

US EPA ARCHIVE DOCUMENT



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

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

April 22, 2009

Dear Registrant:

SUBJECT: Amendment to Organic Arsenicals RED

Background

The Reregistration Eligibility Decision (RED) for MSMA, DSMA, CAMA and Cacodylic Acid (collectively referred to as the organic arsenical herbicides) was signed on July 31, 2006, and revised on August 10, 2006. A public comment period for the RED and supporting assessments was conducted from August 9, 2006 to October 19, 2006 and subsequently extended to January 19, 2007. Documents related to the RED and this amendment can be found at www.regulations.gov, using docket number EPA-HQ-OPP-2006-0201.

In the RED, the Agency found all uses of organic arsenical herbicides ineligible for reregistration largely based on the concern that applied organic arsenical herbicides can convert in the soil to a more toxic form of inorganic arsenic and contaminate drinking water sources. At that time, the Agency also assumed that residues of inorganic arsenic would be found in the meat and milk derived from animals consuming cotton by-products treated with the organic arsenical herbicides, thus contributing to the aggregate human dietary risk. In addition, the Agency identified risks from the parent organic compounds to workers and non-target species in the RED, however these risks were considered manageable through implementation of standard measures such as additional protective clothing, reduced rates and buffer zones.

Previous benefits assessments undertaken in connection with the organic arsenical herbicides RED identified alternatives for most uses, potential impacts for some turf uses, and an emerging pest, glyphosate-resistant Palmer amaranth (pigweed), that was impacting cotton to some degree.

Since the RED was issued, the Agency has engaged technical registrants, university researchers, grower organizations and USDA in discussions of ways to implement the RED in a manner protective of human health and water resources, while allowing for an orderly transition to alternative controls. During the discussions, new

information became available to the Agency indicating that residues of inorganic arsenic in meat and milk from application of organic arsenical herbicides to cotton by-products used for animal feed are unlikely, lessening the Agency's dietary (food) risk concern. Also related to cotton, additional information confirmed Palmer amaranth to be a serious threat to cotton production in the southeastern US.

No new information was presented that substantively changed the Agency's position on uses other than cotton.

On January 16, 2009 (and, in the case of one company, February 5, 2009), EPA and the technical registrants signed an agreement in principle for the phase out of most uses of the organic arsenical herbicides, adoption of mitigation measures to protect drinking water resources during the phase out period, and reregistration of the cotton use of MSMA contingent on mitigation and the expeditious development of additional confirmatory data. Details of the new information that has become available since issuance of the RED, the Agency's revised decision, and the confirmatory data and interim mitigation requirements are presented below.

New Information Related to Cotton

Residue Data

The Methanearsonic Acid Task Force (MAATF), comprised of Drexel Chemical Co., KMG-Bernuth, Inc, and Luxembourg-Pamol, Inc., provided EPA with preliminary results from a study by Dr. Michael Murphy and others at the University of Minnesota. The study was designed to determine if food products derived from cattle drinking water containing arsenic concentrations greater than 10 ppb contained residues of arsenic. Dairy herds were selected based on locations known to have elevated arsenic levels in ground water. Herds were separated into groups based on the concentration of arsenic (ppb) in well water. Bulk tank milk samples, cheese made from milk from these herds and tissues from cull cows were analyzed for the presence of arsenic using a 5ppb limit of quantitation. Milk, whey, cheese, liver, pancreas, and skeletal muscle samples were below the limit of detection for arsenic. Urine arsenic concentration correlated with water arsenic intake. This study did not identify human risk from dairy or meat products derived from dairy cattle drinking water containing up to 114 ppb arsenic. (Murphy, et al, 2008)

In the RED, EPA also noted a concern that organic arsenicals applied to cotton would convert in the soil to the inorganic form and could be taken up by other crops that are commonly rotated with cotton, such as peanuts. During the RED implementation discussions, registrants provided a literature study conducted by the University of Georgia. In the Georgia study MAA (methylarsonic acid) was not detected in peanut kernels from samples grown in treated plots at 30-, 60-, and 90-day plant-back intervals. (Armbrust and Bridges, 2002)

