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Infectious Diseases Society of America

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Public Information and Records Integrity Branch  
Office of Pesticide Programs  
Environmental Protection Agency  
1200 Pennsylvania Ave, NW  
Washington, DC 20460-0001

### Re: Comments on Docket ID Number EPA-HQ-OPP-2006-0234 (Receipt of Application for Emergency Exemption: Gentamicin)

To Whom It May Concern:

The Infectious Diseases Society of America (IDSA) appreciates the opportunity to comment on the Michigan Department of Agriculture's specific exemption request to use the pesticide gentamicin to control streptomycin-resistant fire blight in its apple orchards. We are strongly opposed to such an exemption because of the potential adverse consequences for human health, and we unequivocally urge the Environmental Protection Agency (EPA) to deny this request.

IDSA represents 8,000 physicians and scientists devoted to patient care, education, research, and community health planning in infectious diseases (ID). The discipline of infectious diseases is a subspecialty of both internal medicine and pediatrics, typically involving a two-to-three year fellowship and then board certification. Infectious diseases physicians care for patients with serious infections, including persons with HIV/AIDS, meningitis, heart valve infections, severe bone, joint or wound infections, and those with cancer or transplants who have life-threatening infections caused by unusual organisms. Many of our members also are researchers who study drug resistance and are involved in the development of new and improved antimicrobial agents. As such, our goal is to ensure that patients have access to effective therapies to treat infections.

Gentamicin is a critical antibiotic for the treatment of life-threatening infectious diseases, including neonatal and adult sepsis. It is an aminoglycoside antibiotic, and the Food and Drug Administration (FDA) classifies these drugs as 'highly important' for treating serious human disease. The EPA currently prohibits the importation of fruits and vegetables from countries that use gentamicin as a pesticide on food crops.

There is ample reason to be concerned about adverse human health effects from gentamicin use in plant agriculture. We have very little understanding of the short-term and long-term effects of gentamicin application to the environment. We do not understand the magnitude, extent, and duration of human exposure to gentamicin that may result from environmental application to fruit trees. We also do not understand

the environmental effects of gentamicin in soil and water. Most importantly, we do not understand the risk that bacteria with aminoglycoside resistance genes will be transferred to humans through the food supply following application of gentamicin to fruit trees. These questions need to be addressed, and a risk assessment model should be developed to understand the potential for adverse health consequences in humans. The FDA has used this approach in guidance to industry for microbial safety of antimicrobial use in food animals, and an equally rigorous approach is needed for use in plant agriculture.

Granting the Michigan Department of Agriculture's exemption request would set an unfortunate and dangerous precedent during an era when we cannot afford to lose yet another therapeutic option for treating serious infections. IDSA is extremely concerned about the possibility that the direct or indirect effects of gentamicin use in plant agriculture may seriously compromise gentamicin's effectiveness in the treatment of human bacterial infections. We support further research in this area, but we strongly oppose even one-time use of gentamicin in plant agriculture until the microbial safety has been thoroughly evaluated.

Should EPA agency representatives have questions about IDSA's comments, please contact Robert J. Guidos, J.D., Director of Public Policy and Government Relations, at 703-299-0200.

Sincerely,

A handwritten signature in black ink, appearing to read "Martin J. Blaser". The signature is fluid and cursive, with a long horizontal stroke at the end.

Martin J. Blaser, MD  
President