UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

Office of Chemical Safety
& Pollution Prevention

September 26, 2011

Janelle Kay
Ensystex III, Inc.
C/o Pyxis Regulatory Consulting, Inc.
4110 136th St. NW
Gig Harbor, WA 98332

Subject: Response to Imidacloprid Registration Review Data Call-in ; Registrations: 82957-1 & 82957-4

Dear Ms. Kay:

The Agency has received the 90-day response to the imidacloprid data call-in (RR-129099-30160) you submitted on behalf of Ensystex. In the response, you request the Agency waive the data requirements for field testing for pollinators (GLN. 850.3040), residue analysis of nectar and pollen (Special Study), and seed leaching study (Special Study). The rationale you provided was that the data being requested are "not applicable to Ensystex's registered use patterns."

While Ensystex's technical use products 82957-1 and 82957-4 do not explicitly list the use pattern inferred as relevant to the subject data requirement, (i.e., agricultural crops such as blueberries, corn, cotton, etc.), its labels, like other technical labels permit further formulation into products labeled for use(s) currently registered with the U.S. EPA. The Agency also believes the labeled "ornamental plants" and "trees (including nonbearing fruit and nut trees)" uses are applicable to both the field testing for pollinators and residue analysis of nectar and pollen data requirements.

Ensystex may amend its registration and then seek a waiver to the subject data requirements, or others if applicable. However, under the current label, the Agency must deny Ensystex's request to waive the data requirements for field testing for pollinators, magnitude of residue in pollen and nectar, and seed leaching study required under the imidacloprid registration review data call-in (RR-129099-30160).

If you have any questions, please contact Rusty Wasem of my staff at wasem.russell@epa.gov or (703) 305-6979.

Sincerely,

Neil Anderson, Chief
Risk Management & Implementation Branch I
Pesticide Re-evaluation Division