

RECEIVED JAN 28 2005

**PETITION TO REMOVE THE PROHIBITION FOR
USE OF CALCIUM CHLORIDE AS A SOIL
APPLIED NON SYNTHETIC SUBSTANCE IN
ORGANIC CROP PRODUCTION**

Petition submitted on behalf of:

TETRA Technologies Inc.
25025 I-45 North
The Woodlands, TX 77380

Date: January 26, 2005

Submitted by:
R3 Ag Consulting, LLC
1508 Tollhouse Rd., Suite D
Clovis, CA 93611

Petition Responses Item B

1.	Common Name	Calcium Chloride
2.	Manufacturer	TETRA Technologies, Inc. 25025 I-45 North The Woodlands, TX 77380
3.	Current Use	Fertilizer, soil and foliar amendment
4.	Crop Use	Soil application to all crops. Primary use on row crops and tree & vine crops. May be used via drip irrigation, water run, soil applied or as a foliar amendment. Used as a source of free Calcium and to supply plant requirements for Chlorine and for salt remediation in saline soils.
5.	Source of substance	As part of a mining reclamation program, TETRA is using a brine process to extract CaCl from the Cadiz Dry Lake project near Amboy, CA. A detailed description of the brine process extraction is included in Appendix A.
6.	Previous Review	CaCl (from natural brine process) was listed on the approved NOP list for crop production as a foliar application in the Federal Register notice 10.31.03. We are not aware of any petition to allow use as a soil application being reviewed. KCl was reviewed as a soil application and is allowed for soil use. (Appendix B)
7.	Registrations	CaCl is registered as a fertilizer, category agricultural mineral in those states requiring registration.
8.	CAS No. and labels	CAS No. 10043-52-4 inorganic salt. HI-CAL fertilizer label included in Appendix C. (Note: also refer to Appendix D for chemical properties)

9.	Physical properties	Physical properties of CaCl are included in the MSDS for HI-Cal (Appendix D) Appendix E describes chemical interactions and effects on soil organisms and crops. Calcium chloride is used in a multitude of commercial applications including treatment of human calcium deficiencies, to melt snow and ice on highways, as a food treatment, etc. It has low toxicity and is persistent as free calcium and chlorine salts until used by the plant or leached from the soil profile. Minimal adverse effects on the environment are expected from the use of CaCl as a soil application.
10.	Safety Information	A Material Safety Data Sheet (MSDS) is included with this submission. (Appendix D). Also included in Appendix D are query responses from National Institute of Environmental Health Studies. No adverse data for CaCl were found in these queries.
11.	Research papers with contrasting positions	We are unable to locate any research publications stating that the use of CaCl in a managed fertility program will cause Cl levels to cause detrimental plant growth effects. KCl, as a soil amendment, is allowed by NOP. Yet, the use of KCl has a greater propensity to accumulate Chlorine than CaCl. (See also Appendix E, "OMRI Comments to NOP Proposed Amendments, 04.28.03)

12.	Petition Justification Statement	Appendix F provides an in-depth comparison of HI-CAL Calcium chloride versus Potassium Chloride (Suren Mishra, PhD, TETRA Technologies) and a very informative report from Dr. Tom Ruehr, Cal Poly State University, Earth and Soil Science Department supporting the petition to remove Calcium chloride from the Prohibited Status and allow use as a soil amendment.
13.	Commercial Confidential Information Statement	No data submitted with this application are considered confidential business information.

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5

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**Appendix F
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9-22-04



Dennis =

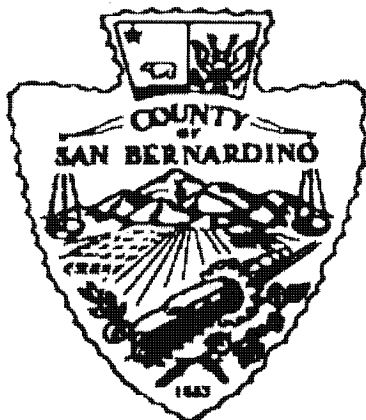
Enclosed are the process at both
Amboy and Lee Chemical - These
will be the two locations where
Organic product would be shipped.

We already have in our system a
control number that will permit
organic shipment from these
two locations. No need to rename
product.

Any questions please call me at
281-369-2249.

Thanks for everything -
Charlie

Hearing Date May 31, 1990
 Agenda Item 4
 Approval Date June 12, 1990
 Revision August 16, 1993



745/DSS/ 88/004185/SAMR/01
 SAMR/ 88-0050/DS 1033-17

REVISED RECLAMATION PLAN
 (90M-03)

TETRA TECHNOLOGIES
 CADIZ DRY LAKE

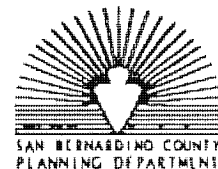
TETRA CHEMICALS
 P.O. BOX 73087
 HOUSTON, TX 77273

THIS RECLAMATION PLAN
 EXPIRES ON
 DECEMBER 31, 2020

APPROVED



RECLAMATION PLAN



Project Title Cadiz Dry Lake

Reclamation Plan Number: 90M-03 Expiration Date: 12/31/2020

Name of Project Proponent: Tetra Chemicals

Address of Project Proponent: P.O. Box 73087
Houston, TX 77273

Project Location: Cadiz Dry Lake, 18 miles south of Cadiz; 12 miles north of SH 62.
(T 2N, R15E, Sections 2,3,10, 11,13)

Type of Operation: Solar Evaporation on a dry lakebed

Mineral Commodity: Liquid Calcium Chloride

Quantity of Ore 21,000 tpy

Operation Time Frame: 30 years Reclamation Time Frame: 2 years

Area to be mined and reclaimed: 685 acres

Total holdings: 6,720 acres

Maximum Anticipated Depth: Water extraction at 270 +/- feet; Ponds at < 10 feet

Reclaimed to: A condition mitigating physical hazards to the public. Trenches and ponds will be backfilled and all buildings and equipment will be removed. Vacant Open Space.

Effect on Future Mining: Reclamation will not preclude future mining of the deposit.

State Agency: Department of Conservation
 Office of Mine Reclamation
 Reclamation Unit
 801 K Street, M.S. 09-06
 Sacramento, CA 95814
 (916) 323-9198

Lead Agency: San Bernardino County
 Land Use Serv. Department
 Environmental Team
 385 N. Arrowhead Avenue
 San Bernardino, CA 92415
 (909) 387-4147

Lead Agency Contact Person:

Richard L. Touslee
 Richard L. Touslee, Senior Associate Planner

Date: April 3, 2002

NOTE: This and supplemental documents for the non-proprietary portions of the project are on file and available for review at the state and lead agency addresses above.

LAND USE SERVICES DEPARTMENT



COUNTY OF SAN BERNARDINO
ECONOMIC DEVELOPMENT
AND PUBLIC SERVICES GROUP

PLANNING DIVISION

385 North Arrowhead Avenue • San Bernardino, CA 92415-0182 • (909) 387-4131
First Floor Fax (909) 387-3249 • Third Floor Fax (909) 387-3223
15505 Civic Drive • Victorville, CA 92392 • (760) 243-8245 • Fax (760) 243-8212
<http://www.sbcounty.gov/landuseservices>

MICHAEL E. HAYS
Director of Land Use Services

April 3, 2002

Tetra Chemicals
P.O. Box 73087
Houston TX 77273

RE: Transfer of Ownership for the Cadiz Dry Lake Project,
CA Mine ID # 91-36-0043
APN 0644-151-21

Dear Sirs:

Your application for a transfer of ownership for the Cadiz Dry Lake Project, currently permitted to Lee Chemical, has been received, reviewed by staff and is approved effective this date.

A. Condition of Approval # 11 (added)

In the event that Tetra Chemicals leases the project to another operator, a copy of that lease shall be provided to the Lead Agency.

