

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460



OFFICE OF CHEMICAL SAFETY AND  
POLLUTION PREVENTION

MEMORANDUM

Date: 13 August 2012

SUBJECT: Conclusions and Recommendations Regarding the Requirement for Inclusion of Adjuvants in Crop Field Trials

FROM: Chemistry Science Advisory Council (ChemSAC)  
Health Effects Division (7509P)

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In recent years, it has been OPP's policy to require the inclusion of adjuvants in the design of crop field trials for end-use product labels that don't specifically prohibit their use when the product is being applied. Additionally, the Agency has required field trial data reflecting the use of adjuvants to support label amendment requests to remove adjuvant restrictions.

While the regulated community has generally adopted this policy for new field trials, there has been concern on their part about the Agency requiring new field trials, conducted with adjuvants, under registration review to replace older trials where adjuvants were not used. Crop Life America (CLA) and the Chemical Producers and Distributors Association (CPDA) have sponsored separate examinations of historical data to determine to what extent adjuvants affect residue levels and the regulatory implications.

Crop Life America Report

CLA has submitted a report for Agency consideration which builds on work OPP previously completed comparing residue data from field trials with and without adjuvants. Using the data provided by the Agency, CLA conducted a simulation (more specifically, a bootstrapping

exercise) in which they evaluated the variability that was intrinsic to the tolerance -setting process with the intent of demonstrating that this variability exceeded that associated with the adjuvants. The analysis shows that, overall, adjuvants increase pesticide residues and that, on average, the increase is by a factor of 1.6. In a separate analysis, the data were subsampled, and each subset was used as input for the OECD calculation spreadsheet. This was repeated multiple times for each dataset. The resulting MRL recommendations for each subset were evaluated for variability, with the assumption that the observed variability reflects that which would occur in MRL recommendations coming from multiple sets of independent field trials.

The CLA report concludes that the inherent variability in field trials, coupled with the characteristics and conservative nature of the OECD calculation method exceeds the variability seen with the use of adjuvants.

#### Chemical Producers and Distributors Association Report

CDPA also used the database provided to them by OPP to perform a statistical analysis using a split plot model to assess the impacts of adjuvants on residue levels. HED has reviewed the report and reproduced the findings. Overall, OPP concurs with the findings of the report that the inclusion of adjuvants in field trials has no significant effect on residue levels.

#### Recommendation from the ChemSAC

ChemSAC has reviewed both the CLA and CDPA submissions. Both analyses support the same general finding using different statistical approaches. Therefore, the ChemSAC does not see a need, from a risk-assessment perspective, to require that adjuvants be used in crop field trials. There is sufficient conservatism built into the use of field trial data in the risk assessment paradigm to ensure use of these data will not underestimate exposure, even if adjuvants were not used in the field trials. Moreover, the monitoring data used in more refined dietary risk assessments reflect real-world agronomic practices, including the use and effects of adjuvants.

Additionally, the ChemSAC agrees that if the OECD calculation method is used to set a tolerance based on field trials conducted without adjuvants, the addition of an adjuvant would not likely result in residue levels exceeding the recommended tolerance. Therefore, the ChemSAC does not see a need, from a tolerance-setting perspective, to require that adjuvants be used in crop field trials. Further, the ChemSAC notes, that while conclusions from the CLA and CDPA reports are not strictly applicable to tolerances that were evaluated prior to adoption of the OECD calculation procedures, when taken in combination with the understanding that adjuvant use is generally wide spread in farming practices and given the relatively few reports of over-tolerance residues, the analysis does provide assurance that existing tolerances are sufficient to address the impact of adjuvants on tolerance levels. Therefore, based on the above rationale, the Agency would not expect the addition of adjuvants to previously registered products that have restrictions regarding the use of adjuvants to result in tolerance exceedances.

Lastly, while the ChemSAC agrees that adjuvants are just one of the many variables that may affect pesticide residue levels, side-by-side field trials have shown, and as acknowledged in the CLA and CDPA reports, adjuvants can significantly increase residues for certain end-use products. Therefore, while the ChemSAC agrees that there is no need for a specific requirement for adjuvants to be included in crop field trials, we would encourage registrants to include them if they believe adjuvants may significantly impact residue levels for a particular product.