

MEMORANDUM

10/29/97

SUBJECT: Chlorpropham. Request by PIN-NIP for Waiver of Enforcement Analytical Method for 3-Chloroaniline Metabolite in Potatoes. DP Barcode: D239919; No CBRS No.; No MRID No.

FROM: David J. Miller, HSO, US Public Health Service
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THRU: Susan V. Hummel, Branch Senior Scientist
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TO: Susan Jennings, PM Team 53
Reregistration Branch
Special Review and Reregistration Division (7508W)

CEB2 has been asked to evaluate Pin Nip Inc.'s request to waive the requirement that conjugates of the 3-chloroaniline metabolite be determined in the enforcement analytical method for potato commodities. Specifically, PIN-NIP states that

On November 17, 1991, PIN NIP submitted its chlorpropham residue study protocol to EPA for comments. The protocol stated PIN NIP would measure levels of chlorpropham and 3-chloroaniline present in whole potatoes, potato skin, potato chips, and potato granules. The protocol did not commit to quantify conjugated 3-chloroaniline.

As a result, PIN-NIP is asking that the requirement to determine whether its analytical method will detect the presence of a 3-chloroaniline conjugate in potatoes be waived as a requirement for reregistration.

On June 12, 1997, HED's Greybeard Committee met to discuss this issue. Their conclusion, sent to the Risk Characterization and Analysis Branch on 6/27/97, is reproduced below:

Greybeard Committee: Chlorpropham
DP Barcode D235550; CBRS None. 06/12/97.

E. R. Butts International, Inc., representing Pin Nip Inc., is requesting (04/24/97) a waiver from the requirement to include a determination of conjugates of the

metabolite 3-chloroaniline in the enforcement analytical method for potato commodities (860.1340). The waiver is granted, because the Metabolism Committee determined that 3-chloroaniline (and its conjugates) are not to be included in the tolerance expression. This issue was addressed for the Chlorpropham Task Force (J. Abbotts, DP Barcode D195867, CBRS 12674, 01/31/95).

CEB2 reaffirms this Greybeard decision: as 3-chloroaniline is no longer considered to be of regulatory concern and is not a metabolite named in the tolerance expression, no enforcement analytical method need be submitted.

SRRD has also submitted to CEB2 a letter from the law firm of McDermott, Will, and Emory through which the CIPC Task Force (Elf Atochem NA, Inc. and Aceto Agricultural Chemical Corporation) is requesting that the PIN NIP request be denied. As part of this request, they state that “[T]he data submitted by the Task Force have demonstrated to the satisfaction of the Agency that the analytical method used by the Task Force will detect 3-CA and conjugated 3-CA in weathered samples.” It is unclear how McDermott, Will & Emory and the Task Force came to this understanding. The following information from a CBRS review of a CIPC Task Force submission *directly contradicts* the stated assertion that the CIPC Task Force method adequately recovers the 3-CA and/or conjugated 3-CA metabolite (J. Abbotts, 1/31/95, CBRS No. 12674, DP Barcode:D195867):

1e. For the record, CBRS reiterates its previous conclusion that recoveries by the analytical method of 3-chloroaniline residues from fortified samples were inadequate for nearly all potato commodities. Residue data do not provide confidence that the method could recover residues from treated samples or processed commodities, where metabolism would be more extensive and the formation of covalently-bound conjugates might occur. However, HED does not at this time designate 3-chloroaniline as a residue to be regulated, and the concern of the previous review is withdrawn.

1f. For the record, CBRS reiterates its conclusion that no method has been validated for its ability to detect residues, free or conjugated, of 3-chloroaniline. However, HED does not at this time designate 3-chloroaniline as a residue to be regulated, and the concern of the previous review is withdrawn.

In summary, **neither** PIN NIP nor the CIPC Task Force has submitted adequate data showing reliable and adequate recovery of weathered 3-CA residues (including its conjugates). Nevertheless, the HED Metabolism Committee has previously determined that 3-chloroaniline is NOT part of the tolerance expression and therefore an enforcement analytical method is NOT required.

cc: RF, SF, List A Rereg. F., DJM.
RDI: Team2:10/28/97; SHummel:10/29/97

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