The expiration date for Reclamation Plan 90M-03 remains December 31, 2020. Mining is to cease prior to that date, so that all requirements of the Reclamation Plan are complete as of December 31, 2020.

The bond instrument you have provided has been reviewed and approved by the Lead Agency and will be forwarded to the Office of Mine Reclamation for their concurrence. Upon final acceptance of the Tetra Chemicals bond, the Lee Chemical CDs will be released. Notification will be by separate correspondence.

Additionally, responsibility for filing and payment of appropriate fees for the CY 2002 Mining Operation Annual Report remain the responsibility of Lee Chemical, as transfer of ownership has occurred after 12/31/01. Tetra Chemicals is now responsible for ongoing compliance with SMARA and the County Code for the annual mine inspection program. Correspondence pertinent to that program will be forwarded under separate cover.

JOHN F. MICHAELSON
County Administrative Officer
JOHN GOSS
Assistant County Administrator
Economic Development and

Board of Supervisors		
BILL POSTMUS	First District	DENNIS HANSBERGER
JON D. MIKELS	Second District	FRED AGUIAR
JERRY EAVES	Fifth District	

Tetra Chemicals
April 3, 2002

An amended plan 90M-03 will be published and forwarded under separate cover in approximately 30-45 days.

Pursuant to Title 8, Sections 82.010410 and 83.010605 of the San Bernardino County Code, any interested person may, within ten (10) days after the date of this notice, appeal in writing to the Planning Commission for consideration thereof. The appeal must be made in writing on forms available from the Public Information Counter.

Should you have any questions, please contact me at (760) 243-8175.

Sincerely:

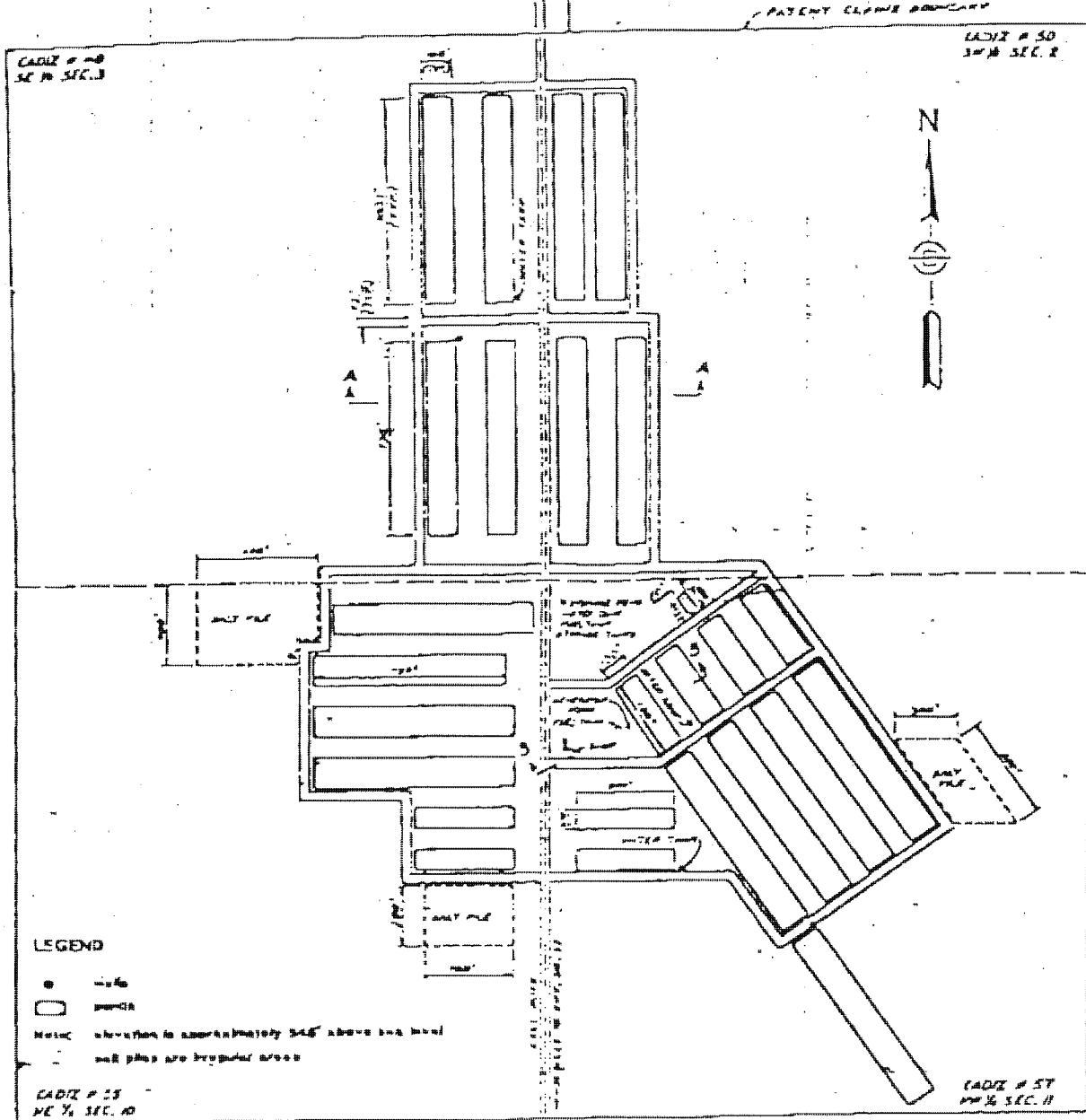


Rich Touslee, Senior Associate Planner
Advance Planning

Cc: Randy Scott, Division Chief
Lee Chemical
Department of Conservation/ Office of Mine Reclamation
File

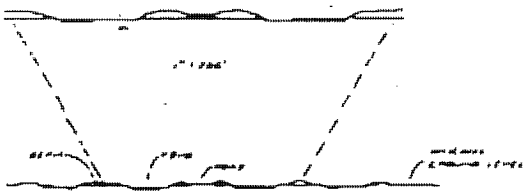
MINING/RECLAMATION PLOT PLAN

PATENT CLAIMS PLOT PLAN
T 2 N RISE



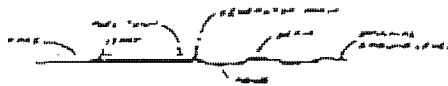
LEGEND

- shaft
- POND
- Note: elevation is approximately 345' above sea level
- well pits are irregular areas



