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### EPA Officially Announces Formation of New Inerts Branch

EPA's Lois Rossi, Registration Division Director, has officially announced formation of the Inert Ingredient Assessment Branch (IIAB), a new branch dedicated to the regulation of pesticide inert ingredients, previously regulated by the Minor Use, Inerts and Emergency Response Branch. (See Attached Copy of EPA Internal Memorandum.) EPA's announcement illustrates its continued efforts to improve the regulation of inert ingredients, and, in particular, erase the backlog of tolerance exemption petitions submitted for new inert ingredients. To lead IIAB, Ms. Rossi tapped Pauline Wagner as Branch Chief, who has served as the acting head of Inerts Team for most of this year. In addition to working with Ms. Wagner this year, Keller and Heckman worked extensively with Ms. Wagner during her tenure at OPPTS's New Chemicals Pre-Notice Branch, which implements the Toxic Substances Control Act (TSCA).

### EPA Review of "Back-Logged" Petitions for Tolerance Exemptions

EPA's approval of new food-use inerts has slowed over the last five years, in part, because of its obligation to re-assess existing tolerances and exemptions for inert ingredients by August 2006 under the Food Quality Protection Act (FQPA). In March 2004, 56 petitions for tolerances or exemptions were pending at EPA. In FY2004, EPA completed 16 of the 56 petitions. To date, during FY2005 (which started October 1, 2004), EPA has completed 11 of the 40 "backlogged" petitions, with 3 petitions withdrawn by petitioners. EPA projects it will complete 10 of the remaining 26 outstanding petitions in FY2005.

### EPA Review of Petitions Filed Since March 2004

Since March 2004, industry has submitted 13 new petitions for tolerances or tolerance exemptions. EPA has completed one of the petitions and is scheduled to complete two for FY2005. EPA indicates that the remaining 10 will be "pending" for FY2006.

### Expected Outcome: Improved Performance

In addition to creating the IIAB, EPA has increased its funding and personnel, with the intention of improving the efficiency of reviews and reducing the existing backlog. EPA will increase efficiency through greater use of EPA's *Methodology for Lower Toxicity Pesticide Chemicals*, June 2002, which encourages the submission of petitions and requests for inert approvals based on existing data and risk assessment objectives, as opposed to rigid data requirements. Due in part to use of this Methodology, EPA now appears to be more receptive to alternative means for supporting a request for approval or a petition, including arguments for bundling or consolidating multiple approvals based on the same or similar information. When developing these arguments, however, the applicant/petitioner should be mindful of protecting its data compensation rights under EPA's draft proposal on *Implementing Data Compensation Rights for Data Submitted in Support of Tolerances or Exemptions*, which has not yet been finalized. Despite these process improvements, inert actions are not tied to a deadline under the Pesticide Registration Improvement Act (PRIA), and thus time-to-approval is based on ease of review, time in the queue, and persuasion by the applicant/petitioner.

If you would like more information about the IIAB or any of these issues, or are interested in assistance on filing a petition with EPA, please contact us.

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