This additional information provides a reasonable basis to assume that the use of the organic arsenicals, namely MSMA, on cotton is not likely to result in residues of inorganic arsenic in the human food supply. While the Agency's concern over the transformation of organic arsenical herbicides to the inorganic form in the soil and contamination of drinking water remains, the Agency's concern for inorganic arsenic in the human diet resulting from applications of the organic arsenical herbicides has largely been addressed by this new information. Because neither study was designed according to EPA guidelines, however, some additional confirmatory data are required, as noted below.

Emerging Palmer Amaranth Problem

Since their introduction in 1997, glyphosate-based weed management systems have been adopted by most cotton growers in the southeastern United States. Until recently, glyphosate was effective at controlling Palmer amaranth and other cotton pests. Uncontrolled, a single mature Palmer amaranth plant can produce over 500,000 seeds and grow up to six feet tall with a base diameter of 6-8 inches, impacting both harvesting efficiency and crop yield. Glyphosate resistant Palmer amaranth (GRPA) was first noted in Georgia in 2005, and has since spread to many of the southern cotton-producing states.

In the 2006 RED and subsequent response to comments, EPA noted reports of GRPA, but lacked sufficient information at that time to quantify the impact of MSMA cancellation. The Agency also noted the potential of MSMA, possibly at reduced rates and combined with other available herbicides, to control GRPA. Current state recommendations call for one layby-directed application of MSMA combined with a variety of herbicides to control GRPA. Information provided by the United States Department of Agriculture, the National Cotton Council, researchers from North Carolina State University, the University of Georgia, and others indicates that GRPA has in fact spread rapidly throughout the southeastern US, and is likely to be a growing problem in the future. (Culpepper, et al, 2008; Holshouser and Wilson, 2008; Norsworthy, et al, 2008)

Phase Out and Risk Mitigation Measures

MSMA use on cotton is eligible for reregistration provided that confirmatory data are developed as outlined in the following section, and applications to amend registrations to include the following mitigation were to be submitted to EPA by March 17, 2009:

- Applications are limited to 1 postemergent application on cotton at 2 lbs ai/A, with a second application at 2 lbs ai/A only if needed as a salvage operation (i.e., if pigweed escapes the first application).
- A 50-foot buffer zone must be maintained around permanent water bodies, such as rivers, streams and lakes.
- Pre-plant cotton use must be deleted.

MSMA use on golf courses, sod farms and highway rights-of-way will be cancelled as of December 31, 2012, with use of existing stocks allowed until December 31, 2013, provided the following mitigation measures are included on amended labels submitted by March 17, 2009:

- Golf course use is limited to spot treatments only (100 square feet per spot), not to exceed 25% of total golf course acreage per year. One broadcast application is allowed for newly constructed golf courses only.
- Sod farm use is limited to 1- 2 broadcast applications per season. A 25-foot buffer zone must be maintained around permanent water bodies.
- Two broadcast applications per year are allowed for use on highway rights-of-way only. A 100-foot buffer zone must be maintained around permanent water bodies. Other rights-of-way uses must be deleted.

All other uses of MSMA and all currently registered uses of DSMA, CAMA, DMA (cacodylic acid and its sodium salt) must be deleted effective December 31, 2009. In some cases this may be all the uses on some products. In addition, MSMA product registrations must be amended to delete the following uses:

- Residential turf
- Forestry
- Non-bearing fruit and nuts
- Citrus, bearing and non-bearing
- Bluegrass, fescue and ryegrass grown for seed
- All uses of MSMA in Florida except use on cotton grown in Calhoun, Columbia, Escambia, Gadsden, Hamilton, Holmes, Jackson, Jefferson, Okaloosa, Santa Rosa, Suwannee, Walton, and Washington counties.
- Drainage ditch banks, railroad, pipeline, and utility rights-of-way, fence rows, storage yards and similar non-crop areas.