SECTION A-A

SECTION A-A
AFTER RECLAMATION

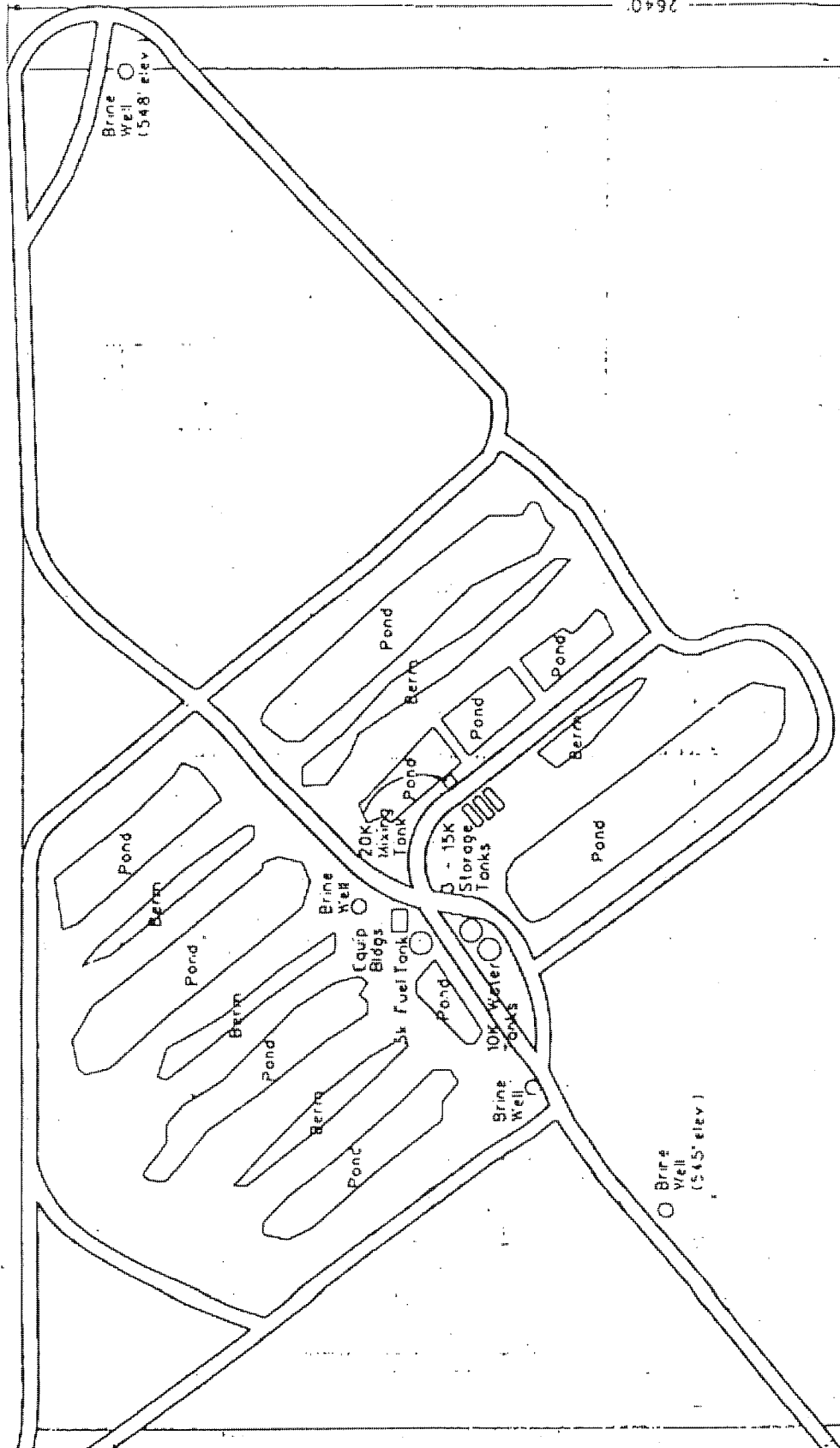


SECTION B-B

1993 ADDITIONAL LANDS PLOT PLAN

2640

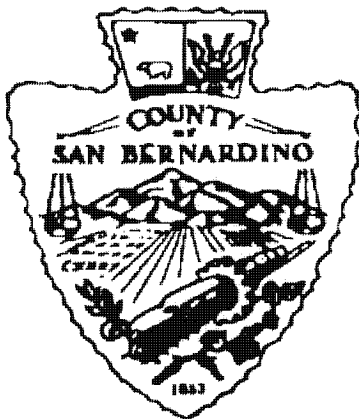
EVAPORATORS



Hearing Date May 10, 2001

Agenda Item 2

Approval Date May 21, 2001



745/DSS/00010737/SMA/01
SMA/DS 881-169/00

MINING/RECLAMATION PLAN
(2001M-03)

TETRA TECHNOLOGIES
AMBOY PLANT

TETRA TECHNOLOGIES, INC
P.O. BOX 38
AMBOY, CA 92304

THIS MINING/RECLAMATION PLAN
EXPIRES ON
MAY 21, 2031

APPROVED



MINING CONDITIONAL USE PERMIT AND RECLAMATION PLAN



Project Title Amboy Plant

Reclamation Plan Number: 2001M-03 Expiration Date: 5/21/2031

Name of Project Proponent: Tetra Technologies, Inc

Address of Project Proponent: P.O. Box 38
Amboy, CA 92304

Project Location: 2 mile east of Amboy, 1 mile south of National Trails Hwy on Saltus Rd.
(T 5/6N, R12/13E, Sections - Multiple)

Type of Operation: Saline Recovery and concentration

Mineral Commodity: Calcium Chloride and sodium chloride

Quantity of Ore 40,000 tpy

Operation Time Frame: 30 years Reclamation Time Frame: 2 years

Area to be mined and reclaimed: 4,792 acres

Total holdings: 10,835 acres

Maximum Anticipated Depth: Water extraction at 270 +/- feet ; Ponds at < 10 feet

Reclaimed to: A condition mitigating physical hazards to the public. Trenches and ponds will be backfilled and all buildings and equipment will be removed. Vacant Open Space.

Effect on Future Mining: Reclamation will not preclude future mining of the deposit.

State Agency: Department of Conservation
Office of Mine Reclamation
Reclamation Unit
801 K Street, M.S. 09-06
Sacramento, CA 95814
(916) 323-9198

Lead Agency: San Bernardino County
Land Use Serv. Department
Environmental Team
385 N. Arrowhead Avenue
San Bernardino, CA 92415
(909) 387-4147

Lead Agency Contact Person:

Richard L. Touslee
Richard L. Touslee, Senior Associate Planner

Date: May 21, 2001

NOTE: This and supplemental documents for the non-proprietary portions of the project are on file and available for review at the state and lead agency addresses above.

1 MINING

1.1 Mining Operation Introduction

TETRA Technologies, Inc.'s operation at Amboy, California recovers brines that are concentrated through the use of solar evaporation to produce granular solar salt and liquid calcium chloride. Figures 1 and 2 show the general location of the project. Figure 3 shows the extent of the TETRA Technologies, Inc.'s holdings.

The brines are recovered from two sources. One source is a series of wells that provide a solution containing both calcium chloride and sodium chloride. These wells are along the northeastern boundary of the property along the playa edge. The other source is a collection of pits and trenches that provide calcium chloride solution. The pits are located in the southeastern portion of the property. The trenches are located in the evaporating complex in the southwestern portion of the property.

TETRA Technologies, Inc. plans to expand the operation by refurbishing existing, or constructing more wells, pits and trenches within the permit boundary (Figure 4).

1.1.1 Description of Proposed Mining Operation

1.2 Sodium Chloride Production

The brine wells produce a weak solution of calcium and sodium chloride that is concentrated by solar evaporation. During the calcium chloride recovery process, sodium chloride is recovered as the sodium chloride salt precipitates out. The sodium chloride is precipitated in several crystallizer basins and then recovered utilizing an elevating scraper.

Along with the sodium chloride, small amounts of calcium-sulfate precipitate contaminates the sodium chloride. This problem is addressed by washing the salt crystals in a countercurrent sand screw washer. The finer sulfate precipitates are readily removed from the coarse salt crystals. The salt crystals are discharged to a stockpile and the calcium sulfate is discharged to a salt-wash-water holding basin where the sulfate is allowed to settle out. This process takes place in the evaporating complex.

The salt wash water basin is routinely recharged with weaker brine solutions as the stronger solutions are advanced to the salt crystallizers. The calcium sulfate solids are periodically removed, once every several years, and placed on existing burden pile areas to dry. Liquid from these solids and runoff is allowed to drain back into the evaporation trenches.

The washed sodium chloride crystals are shipped from the evaporating complex by bulk truck.

1.1.1.2 Calcium Chloride Production

Brines from pits and trenches are gathered and combined with the partially concentrated brine discharged from the salt crystallizers. Two products are made from the brine: untreated calcium chloride solution and treated calcium chloride solution.

The untreated solution is simply allowed to continue concentrating through the solar evaporation process until it reaches a marketable concentration. The untreated material is segregated in storage ponds, located in the evaporating complex. From the storage ponds, it is sold in bulk truck and bulk rail quantities.

