

# **Joint Exhibit 28**



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY AND  
POLLUTION PREVENTION


**MEMORANDUM**


**Date:** July 7, 2014

**SUBJECT:** DCPA: HED Response to (12 Month) Comments on the Residue Chemistry Requirements of the Generic Data Call-In (GDCI-0798701-1140).

PC Code: 078701  
Decision Nos.: 492125  
Petition No.: NA  
Risk Assessment Type: NA  
TXR No.: NA  
MRID No.: NA

DP Barcodes: 420907  
Registration No.: NA  
Regulatory Action: Response to comments  
Case No.: NA  
CAS No.: 1861-32-1  
40 CFR: 180.185

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Amvac Chemical Corporation has submitted 12- month comments to a DCPA (Dacthal) Generic Data Call-In (GDCI) notice (GDCI-0798701-1140, dated 1/31/13) in a letter dated January 29, 2014 (MRID 49307500). Part of this submission included justifications for upgradable residue chemistry studies (Guideline 860.1380 and 860.1900). HED had previously responded to Amvac's 90-day comments on the residue chemistry aspects of GDCI (D.Drew, 10/23/2013, D413176, *DCPA (Dacthal): HED Response to Comments on the Residue Chemistry Requirements of the Generic Data Call In (GDCI-0798701-1140)*) and details pertaining to the outstanding 860 guideline data requirements can be found in that document. In this memorandum, HED is responding to the two residue chemistry justifications presented in the January 29, 2014 letter (Guideline 860.1380 and 860.1900).

### 860.1380 Storage Stability

In the 10/23/13 HED memorandum (D413176) the following GDCI storage stability requirement was reiterated: The final report for a 4-year storage stability study (MRID 43938901) on DCPA support the conclusion that residues of DCPA, MTP, TPA and HCB are stable in frozen samples of broccoli, onion bulbs, celery, snap beans, bell peppers, and sweet potatoes stored for 4 years. However, the registrant must submit storage intervals and conditions for field trial samples analyzed in MRIDs 00017975, 00018299, 00033087, 00038919, 00058377, 00058378, 00072099, 00090259, 00114643, 00114678, 00114679, 00114680, 00114681, 00121864, and 00130562. If it can be confirmed that samples from these earlier field trials had been stored frozen for durations not significantly longer than 4 years, all field trial data will be considered to be fully validated by the 4-year storage stability study.

Amvac has responded that they were unable to locate many of those older (1960s-1970s) field trial studies. HED has located copies of these field trial reports (MRIDs listed in the paragraph above) and has verified that, in all but one of the relevant studies, samples could not have been stored frozen for longer than 4 years. While many of the reports did not specify the exact frozen storage durations, HED was able to discern the maximum time that samples could have possibly been stored by comparing the sampling (or harvest) dates to either the analysis dates or to the final report dates.

For MRID 00114678, HED was unable to discern the sampling dates, mainly because of very poor quality copy of the study; however, it is unlikely that any samples were stored longer than 4 years. The longest possible storage duration in any of the relevant studies where the actual durations were not specified was 18 months (based on date of harvest to date of analysis). In studies where the frozen storage durations were specified, samples were stored up to 212 days, with most samples having been stored for less than 2 months. HED did not consider MRIDs 00017975 and 00018299 to be relevant studies for this exercise as those results were explicitly stated as not used to determine tolerance levels of DCPA. Also MRIDs 00038919 and 0058378 were discounted since they are animal metabolism studies.

The GDCI storage stability requirement (860.1380) for DCPA is fulfilled. The field trial data are considered to be validated by the 4-year storage stability study (MRID 43938901).

### 860.1900 Field Accumulation in Rotational Crops

Amvac has submitted information on the storage durations of samples in the 860.1900 rotational crop studies (MRIDs 41255504 and 42298303) and compared them to the storage intervals of the multi-crop storage stability study (MRID 43938901). HED notes that the submitted information indicates that sample storage durations in the rotational crop studies are covered by demonstrated stability intervals. However, this information was never identified as a data gap and is not part of the GDCI.

The 860.1900 GDCI requirement specifically pertains to the need for additional field trials on rotated crops to determine the appropriate tolerance for residues of DCPA on those rotated crops (See D413176, 10/23/13 for details). Those data remain outstanding.