The label revisions needed to implement these provisions are outlined in the attached label table. Registrants were required to submit requests to cancel uses and revise labeling by March 17, 2009. EPA is now poised to issue a notice of receipt of such requests for the purpose of seeking public comment. After considering comments, the Agency will issue a cancellation order with existing stocks provisions.

Additional Data for the Cotton Use

The following confirmatory data are required to support the use of MSMA on cotton:

1. Magnitude of the residue in meat and milk (Guideline 860.1480)

Registrants must develop confirmatory data that demonstrate no detectable residues of inorganic arsenic will be found in the edible tissues and milk of cows

consuming cotton feed items treated with MSMA. Data may be developed in a tiered fashion.

Tier 1 will test residues of inorganic arsenic in cows from herds in Minnesota, known to consume water with high levels of inorganic arsenic, previously studied by Murphy, et al, 2008. Samples will include animals from herds with high, medium and low exposure. High exposure to inorganic arsenic in water in MN is expected to be in the 50-70 ppb range. The detection limit goal for inorganic arsenic is 2 ppb.

The Task Force submitted the Tier 1 protocol on January 29, 2009, and intends to submit results of the study by July 30, 2009.

Tier 2 will be conducted only if inorganic arsenic is found in the edible tissues or milk from any of the MN cows. The Tier 2 study will follow EPA guidelines for an animal feeding study (860.1480). EPA will consider modifications to the guideline as appropriate during the protocol development process. Test substance will be inorganic arsenic. Doses will be determined according to EPA guidelines and available scientific data. The MAATF agreed to submit a framework for the Tier 2 study by April 1, 2009, a protocol by August 31, 2009, and the final study, if needed, by August 30, 2010.

2. Field rotational crop study (Guideline 860.1900)

Registrants must provide data demonstrating no residues of inorganic arsenic in food crops (peanuts) that are rotated with cotton. This requirement may be satisfied with data from the open literature or a new study conducted in accordance with guideline 860.1900. These data are due no later than August 30, 2010.

FQPA Safety Finding

As part of the FQPA tolerance reassessment process, EPA has assessed the risks associated with the organic arsenical herbicides. EPA has determined that risk from dietary exposure (food + water) to the parent, organic compounds is not of concern and finds with reasonable certainty that no harm will result from aggregate exposure to the parent, organic compounds.

New information has largely addressed EPA's concern for residues of the transformation product, inorganic arsenic, in meat and milk. Further, since all residential uses will be cancelled, an aggregate assessment for inorganic arsenic is not warranted.

Table 1 below presents a summary of the revised organic arsenical herbicide tolerance decision.

Table 1. Revised Tolerance Reassessment Summary for the Organic Arsenical Herbicides.

Commodity	Current Tolerance (ppm)	Tolerance Reassessment (ppm)	Comments
Tolerances Listed Under 40 CFR § 180.289 (a)(1) MSMA/DSMA			
Cotton, undelinted seed	0.7	0.7	Confirmatory data are required.
Cotton, hulls	0.9	0.9	Confirmatory data are required.
Fruit, citrus	0.35	Revoke	Use will be cancelled as of 12/31/09
Tolerances Listed Under 40 CFR § 180.311 (a)(1) Cacodylic Acid			
Cotton, undelinted seed	2.8	Revoke	Use will be cancelled as of 12/31/09

FIFRA Findings

In the 2006 RED, EPA found all uses of the organic arsenical herbicides ineligible for reregistration based on a concern for residues of inorganic arsenic in drinking water exceeding the OPP's level of concern, the availability of adequate alternatives, and generally low benefits. EPA confirms these finding for DSMA, CAMA, cacodylic acid and its sodium salt, and most uses of MSMA. Based on the new information outlined above, however, the Agency finds the use of MSMA on cotton only to be eligible for reregistration contingent on the implementation of measures to protect water resources and the development of the confirmatory data described in this document.