The treated calcium chloride solution has magnesium removed from it by contacting partially concentrated brine with a quick-lime solution ($\text{CaO} + \text{H}_2\text{O}$). This temporarily elevates the pH of the brine causing magnesium hydroxide (MgOH_2) to precipitate. The reaction is rapid, and the brine quickly normalizes from an initially high pH value of about 9. The precipitated solids are allowed to settle out as the brine continues to concentrate in designated settling basins.

The precipitated solids are allowed to collect in the settling basins. Periodically, every several years, the settled solids are removed and placed on overburden piles adjacent to the settling basins. The liquid that drains from the solids and any subsequent precipitation is allowed to run back into the settling basins.

Once the treated brine reaches market grade strength, the clear brine is decanted from the settling basin and placed in storage ponds located in the evaporating complex. The treated calcium chloride is shipped from the site by bulk truck and rail.

1.1.2 History of Area

The Bristol Dry Lake playa and surroundings have been used for the mining of gypsum, sodium chloride and calcium chloride since 1908. The initial operations were for the recovery of gypsum at the edge of the playa. Gypsum was recovered until the mid-1920's. While the location of the gypsum operation is generally known, the area has eroded and has largely returned to the natural state of a flat playa margin.

Rock salt was recovered using open-pit mining methods until the mid-1970's. The original claim holders operated the site until 1921 when the claims were taken over by the California Rock Salt Company. In 1923, ownership shifted to the California Salt Company. In 1938, Leslie Salt purchased half of the California Salt Company and in 1958 bought out the remaining half. In 1992, Cargill, Incorporated purchased Leslie Salt. Cargill operated the site until August of 1998 when the current owner, TETRA Technologies, Inc. purchased it.

Over the years, the United States Geological Survey (USGS), the Metropolitan Water District (MWD), Southern California Edison Utility Company, and the various owners did exploratory work

in the playa area. In 1952, core drilling to a depth of 1005 feet was performed. Core was recovered to a depth of 950 feet that indicated continuous alternating salt and sediment beds to at least that depth. Extensive exploration work to a depth of around 100 feet was performed in the early 1960's. The work indicated extensive salt beds under much of the claim area. In 1985, deep core drilling to a depth of approximately 1750 feet was performed. Core recovered to a depth of approximately 1700 feet also indicated continuous alternating salt and sediment beds (Rosen, 1989, pgs. 92-116).

1.1.3 Extraction Method and Equipment Description

Brine is extracted from the wells with submersible down-hole pumps. The down-hole pumps discharge the brine into surface piping that carries the brine to a polypropylene collection tank. Brine is pumped from the collection tank through six-inch high-density polyethylene pipeline to the first collection ditch. The collection ditch takes the weak brine to the mine area.

Once the brine is in the mine area, it is allowed to concentrate in one of three production areas. All of the brine concentration areas are sections of the prior open-pit mining operation that have been converted to evaporation basins.

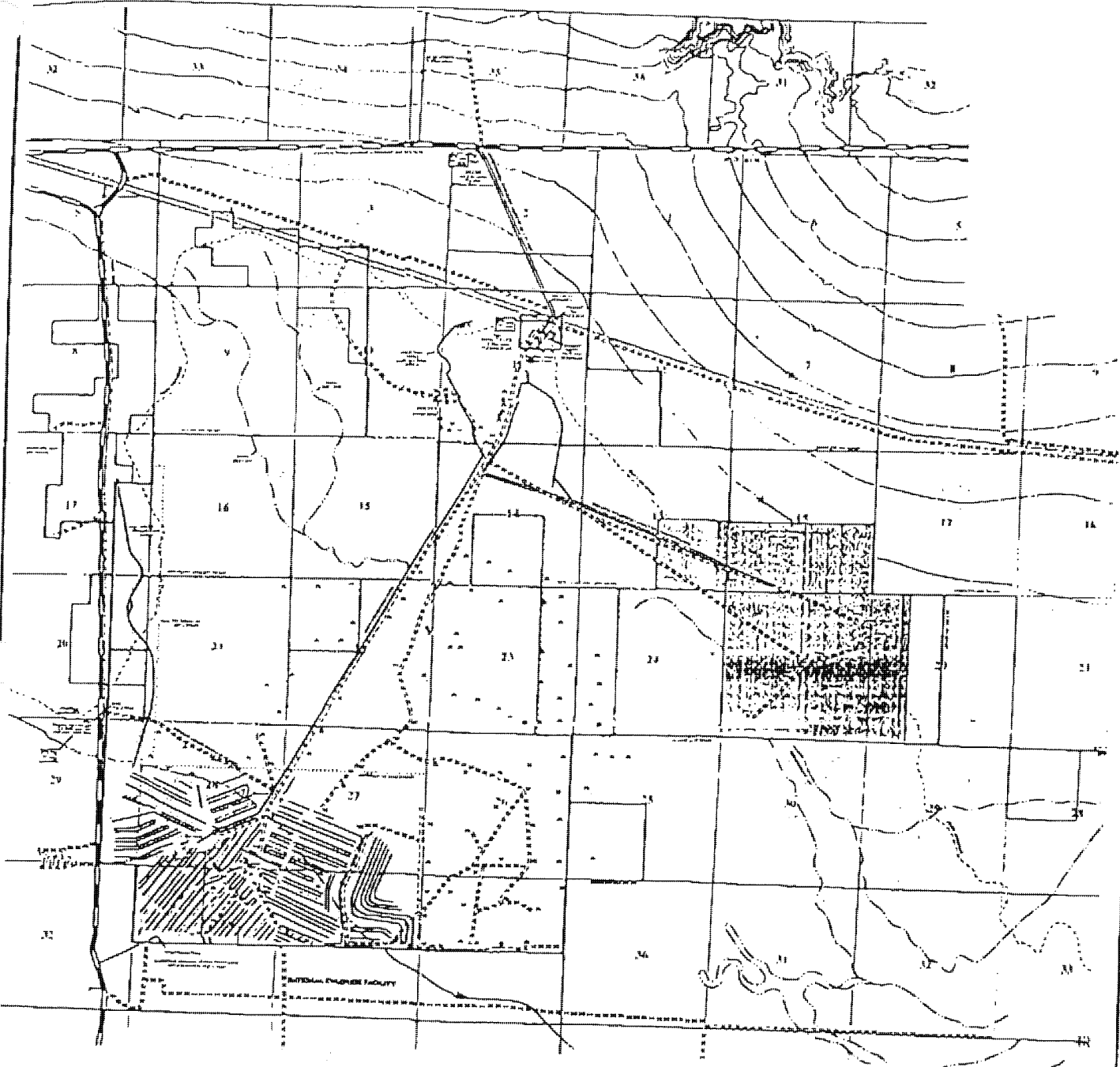
As the brine traverses the collection ditch, some concentration takes place. When the brine reaches the mine area, it is placed in a weak brine concentrator and allowed to concentrate. At the appropriate concentration the brine is pumped into a salt crystallizer. As the brine continues to concentrate, salt crystallizes out on the bottom of the crystallizer. The majority of the salt is collected in the crystallizers before the brine is advanced.

Brine leaving the crystallizers is generally treated with lime to remove magnesium. Alternatively the brine is left untreated and allowed to concentrate further for sale as untreated material. The lime-treated brine is placed in settling basins, where the magnesium solids are allowed to settle out. When the treated or untreated brines reach marketable concentrations they are stored in finished product ponds.

Pumping of the brine is done with centrifugal type pumps. The more frequently operated pumps are electric; others are diesel driven portable pumps. Interconnecting pipelines are made of a combination of steel and hi-density polyethylene.

The crystallized salt is harvested by draining the crystallizer, loosening the salt with a bulldozer, and picking up the salt with an elevating scraper. Once the salt is harvested, it is de-lumped and washed prior to sale. The de-lumper is a basic hammer mill. The salt washer is a sand screw utilizing countercurrent flow of wash solution that removes calcium sulfate precipitates.

