

PRODUCT INTEGRITY – A COMPREHENSIVE PROGRAM USED TO PREVENT CROSS-CONTAMINATION INCIDENTS AT DOW AGROSCIENCES. David G. Ouse, Research Biologist and Jim Gifford Senior Technician, Crop Protection Research and Development, Dow AgroSciences, 9330 Zionsville Road, Indianapolis, IN 46268.

It is common in the agriculture industry to share equipment in the manufacture of agrichemicals as the volumes of many products do not justify the expense of having dedicated equipment. Therefore, a Product Integrity program has been developed at Dow AgroSciences to manage the change-over from one product to another in our manufacturing process. The central focus of our Product Integrity Policy states that our products will not contain extraneous ingredients at levels that could cause regulatory or performance issues.

In order to effectively manage the production of our products a series of Product Integrity Requirements have been developed to define processes that effectively manage this risk. Dow AgroSciences' Product Integrity Requirements do not allow the sharing of process equipment between insecticides or fungicides with herbicides. Additionally, herbicide and insecticide or fungicide production is required to be separated by a solid wall in order to avoid any mix ups or misidentification of ingredients. The clean out of equipment from one product to another is required to ensure that the preceding active ingredient will not cause issues in the following product. In order to determine what level to clean the equipment an acceptable cleaning level (ACL) is calculated. The ACL is calculated by using the no-observable effect level (NOEL) of the preceding active ingredient on the most sensitive crop the following product is labeled for use on. This NOEL is divided by a safety factor and also divided by the maximum use rate of the next product. Thus, an ACL is a biological value that if exceeded could cause crop injury. Additionally, EPA has established maximum levels at which extraneous ingredients can be present in another product in USEPA Pesticide Regulation Notice 96-8. At Dow AgroSciences' we use the lowest value either the calculated biological ACL or the EPA default level.

Dow AgroSciences also periodically assesses our internal and external contract facilities for alignment with our Product Integrity Requirements in order to ensure compliance with our Product Integrity Program. Collectively, our processes and assessment program enables us to effectively manage risk and prevent cross-contamination from preceding products in equipment that is shared.