EPA estimates that the drinking water risk from the remaining use on cotton to be between 1×10^{-4} and 4×10^{-4} . This estimate is based on conservative assumptions related to the conversion rate of applied organic arsenical herbicide to the inorganic form, and the percent of a given watershed that is treated. Using these same assumptions, the Agency estimates that applications of MSMA to cotton will result in residues of inorganic arsenic in water at levels of approximately 4 ppb, less than the established MCL of 10 ppb.

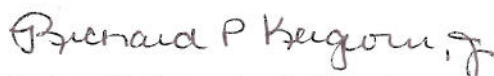
Information provided by cotton growers indicates at least a 25% loss of revenue in fields infested with glyphosate-resistant Palmer amaranth. (Culpepper, 2008). EPA concludes that in light of the benefits associated with the use of MSMA on cotton, the risks associated with such use are not unreasonable and finds this use eligible for reregistration.

Future Review

Because the Agency has residual concerns for drinking water contamination and ecological risk, and because both the science related to the toxicity of inorganic arsenic as well as the research related to control of Palmer amaranth are evolving, the Agency will expedite the Registration Review of MSMA on cotton to begin in 2012 to ensure the timely review of any new information. In conjunction with Registration Review, registrants may submit information related to the mechanism of toxicity for inorganic arsenic, and the Agency will determine if review by the FIFRA Scientific Advisory Panel (SAP) or the Agency's Science Advisory Board (SAB) is warranted at that time.

If you have questions on the Organic Arsenicals RED or any of the requirements outlined in this amendment, please contact Tom Myers, Team Leader at 703 308-8589.

Sincerely,



Richard P. Keigwin, Jr., Director
Special Review and Reregistration Division

Attachment: Label Table

References

- Armbrust, K. L. and D. C. Bridges, 2002. Dissipation of Monosodium Methane Arsonate (MSMA) on Peanuts. *J. Agric. Food Chemistry*. 50 (7): 1959-1963
- Culpepper, A. S., J. R. Wtaker, A. W. MacRae and A. C. York, 2008. Distribution of Glyphosate-Resistant Palmer Amaranth (*Amaranthus palmeri*) in Georgia and North Carolina. *Journal of Cotton Science*. 12:306-310.
- Holshouser, D and H. Wilson, 2008. Prevention and Control of Palmer Amaranth in Cotton. University of Virginia Extension Publication No 2805-1001
- Murphy, M. 2008. Water Arsenic and Dairy Food Safety. Abstract. Society of Toxicology Meeting Seattle, WA
- Norsworthy, J.K., G. M. Griffith, R. C. Scott, K. L. Smith and L. R. Oliver, 2008. Confirmation and Control of Glyphosate-Resistant Palmer Amaranth (*Amaranthus palmeri*) in Arkansas. *Weed Technology*. 22 (1): 108-113.

Labeling Changes Summary Table for Products Containing MSMA

The following table sets forth the label changes that must be made for products containing MSMA.
An application for amended registration making these changes were to be submitted by March 17, 2009.

Summary of Labeling Changes for Monosodium Methanearsonate (MSMA)		
Description	Amended Labeling Language	Placement on Label
Manufacturing Use Products		
For all Manufacturing Use Products	<p>“Only for formulation into an herbicide for the following use(s): cotton, golf courses, sod farms, or highway rights-of-way.”</p> <p>“This product may not be used to formulate a pesticide product unless such pesticide product has either received its initial registration from EPA after January 16, 2009, or EPA has approved an amendment to such registration after January 16, 2009.”</p> <p>“Only end-use products labeled for use on cotton are allowed to be formulated after December 31, 2012. All other uses must be deleted.”</p>	Directions for Use
End Use Products		
Note to Registrant	<p>The use sites and uses listed below must be deleted. In addition, any language inconsistent with the language required for end use products below MUST be deleted from product labels.</p> <ul style="list-style-type: none"> • Residential turf (including, but not limited to: athletic fields, parks, lawns, yards, or playgrounds) • Forestry • Non-bearing fruit and nuts • Citrus, bearing and non-bearing • Bluegrass, fescue and ryegrass grown for seed • All uses in Florida except use on cotton grown in Calhoun, Columbia, Escambia, Gadsden, Hamilton, Holmes, Jackson, Jefferson, Okaloosa, Santa Rosa, Suwannee, Walton, and Washington counties. • Drainage ditch banks, railroad, pipeline, and utility rights of way, fence rows, storage yards and similar non-crop areas. 	Not Applicable