A rubber-tired loader is used to load dump trucks. Pneumatic haul trucks are loaded using the loader and a conveyor/chute assembly. All of the equipment used in the process is of the semi-portable design found in much of the sand and gravel industry. All trucks leaving the site are weighted on a platform scale near the northern entrance to insure that they are not overloaded.



TETRA TECH, INC - MINING PLOT PLAN



The National Organic Program

AMS USDA SEARCH

Petitioned Substances and Materials

Last Updated: October 10, 2002

Available TAP Reviews are linked to the corresponding petitioned substance or material.

- Background Paper for the Petitions of Ammonium Hydroxide, Cyclohexamine, Diethylaminoethanol, Morpholine, and Octadecylamine

Name of Substance or Material	Date Petition Submitted	Use of Substance or Material	Petitioner Information	Result of Materials Review
(1) Leather Meal	10/03/00	Crop production: as a fertilizer	Hynite Corporation 4301 E. Depot Road Oak Creek, WI 53154 P: (414) 762-1068	Prohibited Synthetic
(2) Sodium Chlorate	10/03/00	Crop production: as a defoliant in cotton production	S&E Organic Farms, Inc. 1716 Oak St., Suite 5 Bakersfield, CA 93301 P: (805) 334-2771	Prohibited Synthetic
(3) Monocalcium Phosphate	10/03/00	Crop production: as a soil amendment	Living Acres Weeks Mills Road New Sharon, ME 04955 P: (207) 778-2390	Prohibited Synthetic
(4) Calcium Sulfate	11/02/00	Processing: as a processing aid	FarmSoy Company 96 The Farm Summertown, TN 38483 P: (931) 964-2411	Approved "From Non-synthetic Sources Only"
(5) *Ammonium Hydroxide	11/29/00	Processing: as a processing aid	Spray Chem Chemical Company, Inc. 705 Keenan Court Durham, CA 95938 P: (530) 895-3658	Approved Synthetic "with annotation"
(6) *Cyclohexamine	11/29/00	Processing: as a processing aid	California Natural Products, Inc. 1250 E. Lanthrop Road Lanthrop, CA 95330 P: (209) 858-2525	Approved Synthetic "with annotation"
(7) *Diethylaminoethanol	11/29/00	Processing: as a processing aid	General Mills 201 General Mills Blvd Minneapolis, MN 55426-1350 P: (763) 764-3058	Allowed Synthetic "with annotation"
(8) *Morpholine	11/29/00	Processing: as a processing aid	Smucker Quality Beverages, Inc Speedway Avenue Chico, CA 95926 P: (530) 899-5058	Prohibited Synthetic
(9) *Octadecylamine	11/29/00	Processing: as a processing aid	Organic Valley/CROPP Cooperative 507 Main St. La Farge, WI 54639 P: (608) 625-2602	Approved Synthetic "with annotation"
(10) Hydroxyquinoline Sulfate	11/29/00	Livestock production: as a health treatment	Horizon Organic Dairy 6311 Horizon Lane Longmont, CO 80503 P: (303) 5530-2711 F: (303) 527-3392	Prohibited Synthetic

(11) Poloxalene	12/05/00	Livestock production: as a health treatment	Horizon Organic Dairy 6311 Horizon Lane Longmont, CO 80503 P: (303) 530-2711	Approved "For Emergency Treatment of Bloat"
(12) Dimethylpolysiloxane	12/07/00	Processing – as an anti-foam agent	Cyanotech Corporation 73-4460 Queen Kaahumanu Highway Suite 102 Kailua-Kona, HI 96740 P: (808) 326-1353	"On Hold - per petitioner's request"
(13) Peracetic Acid (C,L,P)	01/31/01	Processing: as an anti-microbial water treatment additive and/or as an equipment sanitizer or disinfectant	Enviro Tech Chemical Services, Inc. P.O. Box 577470 Modesto, CA 95358 P: (209) 581-9576	Approved Synthetic "November NOSB Meeting"
(14) Potassium Hydroxide (view comments)	03/01/01	Processing: as a processing aid	J.R. Wood Inc. 7916 W. Bellevue Road Atwater, CA 95301 P: (209) 358-5643	Approved - Annotation is amended.
(15) Cellulose Casings	03/14/01	Processing: as a processing aid	Organic Valley/CROPP Cooperative 507 Main Street La Farge, WI 54639 P: (608) 625-2602	Petition Returned "Formulated Product"
(16) 2-Ethyl Hexyl Acrylate	03/08/01	Crop production: in the production of mulch	Cruickshank International P.O. Box 28 271 Remuera Auckland 1005 New Zealand	Petition Returned "Requires Additional Information"
(17) Vinyl Acetate	03/28/01	Crop production: in the production of mulch	Cruickshank International P.O. Box 28 271 Remuera Auckland 1005 New Zealand	Petition Returned "Requires Additional information"
(18) Sodium Phosphates	03/21/01	Processing: as a processing aid	Carousel Foods of America, Inc. 535 Smith Street Farmingdale, NY 11735	Denied - Annotation remains as published in section 205.605 (b)(33).
(19) Ammonium Chloride	03/25/01	Processing: as a binder in fertilizer granulation	Pacific Calcium 32117 Hwy 97 Tonasket, WA 78855 P: (540) 486-1201	Petition Returned "Requires Additional Information"
(20) 1,4 Dimethylnaphthalene	04/03/01	Crop production: as a plant growth regulator	D-I-1-4, Inc. 3719 Thomasson Crossing Dr. Triangle, VA 22172	Will be considered at Sept. 2002 NOSB Meeting
(21) Calcium Chloride	014/12/01	Crop production: as a foliar application	Bio-Gard Agronomics, Inc. 2042 Peach Orchard Dr. Suite 109 Falls Church, VA 22043 <i>No # in Directory Assistance</i>	Prohibited Synthetic (Non Brine Process) Prohibited Natural (Brine Process) "with annotation"
(22) Copper Sulfate	06/29/01	Crop production: to amend annotation	CA Certified Organic Farmers 1115 Mission Street Organic Farmers Santa Cruz, CA 95060-3526	Approved Synthetic "with annotation"
(23) Sodium (Chilean) Nitrate General Use Spirulina Aquaculture	06/29/01	Crop production: to amend annotation	Cyanotech Corp. 73-4460 Queen Kaahumanu #102 Kailua-Kona, HI 96740	Will be considered at Sept. 2002 NOSB Meeting

Rules and Regulations

Federal Register

Vol. 68, No. 211

Friday, October 31, 2003

This section of the FEDERAL REGISTER contains regulatory documents having general applicability and legal effect, most of which are keyed to and codified in the Code of Federal Regulations, which is published under 50 titles pursuant to 44 U.S.C. 1510.

The Code of Federal Regulations is sold by the Superintendent of Documents. Prices of new books are listed in the first FEDERAL REGISTER issue of each week.

DEPARTMENT OF AGRICULTURE

Agricultural Marketing Service

7 CFR Part 205

[Docket Number TM-02-03]

RIN 0581-AC19

National Organic Program; Amendments to the National List of Allowed and Prohibited Substances

AGENCY: Agricultural Marketing Service, USDA.

ACTION: Final rule.

SUMMARY: This final rule amends the U.S. Department of Agriculture's (USDA) National List of Allowed and Prohibited Substances (National List) to reflect recommendations submitted to the Secretary by the National Organic Standards Board (NOSB). Technical corrections have also been included in this final rule to clarify specific sections of the National List and adequately reflect previous NOSB recommendations. Consistent with recommendations from the NOSB, this final rule would: add ten substances, along with any restrictive annotations, to the National List, revise the annotations of two substances, and make eight technical revisions.

EFFECTIVE DATE: This rule becomes effective November 3, 2003.

FOR FURTHER INFORMATION CONTACT: Richard H. Mathews, Program Manager, National Organic Program, Telephone: (202) 720-3252; Fax: (202) 205-7808.

