

## **Proposed Revision of FIFRA Regulations for Data Requirements and Data Submitters' Rights**

### Background

On November 5, 2010, EPA published proposed revisions to certain provisions of the 40 C.F.R. part 152, subpart E regulations governing satisfaction of data requirements and protection of data submitters' rights under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA). These regulations have not been updated since 1984, and according to EPA the revisions are needed to align them with changes to FIFRA and Agency implementation procedures. Although this general "housekeeping" may be needed, the Agency also proposes to make an unwarranted revision to section 152.84 of subpart E that would result in generic applicants having to submit an offer to pay when they file a registration application instead of anytime before the agency approves the application. CPDA has historically opposed any requirement to submit an offer to pay at the time an application is submitted because it allows data owners to undertake actions such as filing a petition to deny the registration or initiating arbitration. These activities unnecessarily complicate the registration process, and subject generic registrants to unjustified increased costs to register a product.

### Update

On February 3, 2011, CPDA submitted comments that expressed our lack of support for the proposed revision to section 152.84 and urged EPA not to end this long-standing policy. CPDA noted that the Agency has not cited any problems caused by this policy during the 26 years it has been in effect. Moreover, the two reasons EPA cites for making the change (need for data gap letters has diminished and a PRIA II mandate) do not justify terminating a policy that has not hindered the registration process, and which has provided generic applicants a means of minimizing opportunities for data submitters to file harassing petitions to deny registration or to initiate binding arbitration early in the registration process. CPDA disputed EPA's reliance on PRIA II by pointing out that the statute only authorizes EPA to determine by rule the contents of a complete application but does not compel the Agency to require an offer to pay to be part of the 21-day completeness determination. CPDA also suggested a possible equitable procedure to implement a change in section 152.84 that would provide a balance of the needs of data submitters and generic registrants. Generic registrants would notify data submitters of their intent to submit an application prior to submitting it, and they would submit the offers to pay (i.e., the certification form) upon EPA's notice that cited data are acceptable. This approach would allow data owners an opportunity to file petitions to deny and generic applicants a means of avoiding pointless and costly binding arbitration early in the registration process.