



December 6, 2011

James E. Swauger, Ph.D., DABT  
Vice President, Regulatory Oversight  
R.J. Reynolds Tobacco Company  
401 N. Main Street  
Winston-Salem, North Carolina 27101

Dear Mr. Swauger:

This is in response to your inquiry on behalf of Philip Morris USA Inc., U.S. Smokeless Tobacco Company LLC, Lorillard Tobacco Company, and Alliance One International, Inc., regarding the special rule on tobacco containing pesticide chemical residue under section 907(a)(1)(B) of the Federal Food, Drug, and Cosmetic Act (FD&C Act).

Section 907(a)(1)(B) of the FD&C Act establishes that:

Beginning 2 years after the date of enactment of the Family Smoking Prevention and Tobacco Control Act, a tobacco product manufacturer shall not use tobacco, including foreign grown tobacco, that contains a pesticide chemical residue that is at a level greater than is specified by any tolerance applicable under Federal law to domestically grown tobacco.

This special rule provides that, effective June 22, 2011, manufacturers cannot use any tobacco, whether domestically or foreign grown, that contains a pesticide chemical residue that exceeds any tolerance level established under Federal law that applies to domestically grown tobacco. The Family Smoking Prevention and Tobacco Control Act does not establish any tolerance limits for pesticide chemical residues that apply to domestically grown tobacco. To determine whether there are pesticide residue tolerance levels applicable to domestic tobacco, the Food and Drug Administration (FDA) consulted with the U.S. Department of Agriculture (USDA) and U.S. Environmental Protection Agency (EPA). According to USDA and EPA, under their laws there are currently no established tolerance limits for pesticide chemical residues that apply to domestically grown tobacco. If such a tolerance is established, we plan to provide this information to tobacco product manufacturers.

We note that under the Federal Insecticide, Fungicide, and Rodenticide Act, pesticides generally may not be sold or distributed in the United States unless first registered by EPA. This includes pesticides sold or distributed for use on domestically grown tobacco. As part of the registration process, EPA evaluates the pesticide to, among other things, ensure that it will not pose unreasonable risks to human health or the environment.

If you have any additional questions about this provision of the law, please email them to:  
[AskCTP@fda.hhs.gov](mailto:AskCTP@fda.hhs.gov).

Sincerely,

Lawrence R. Deyton, M.S.P.H., M.D.  
Director, Center for Tobacco Products