SUPPLEMENTARY INFORMATION:

I. Background

On December 21, 2000, the Secretary established, within the National Organic Standards (NOS) (7 CFR part 205), the National List (§§ 205.600 through 205.607). The National List is the Federal list that identifies synthetic substances and ingredients that are

allowed and nonsynthetic (natural) substances and ingredients that are prohibited for use in organic production and handling. Since established, the National List has not been amended. However, under the authority of the Organic Foods Production Act of 1990 (OFPA), as amended (7 U.S.C. 6501 *et seq.*), the National List can be amended by the Secretary based on proposed amendments developed by the NOSB.

This final rule amends the National List to reflect recommendations submitted to the Secretary by the NOSB from June 6, 2000 through October 20, 2002. Between the specified time period, the NOSB has recommended that the Secretary add ten substances to §§ 205.601 through 205.603 of the National List based on petitions received from industry participants. These substances were evaluated by the NOSB using the criteria specified in OFPA (7 U.S.C. 6517 and 6518) and the NOS. The NOSB also recommended that the Secretary revise the annotations of two substances included within sections 205.602 and 205.605.

The NOSB has recommended that the Secretary add additional substances to sections 205.603 and 205.605 which have not been included in this final rule but are under review and, as appropriate, will be included in future rulemaking.

In addition to the amendments made based on June 6, 2000 through October 20, 2002, NOSB recommendations, this final rule also makes technical revisions to specific sections of the National List that provide clarity and adequately reflect the intent of the paragraphs identified within those sections.

II. Overview of Amendments

The following provides an overview of the amendments made to designated sections of the National List:

Section 205.601 Synthetic Substances Allowed for Use in Organic Crop Production

This final rule amends the introductory paragraph of § 205.601 by adding language to clarify that synthetic substances used in crop production must be used in a manner which does not contribute to contamination of crops, soil, or water. The amendment further clarifies that synthetic substances, except those in paragraphs (c), (j), (k), and (l), may only be used when the provisions of § 205.206(a)

through (d) prove insufficient to prevent or control the target pest.

This final rule amends paragraph (a) of § 205.601 (as algicide, disinfectants and sanitizers, including irrigation cleaning systems) by adding the following materials:

Copper Sulfate, for use as an algicide, is limited to one application per field during any 24-month period. Application rates are limited to those which do not increase baseline soil test values for copper over a timeframe agreed upon by the producer and accredited certifying agent.

Ozone Gas, for use as an irrigation system cleaner only; and

Peracetic acid, for use in disinfecting equipment, seed, and asexually propagated planting material.

Paragraph (a) is further amended by correcting the spelling of the word "demisters" contained in subparagraph (a)(4) to "demossers."

This final rule amends paragraph (e) of § 205.601 by adding the following material:

Copper Sulfate, for use as tadpole shrimp control in rice production, is limited to one application per field during any 24-month period. Application rates are limited to levels which do not increase baseline soil test values for copper over a timeframe agreed upon by the producer and accredited certifying agent.

This final rule amends paragraph (f) by changing "As insect attractants" to "As insect management."

This final rule amends paragraph (i) of § 205.601 (as plant disease control) by adding the following substance:

Peracetic acid, for use to control fire blight bacteria.

Paragraph (i) is further amended by removing the annotation contained in subparagraph (i)(3).

This final rule revises paragraph (k) of § 205.601 (as plant growth regulators) by inserting the word "gas" behind "ethylene" to be consistent with the June 2000 NOSB recommendation for the substance. Section 205.601(k) now reads "As plant growth regulators—Ethylene gas, for regulation of pineapple flowering."

This final rule revises paragraph (m) of § 205.601 by inserting a new subpart (2) as follows:

(2) EPA List 3—Inerts of unknown toxicity—for use only in passive pheromone dispensers.

Section 205.602 Nonsynthetic Substances Prohibited for Use in Organic Crop Production

This final rule amends § 205.602 by adding the following substance:

Calcium chloride, except as a brine-sourced foliar spray to treat physiological disorders associated with calcium uptake.

This final rule revises current paragraph (h) of § 205.602 by amending its annotation to read as follows:

Sodium nitrate—unless use is restricted to no more than 20% of the crop's total nitrogen requirement; use in spirulina production is unrestricted until October 21, 2005.

Section 205.603 Synthetic Substances Allowed for Use in Organic Livestock Production

This final rule revises current subparagraph (4) of § 205.603(a) by correcting the spelling of the word "chlorohexidine" to "chlorhexidine."

This final rule revises paragraph (b)(4) by replacing "Bordeaux mixes" with "as external pest control."

This final rule amends paragraph (d) of § 205.603 (as feed additives) by adding the following three substances:

DL—Methionine, DL—Methionine—Hydroxy Analog, and DL—Methionine—Hydroxy Analog
Calcium—for use only in organic poultry production until October 21, 2005.

This final rule revises current subparagraph (1) of § 205.603(d) by removing examples (i) and (ii) copper sulfate and magnesium sulfate, as they are both approved for use by FDA and do not need to be listed individually as examples. As currently published, subparagraphs § 205.603(d)(1)(i) and (ii) may have misled some readers to believe that the use of trace minerals are limited only to copper sulfate and magnesium sulfate. Therefore, the revision made in this final rule for current subparagraph (1) of § 205.603(d) reads "Trace minerals, used for enrichment or fortification when FDA approved."

This final rule amends current paragraph (e) of § 205.603 (as synthetic inert ingredients as classified by the Environmental Protection Agency (EPA), for use with nonsynthetic substances or synthetic substances listed in this section and used as active pesticide ingredients in accordance with any limitations on the use of such substances) by redesignating current paragraph (f) of § 205.603 as subparagraph (1) under § 205.603(e). While drafting § 205.603 for final publication in the **Federal Register**,

current paragraph (f) was intended to be designated as § 205.603(e)(1), however, its designation was not properly assigned. Therefore, this final rule redesignates current paragraph (f) of § 205.603 as subparagraph (e)(1) of the same section.

Section 205.605 Nonagricultural (Nonorganic) Substances Allowed as Ingredients in or on Processed Products Labeled as "Organic" or "Made With Organic (Specified Ingredients or Food Group(s))"

This final rule amends current paragraph (a) of § 205.605 by adding agar-agar, carageenan and tartaric acid as technical corrections. These substances were included on the National List proposed in the **Federal Register** on December 16, 1997, but were inadvertently omitted from the National List published in the **Federal Register** on March 13, 2000, and the final rule published on December 21, 2000, Final Rule (7 CFR part 205).

This final rule revises current paragraph (b)(10) of § 205.605 by amending its annotation to read as follows:

Ethylene, allowed for postharvest ripening of tropical fruit and degreening of citrus.

Paragraph (b) is further amended by adding tartaric acid as a technical correction.

Ethylene, for organic crop production, was a substance that was petitioned and reviewed for inclusion onto the National List after promulgation of the proposed rule published in the **Federal Register** on March 13, 2000. The NOSB approved and recommended that ethylene gas be included on the National List with the annotation "for regulation of pineapple flowering." After receiving the NOSB recommendation for the material, the NOP, while finalizing the NOS, included the material on the National List without receiving public comment on the material through the Federal rulemaking process. As a result, the proposed rule requested public comment on the use of ethylene gas and this final rule addresses comments that were received on the use of ethylene gas for regulation of pineapple flowering.

III. Related Documents

Eight notices were published regarding the meetings of the NOSB and its deliberations on recommendations and substances petitioned for amending the National List. Substances and recommendations included in this final rule were announced for NOSB deliberation in the following **Federal Register** Notices: (1) 64 FR 54858, October 8, 1999, (Ethylene); (2) 65 FR

33802, May 25, 2000, (Ethylene gas); (3) 65 FR 64657, October 30, 2000, (Calcium borogluconate and Peracetic acid); (4) 66 FR 10873, February 20, 2001, (Poloxalene); (5) 66 FR 48654, September 21, 2001, (Calcium chloride, Copper sulfate, Methionine); (6) 67 FR 19375, April 19, 2002, (Potassium sorbate and Sodium propionate); (7) 67 FR 54784, August 26, 2002, (Ozone gas, Pheromones, Sodium (Chilean) nitrate, Propylene glycol, Magnesium hydroxide/Magnesium oxide, Kaolin pectin, Bismuth subsalicylate, Flunixin, Xylazine, Tolazoline, Butorphanol, Mineral oil, Activated charcoal, Epinephrine); and (8) 67 FR 62950, October 9, 2002, (Potassium sulfate and Calcium propionate).

