of pharmaceutical substances or combinations of substances:

- Having properties for treating or preventing disease
- Administered with a view to restoring, correcting or modifying physiological functions by exerting a pharmacological, immunological or metabolic action, or to making a medical diagnosis.

Mission and Purpose

The Pharmaceutical AG exists to serve as a scientific resource to all stakeholders impacted by the topic of pharmaceuticals in the environment, and fulfills the following mission and purpose:

- Serve as a focal point within SETAC as a means of involving the membership in research and discussions
- Stimulate critical assessment in order to establish the best available science
- Encourage the worldwide incorporation of the best available science and strategic approaches
- Advance the overall understanding of the fate, effects, and potential environmental consequences of pharmaceuticals
- Provide scientific support to ensure effective regulatory decision making
- Provide a neutral platform and focal point for collaborative identification, evaluation, and resolution of scientific issues

Roles and Responsibilities of the Pharmaceuticals AG

To achieve its mission and purpose, the roles and responsibilities of the Pharmaceuticals AG include developing and implementing a long-range strategic plan for stimulating and participating in the advancement of Pharmaceuticals AG-related environmental science. Roles and responsibilities focus on identification of research needs and fostering scientific exchange. In specific, the steps the Pharmaceuticals AG may take to meet its mission and purpose include, but are not necessarily limited to:

- Preparation of technical papers (general information, issue specific)
- Developing a specific area of the SETAC web site for the Pharmaceuticals AG
- Developing a discussion forum on the SETAC web site
- Sponsoring general pharmaceuticals technical sessions at meetings
- Holding targeted (subject specific) discussion groups at meetings
- Implementing short courses, for example in advance of either SETAC or other conferences (i.e., DIA/ILSI-HESI)
- Presentations to government agencies
- Communication of updates in the SETAC Globe
- Developing guidelines for conducting studies with pharmaceuticals
- Providing educational materials for the public and school systems