

# Gradient Corporation



## NEWS ALERT

### US Environmental Protection Agency Proposed Rule Regarding Registration of Antimicrobial Products

On October 10, 2008, the US Environmental Protection Agency (US EPA) released a proposed rule that would change data requirements for the registration of antimicrobial products (Regulations.gov, 2008). US EPA is now requesting comments from interested stakeholders on the proposed rule, as well as on several related supporting documents.

#### What products might this affect?

The definition of antimicrobial pesticides in the proposed rule is broader than the existing statutory definition, and includes chemicals already defined as antimicrobial pesticides in FIFRA under section 2(mm) (e.g., sterilizing agents and disinfectants), as well as antimicrobials used in/on food or feed, antifoulant paints and coatings, and wood preservatives.

#### What testing requirements are being considered?

US EPA has proposed additional toxicology, exposure, and fate and transport analyses necessary for antimicrobial registration that depend on use patterns--different data requirements are mandated for "low" vs. "high" use products. New testing regimens will apply to all future registrations and may affect registrations in progress. Also, due to the expanded definition, additional product manufacturers may need to adhere to the revised antimicrobial testing strategy. Some of the specific key changes for the registration are:

- Conditional inclusion of neurotoxicity and immunotoxicity studies;
- Photodegradation studies for wood preservatives;
- Soil residue dissipation studies;
- Non-dietary ingestion exposure evaluations;
- Activated sludge sorption isotherm studies;
- Biodegradability evaluations;
- Porous pot studies; and
- Modified activated sludge respiration inhibition test.

#### From a scientific perspective, what are some possible areas for comment?

Technical issues in the proposed rule that could be considered in comments to the Agency include:

- The scientific justification for the triggers that warrant additional toxicology testing;
- The appropriateness of high vs. low exposure classifications; and
- The appropriateness of the newly proposed fate and transport studies for specified uses.

Please contact us if you would like more information.

Please contact Dr. Barbara Beck or Manu Sharma if you are interested in discussing possible responses to the proposed rule:

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Gradient is a nationally renowned consulting company offering expertise in toxicology, risk assessment, environmental chemistry, and fate and transport. We can apply our extensive knowledge in these disciplines to evaluate the proposed rule and help ensure that proposed test methods and testing strategies are scientifically well-founded. Upon finalization of the rule, Gradient can also be of assistance in evaluating study results and determining the significance of such results in the revised risk assessment framework.



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