IV. Statutory and Regulatory Authority

The Organic Foods Production Act of 1990 (OFPA), as amended (7 U.S.C. 6501 *et seq.*), authorizes the Secretary, at § 6517(d)(1), to make amendments to the National List based on proposed amendments developed by the NOSB. Sections 6518(k)(2) and 6518(n) of OFPA authorize the NOSB to develop proposed amendments to the National List for submission to the Secretary and establish a petition process by which persons may petition the NOSB for the purpose of having substances evaluated for inclusion onto or deletion from the National List. The National List petition process is implemented under § 205.607 of the NOS. The current petition process (65 FR 43259) can be accessed through the NOP Web site at <http://www.ams.usda.gov/nop>.

A. Executive Order 12866

This action has been determined to be non-significant for purposes of Executive Order 12866, and therefore, does not have to be reviewed by the Office of Management and Budget.

B. Executive Order 12988

Executive Order 12988 instructs each executive agency to adhere to certain requirements in the development of new and revised regulations in order to avoid unduly burdening the court system. The final rule was reviewed under this Executive Order and no additional related information has been obtained since then. This final rule is not intended to have a retroactive effect.

States and local jurisdictions are preempted under section 2115 of the Organic Foods Production Act (OFPA) (7 U.S.C. 6514) from creating programs of accreditation for private persons or State officials who want to become certifying agents of organic farms or handling operations. A governing State official would have to apply to USDA to

be accredited as a certifying agent, as described in section 2115(b) of the OFPA (7 U.S.C. 6514(b)). States are also preempted under sections 2104 through 2108 of the OFPA (7 U.S.C. 6503 through 7 U.S.C. 6507) from creating certification programs to certify organic farms or handling operations unless the State programs have been submitted to, and approved by, the Secretary as meeting the requirements of the OFPA.

Pursuant to section 2108(b)(2) of the OFPA (7 U.S.C. 6507(b)(2)), a State organic certification program may contain additional requirements for the production and handling of organically produced agricultural products that are produced in the State and for the certification of organic farm and handling operations located within the State under certain circumstances. Such additional requirements must: (a) Further the purposes of the OFPA, (b) not be inconsistent with the OFPA, (c) not be discriminatory toward agricultural commodities organically produced in other States, and (d) not be effective until approved by the Secretary.

Pursuant to section 2120 (f) of the OFPA (7 U.S.C. 6519(f)), this regulation would not alter the authority of the Secretary under the Federal Meat Inspection Act (21 U.S.C. 601 *et seq.*), the Poultry Products Inspections Act (21 U.S.C. 451 *et seq.*), or the Egg Products Inspection Act (21 U.S.C. 1031 *et seq.*), concerning meat, poultry, and egg products, nor any of the authorities of the Secretary of Health and Human Services under the Federal Food, Drug and Cosmetic Act (21 U.S.C. 301 *et seq.*), nor the authority of the Administrator of the Environmental Protection Agency (EPA) under the Federal Insecticide, Fungicide and Rodenticide Act (7 U.S.C. 136 *et seq.*).

Section 2121 of the OFPA (7 U.S.C. 6520) provides for the Secretary to establish an expedited administrative appeals procedure under which persons may appeal an action of the Secretary, the applicable governing State official, or a certifying agent under this title that adversely affects such person or is inconsistent with the organic certification program established under this title. The OFPA also provides that the U.S. District Court for the district in which a person is located has jurisdiction to review the Secretary's decision.

C. Regulatory Flexibility Act

The Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*) requires agencies to consider the economic impact of each rule on small entities and evaluate alternatives that would accomplish the

objectives of the rule without unduly burdening small entities or erecting barriers that would restrict their ability to compete in the market. The purpose is to fit regulatory actions to the scale of businesses subject to the action. Section 605 of the RFA allows an agency to certify a rule, in lieu of preparing an analysis, if the rulemaking is not expected to have a significant economic impact on a substantial number of small entities.

Pursuant to the requirements set forth in the RFA, the Agricultural Marketing Service (AMS) performed an economic impact analysis on small entities in the final rule published in the **Federal Register** on December 21, 2000. AMS has also considered the economic impact of this action on small entities and has determined that this final rule will have an impact on a substantial number of small entities. However, AMS has determined that the impact on entities affected by this rule will not be significant. The effect of this rule will be to allow the use of additional substances in agricultural production and handling. This action relaxes the regulations published in the final rule and provides small entities with more tools to use in day-to-day operations. The AMS concludes that the economic impact of this addition of allowed substances, if any, will be minimal and entirely beneficial to small agricultural service firms. Accordingly, the Administrator of the AMS hereby certifies that this rule will not have a significant economic impact on a substantial number of small entities.

Small agricultural service firms, which include producers, handlers, and accredited certifying agents, have been defined by the Small Business Administration (SBA) (13 CFR 121.201) as those having annual receipts of less than \$750,000 and small agricultural producers are defined as those having annual receipts of less than \$5,000,000.

The U.S. organic industry at the end of 2001 included nearly 6,600 certified crop and livestock operations, including organic production and handling operations, producers, and handlers. These operations reported certified acreage totaling more than 2.34 million acres, 72,209 certified livestock, and 5.01 million certified poultry. Data on the numbers of certified handling operations are not yet available, but likely number in the thousands, as they would include any operation that transforms raw product into processed products using organic ingredients. Growth in the U.S. organic industry has been significant at all levels. From 1997 to 2001, the total organic acreage grew by 74 percent; livestock numbers

certified organic grew by almost 300 percent over the same period, and poultry certified organic increased by 2,118 percent over this time. Sales growth of organic products has been equally significant, growing on average around 20 percent per year. Sales of organic products were approximately \$1 billion in 1993, but are estimated to reach \$13 billion this year, according to the Organic Trade Association (the association that represents the U.S. organic industry). In addition, USDA has accredited 85 certifying agents who have applied to USDA to be accredited in order to provide certification services to producers and handlers. A complete list of names and addresses of accredited certifying agents may be found on the AMS NOP Web site, at <http://www.ams.usda.gov/nop>. AMS believes that most of these entities would be considered small entities under the criteria established by the SBA.

D. Paperwork Reduction Act

Pursuant to the Paperwork Reduction Act of 1995, the existing information collection requirements for the NOP⁹ are approved under OMB number 0581-0181. No additional collection or recordkeeping requirements are imposed on the public by this final rule. Accordingly, OMB clearance is not required by section 350 (h) of the Paperwork Reduction Act, 44 U.S.C. 3501, *et seq.*, or OMB's implementing regulation at 5 CFR part 1320.

E. Comments Received

Altogether, 23 comments were received on these proposed revisions and amendments. Commenters included consumers, producers, processors, the National Organic Standards Board (NOSB), certifying agents, food industry organizations, State governments, and trade organizations.