PPE Requirements for all MSMA formulations	<p>“Personal Protective Equipment (PPE)”</p> <p>“Some materials that are chemical-resistant to this product are” (<i>registrant inserts correct chemical-resistant material</i>). “If you want more options, follow the instructions for category” [<i>registrant inserts A, B, C, D, E, F, G, or H</i>] “on an EPA chemical-resistance category selection chart.”</p> <p>“All mixers, loaders, applicators, and other handlers must wear:</p> <ul style="list-style-type: none"> > Long-sleeved shirt and long pants, > Shoes plus socks, and > Chemical-resistant gloves.” 	Immediately following/below Precautionary Statements: Hazards to Humans and Domestic Animals
Application Restrictions for all products	<p>“Do not apply this product in Florida except on cotton in the countries listed in the cotton use section of the label.”</p> <p>“Aerial application is prohibited, except when applying to cotton.”</p>	Directions for Use
Application Restrictions for cotton	<p>Cotton (Postemergent use only)</p> <p>Only 1 application at 2 lbs ai/A is allowed per season, except when a salvage operation is needed.</p> <p>If a salvage operation is needed (i.e., if pigweed escapes the first application), then a second or repeat application at 2 lbs ai/A is allowed.</p> <p>A second or repeat application, if needed, should be timed 1 to 3 weeks after the first application. Apply only as a salvage operation. Apply only to healthy rapidly growing cotton 3 inches high, but no later than 6 inches high or early square, whichever occurs first. Preference should be given to directed spray. In order to minimize injury, the second application should be made as a directed spray when possible.</p> <p>Do not make more than two (2) applications per season.</p> <p>“Do not apply more than a total of 4 lbs ai/A per season.”</p> <p>“Do not apply pre-plant to cotton.”</p> <p>“Do not apply within 50 feet of permanent water bodies or aquatic habitat, including, but not</p>	Directions for Use

	limited to, lakes, reservoirs, rivers, streams, marshes, ponds, and estuaries.”	
Application Restrictions For golf courses	<p>“Do not apply in Florida except on cotton grown in the following counties: Calhoun, Columbia, Escambia, Gadsden, Hamilton, Holmes, Jackson, Jefferson, Okaloosa, Santa Rosa, Suwannee, Walton, and Washington.”</p> <p><u>Golf Courses</u> For newly constructed golf courses only one broadcast application is allowed. For all other applications to golf courses, only spot treatments (100 square feet maximum per spot) are allowed. A spot treatment must not exceed 25% of total golf course acreage per year.</p> <p>“After December 31, 2013, applications to golf courses are prohibited.”</p>	Directions for Use
Application Restrictions For sod farms	<p><u>Sod Farms</u> Only 2 broadcast applications are allowed per season.</p> <p>“Do not apply within 25 feet of permanent water bodies or aquatic habitat, including, but not limited to, lakes, reservoirs, rivers, streams, marshes, ponds, and estuaries.”</p> <p>“After December 31, 2013, applications to sod farms are prohibited.”</p>	Directions for Use
Application Restrictions For highway rights-of-way (ROW)	<p><u>Highway Rights-Of-Way (ROW)</u> Only 2 broadcast applications are allowed per season.</p> <p>“Do not apply within 100 feet of permanent water bodies or aquatic habitat, including, but not limited to, lakes, reservoirs, rivers, streams, marshes, ponds, and estuaries.”</p> <p>“After December 31, 2013, applications to highway rights-of-way are prohibited.”</p>	Directions for Use