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

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

Memorandum

To: Office of Pesticide Programs Staff
Office of Chemical Safety and Pollution Prevention

From: Jeff Herndon, Associate Division Director
Office of Pesticide Programs, Registration Division

9/11/12

Subject: Confidential Statements of Formula for Technical Grade Active Ingredients
REVISED

Some registrants of Technical Grade Active Ingredients (TGAI) have proposed a different approach to completing EPA Form 8570-4, the Confidential Statement of Formula (CSF), for TGAIs. Instead of providing multiple, alternate CSFs reflecting each manufacturing site (Box 2 of the CSF) and each country in which the product is produced (Box 6 of the CSF), the registrants have proposed to provide an attachment to the CSF that lists the following:

- additional sites at which the technical may be manufactured (Box 2 of the CSF); and
- additional countries in which the TGAI is produced (Box 6 of the CSF).

Through discussions with the regulated community, the Office of Pesticide Programs (OPP) has determined that this approach will still allow the agency to fully evaluate the proposed products to make a sound regulatory decision. Further, OPP believes this approach can help to alleviate the agency's handling and tracking of many pages of alternate CSFs and help to reduce registrant burden. Therefore, OPP will accept an attachment to a basic or an alternate[1] CSF listing alternate manufacturing sites and production countries. OPP understands these attachments will provide the same information and assurances that would be needed if submitted as a new, alternate CSF, as follows:

- The manufacturing process associated with the new site will result in the same impurity profile as the original manufacturing site listed on the original (basic or alternate) CSF.
- The following information specific to the alternate site or sites will be provided:
    - The name(s) and address(es) of the alternate site or sites,
    - The establishment numbers for the alternate site or sites, and
    - The MRID for the supporting representative batch analysis and the date of approval for the manufacturing site.

[1] Please note that a new registration, a new basic CSF or an alternate CSF may be necessary when an alternate manufacturing site results in a different impurity profile; a new impurity; or a higher level of an existing impurity outside of the certified limits.

    - For submissions of new manufacturing sites, reviewers may wish to write the MRID of the submission on the form once the MRID is assigned to assist with agency tracking. That information should then be added by the registrant at the time of the next submission of the CSF.
    - For previously approved manufacturing sites, reviewers may wish to write the DP Barcode of the review associated with the MRID numbers on the registrants' submission to assist with agency tracking.
- Box 2 of the CSF to which the attachment applies will indicate "see attachment" and clearly link the two documents.
- Box 6 of the basic or alternate CSF to which the attachment applies will indicate "see attachment" if the approved (or proposed) manufacturing sites are in more than one country.
- The attachment will indicate the date of the CSF to which the attachment applies (the dates will match, as the attachment form would not be appropriate in the absence of a cover CSF).
- The form and attachment will be identically signed and dated by the registrant.

Attached is an example of the format in which registrants may provide this information. The information in bold and red reflects the conditions above.

Please also note that it is not appropriate to require this information of registrants in this format; however, if the information is provided in this format and all conditions are met, the Agency has committed to accepting this submission format. It is important to keep in mind that, in cases where this option is used, the CSF form and attachment will represent the complete CSF. Therefore, any CSF changes would require submission and review of both the CSF and the attachment. In addition, if a registrant is using this approach to replace existing CSF(s), they should clearly identify the CSFs the new version is intended to replace.

Please let Jeff Herndon (RD), Debbie McCall (RD), Karen Hicks (AD), Maria Piansay (PRD), or Andrew Bryceland (BPPD) know if you have any questions.

Cc: Andrew Bryceland, BPPD
Karen Hicks, AD
Debbie McCall, RD
Maria Piansay, PRD

CONFIDENTIAL BUSINESS INFORMATION

ATTACHMENT [A]
TO [**DATE must match associated CSF and signature below**] CONFIDENTIAL STATEMENT OF FORMULA [EPA Form 8570-4]

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IDENTIFICATION INFORMATION FOR THE PRODUCERS
OF TECHNICAL GRADE ACTIVE INGREDIENT (TGAI)

Pete's Technical Pesticide Product
EPA REGISTRATION NUMBER: **00000-29**

Basic ☒ Alternate ☐

Name and Address of Additional Producer(s)	EPA Establishment Number	Date on CSF on which the manufacturing site first appears(ed)	Date of EPA letter approving the CSF (and, therefore, the manufacturing site)	MRID number(s) of supporting data (e.g., representative batch analysis)	Date of EPA review accepting the supporting data
Pete's Example Site 12345 Example Lane Anytown, Anystate Zip, USA	**00000-AS-1**	**June 1, 2005**	**November 1, 2005**	**223456789**	**November 1, 2005**
Pete's Sample Location 23456 Sample Court Anytown, Anystate Zip, USA	**00000-AS-3**	**December 1, 2007**	**January 30, 2008**	**123456789**	**January 30, 2008**
Pete's Sample Site 34567 Exotic Ave. Downtown, Brazil	**00000-Brazil- 5**	**Date of Amendment**	**Pending approval**	**Data submitted, MRID not yet assigned**	**Pending approval**

_____
(Typed Name & Title of Registrant Approving Official)

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(Signature of Registrant Approving Official)

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Date (must match associated CSF)