

DATE: **December 11, 2003**

TO: **AWT Membership**

FROM: **AWT Legislative/Regulatory Committee**

SUBJECT: **Clarification of alternatives to the discontinued USDA “White Book”**

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In an effort to keep you informed of regulatory changes which will or may affect a significant number of members, this overview is intended to clarify the discontinuance of the USDA FSIS program for listing of authorized products in the USDA “White Book”. An effort is also made to provide guidance regarding how this subject may best be handled for your company’s position in the affected marketplace.

## **Overview**

Prior to 1999, any water treatment chemical used in a manufacturing plant *which was subject to inspection by the U.S. Department of Agriculture’s (USDA) Food Safety and Inspection Service (FSIS)* had to be authorized or “approved” for use by USDA and was included in a “List of Proprietary Substances and Non-Food Compounds” (the so-called “White Book”) sent out by the USDA to the FSIS local inspectors for their use.

In that year the USDA ceased publication of the “White Book” and mandated that in the future, regulated facilities (meat, poultry, pasteurized egg) under the inspection of USDA inspectors, would be responsible for insuring that the chemicals used in their facility are used and handled in a manner that does not cause the adulteration of food. For the facility, this meant that they were responsible for controlling access to chemicals to prevent accidental misuse, insure that the chemicals are used in a manner consistent with the manufacturer’s instructions, insure that empty containers are disposed of in a manner consistent with good manufacturing practices, and that the components of the chemical compounds used are not carcinogenic or poisonous under normal conditions of use and in the case where the chemicals can come in contact with food – such as steam that the products used meet the regulations spelled out in 21 CFR §173.310. The USDA FSIS *did not* mandate that a *third party* provide certification that the chemicals being used are in compliance.

In order to satisfy that the chemicals are not carcinogenic or poisonous in normal use and that they meet the regulations spelled out in 21 CFR §173.310, the food manufacturer will normally ask their supplier(s) for a letter of assurance. This documentation, substantiating compound safety and efficacy, is appropriate for all chemical compounds that are used in the areas of food processing, handling and storage and that do not otherwise require declaration on food labeling under Title 7 (part 59) and Title 9 (parts 317 and 381). This letter of assurance should contain the following:

1. Name and address of the supplier.
2. Brand name, code or other designation that uniquely identifies the compound. Identification should ensure that the specific chemical ingredients of the compound are traceable in the event of food contamination. This normally can be satisfied by providing a list of the chemical ingredients (not percentages) in the letter.
3. The letter should state that the material will be safe and effective under the intended conditions of use and will not adulterate the food product.
4. The letter should specify the applicable limits of the product to be used, feed rates of the product and how often it is to be used.

5. Signature of an official of the supplying firm.

A supplier's letter of assurance may be limited to a specific shipment, in which case it would be attached to the invoice, or it may be a continuing letter of assurance that need not accompany each shipment. New formulations, or changes in labeling involving product identification or usage should be accompanied by new letters of assurance.

As a water treatment professional you will probably be the person asked to supply a "letter of assurance". If your company does not blend or manufacture a product, the burden for this document would be placed on your blender or manufacturer. If you are a chemical blender or manufacturer, you have three options:

1. For compounds previously contained in the "White Book", a letter of assurance can be given if you have not changed the formulation or added different chemicals to the formulation and verified that none of your chemicals in the composition of the formulation have since been added to the FDA list of prohibited chemicals in 21 CFR §189. The letter of assurance can document that all of the above is true and it can reference that the product had previously been authorized by the USDA for use in the application.
2. For new chemicals, each component must be reviewed for FDA compliance using the guidelines specified in 21 CFR §170 - 189. If the formulation does meet the requirements, you may issue your own letter of assurance. This letter of assurance should document that the product has been reviewed by your technical staff for meeting the requirements put out in 21 CFR §170 – 189 and that you are providing this letter of assurance to document that the product is safe for use.
3. Lastly, you can have an independent or third party evaluation. This can be provided for a fee by NSF (National Sanitation Foundation), and possibly U/L (Underwriters Laboratories). The third party will provide you with a letter of assurance and in the case of NSF will publish a new "White Pages book", listing your product by name.

Whatever method you choose you will be in compliance with the FSIS guidelines. However, the responsibility for acceptance of your letter of assurance lies in the hands of your customer, because they are ultimately responsible for insuring the product meets the food safety guidelines.

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***A more complete description of the relevant regulations is available on the AWT web site. It is likely that a variety of interpretations (particularly regarding the "letter of assurance") by local, state and federal inspectors, plant management, and other involved parties may mandate additional assurances. The recommendations here represent the best opinions of this committee but in no way should be construed as relieving each chemical manufacturer of their responsibility of familiarizing themselves with these regulations and insuring compliance with them.***

We, as a committee, hope this overview aids in clarifying the changes in the USDA regulations and the alternatives for documenting to your client that your product meets the USDA FSIS guidelines. If you have any questions, we will be establishing a new

message board on the AWT “Members Only” web page – please list your questions and a member of the committee will respond. If at present you cannot logon to this section and you still have questions, call the AWT offices and talk to a member of the staff and they will pass your questions on to the committee.