Section 205.601 Synthetic Substances Allowed for Use in Organic Crop Production

No comments were opposed to the revision of the introductory text concerning use of materials as required in 205.203(c) and 205.206(a)-(d). One commenter, however, questioned whether every substance in 205.601 has to be measured against the criteria in 205.206(a)-(d). The commenter pointed out that algicides should be measured against these criteria in paragraphs 205.206(a)-(d), but that disinfectants, sanitizers, and cleaning materials in irrigation systems should not have to meet the criteria in (a)-(d). The commenter suggests revising paragraph 205.601(b) to include algicides and

removing the term algicides from 205.601(a). We agree that the use of disinfectants and sanitizers listed in § 205.601(a) should not be measured against the criteria in paragraphs 205.206 (a)–(d). Accordingly, we have amended the introductory text to exclude disinfectants and sanitizers. We disagree, however, with removing algicides from § 205.601(a). We recognize that there may be similar types of changes that could be made to improve the organization of the National List and the categories of materials and substances. Therefore, we will request that the NOSB begin work on addressing such organizational issues for inclusion in future rulemaking. One commenter asked that the final rule be written in plain English so that an average person will understand what is being said. We have made considerable efforts to write these regulations in plain English, but note that the regulations dealing with the National List are inherently difficult to understand because of their technical nature.

(a) As algicides, disinfectants and sanitizers, including irrigation cleaning systems—(3) Copper Sulfate. Two commenters opposed the addition of copper sulfate to the National List when it was published in December, 2000 and restated their opposition; one commenter cited problems with harmonization with European standards which do not allow the use of copper sulfate. USDA is currently engaged in discussions with the European Union (EU) concerning harmonization and mutual recognition of our respective standards for organic production and processing, and we believe these issues will be addressed in those discussions. Copper sulfate has been the subject of considerable debate and review at more than one NOSB public meeting, and the annotations restricting its use reflect an attempt by the NOSB to address all of the concerns raised regarding the use of copper sulfate in organic systems. Two commenters requested that the phrase “in aquatic rice systems” be added as it was stated in the NOSB recommendation. These two comments have merit and we have made the requested change.

(5) Ozone gas. No commenters opposed the addition of ozone gas.

(6) Peracetic acid. One commenter noted that many peracetic acid formulations contain small amounts of toxic stabilizer compounds, and that the National List should only be for formulations of this material that do not have synthetic stabilizers in them. However, we believe the NOSB understands the full nature of peracetic acid and its uses and made its

recommendation accordingly. The public is invited to petition the NOSB to reconsider any material at any time that new information becomes available. Such information should also be forwarded to the NOSB prior to its re-review of any materials on the National List before the sunset date of five years after being added to the List. One commenter asked that this paragraph be further amended to require that documentation be shown that alternatives including biocontrols have been tried. However, with the revision to the introductory text in this subsection, we believe the additional annotation is not necessary and the final rule remains as proposed.

(e) As insecticides (including acaricides or mite control)—(3) Copper Sulfate. The word “aquatic” will be added before the words “rice production” to be consistent with the revised wording in paragraph (a) (3).

(f) As insect attractants—Pheromones. Commenters pointed out that the word “attractants” may be somewhat inaccurate. Pheromones may also include mating disruption or other general confusion, not necessarily synonymous with attraction. We have amended the paragraph to state “as insect management.” We also received two comments urging a policy guidance statement be issued to clarify types of pheromones permitted as those that are EPA-exempt or EPA-registered without additional synthetic toxicants (unless those are also on the List) or those containing no List 1 or List 2 inert. We will publish on our Web site such policy guidance.

(i) As plant disease control—(3) Hydrated lime. Numerous commenters pointed out that the annotation is incorrectly written in the current regulations. As currently written, the annotation reads “must be used in a manner that minimizes copper accumulation in the soil.” However, there is no copper in hydrated lime. The annotation referred to an earlier reference to “Bordeaux mixes” that are a combination of copper sulfate plus hydrated lime. Accordingly, we have deleted the annotation altogether as suggested by the commenters.

(7) Peracetic acid. Commenters pointed out that the proposed annotation referring to EPA approval is unnecessary, as the material is currently regulated by EPA and it is unnecessary to restate EPA’s status in the NOP regulation. These comments have merit and we have amended the annotation to read “for use to control fire blight bacteria.” And one comment opposed the addition of additional synthetic materials to the National List,

specifically, the addition of paracetic acid to section 205.601. The commenter raised concerns that the addition of synthetic materials to the National List could continue a disturbing trend of moving organic systems away from the basic principles of minimizing use and dependence on purchased inputs, especially synthetic substances. Congress recognized that synthetic materials might be necessary for organic production to develop and that is why the National List was created in the first place. Moreover, the process of adding a material to the National List is sufficiently rigorous that by itself, the process will provide a natural limit to the number of materials that may be added to the List.

(k) As plant growth regulators. No commenters opposed to the addition of “gas” behind “ethylene.”

(m) As synthetic inert ingredients as classified by the EPA, for use with nonsynthetic substances or synthetic substances listed in this section and used as an active pesticide ingredient in accordance with any limitations on the use of such substances—(2) EPA List 3—Inerts of unknown toxicity—for use only in passive pheromone dispensers. One commenter objected to the addition of any List 3 Inert unless a Technical Advisory Panel (TAP) review is conducted and the NOSB approved the substance for addition to the National List. However, we believe the annotation accurately reflects the NOSB’s understanding that in passive pheromone dispensers, the allowance of List 3 Inerts poses no significant harm to sustainable systems, including crops, soil, and water. Accordingly, no change is made to this provision.

Section 205.602 Nonsynthetic Substances Prohibited for Use in Organic Crop Production

No comments were opposed to the addition of calcium chloride.

The language in the proposed rule on sodium nitrate differs in two places, and may be misleading. The amendment to paragraph (g) should read: Sodium nitrate—unless use is restricted to no more than 20 percent of the crop’s total nitrogen requirement; use in spirulina production is unrestricted until October 21, 2005.” Two commenters opposed the use of sodium nitrate in any amount, or for any crop production, and one of those commenters cited problems with harmonization with European standards for organic crop production. USDA is currently engaged in discussions with the European Union (EU) concerning harmonization and mutual recognition of our respective standards for organic production and processing, and we

believe these issues will be addressed in those discussions. Sodium nitrate was a subject of considerable debate and review at more than one NOSB public meeting, and the annotation restricting its use reflects an attempt by the NOSB to address all of the concerns that were raised regarding the use of sodium nitrate in organic systems.

The NOSB also commented that the natural substance sodium chloride (also known as salt) should be prohibited and added to 205.602, with the annotation that it be permitted in organic cotton production to comply with emergency spray programs or to prevent immediate loss of crop. The NOSB pointed out that failure to add this material to 205.602 means that it may be used without restriction, when the NOSB recommended its addition to the list of prohibited natural materials in 1995. However, we did not include this material for comment in the proposed rule that was issued in April 2003. Therefore, we believe it is inappropriate to add this material to this final rule without offering the public a chance to comment on the NOSB's recommendation. This material can be included in subsequent rulemaking so that the public can comment on its proposed addition to 205.602, with the annotation recommended by the NOSB.

Section 205.603 Synthetic Substances Allowed for Use in Organic Livestock Production

(b) As topical treatment, external parasiticide or local anesthetic as applicable—(4) hydrated lime. The annotation following hydrated lime refers to Bordeaux mixes, which the NOSB correctly points out is a crop protection material, not a livestock material. The NOSB recommended changing the annotation to replace "Bordeaux mixes" with "as external pest control." We agree and have revised the annotation accordingly.

(d) As feed additives—(1) DL-Methionine; DL-Methionine—hydroxy analog, and DL-Methionine—hydroxy analog calcium—for use only in organic poultry production until October 21, 2005. We received two comments in opposition to the addition of these three methionine materials as a feed additive for organic poultry feed; one comment cited problems with EU harmonization, which we have addressed above. Methionine has been the subject of considerable debate and review at more than one NOSB meeting, and the annotation restricting its use reflects an attempt by the NOSB to address all of the concerns raised regarding the use of methionine in organic systems.

(2) Trace minerals, used for enrichment or fortification when FDA approved. We received two comments raising concerns on this proposed change. One commenter seemed to think that we were eliminating trace minerals from allowed synthetic materials for use in livestock production. We are not eliminating their use; rather we eliminated the references to copper sulfate and magnesium sulfate to eliminate the perception that only those two trace minerals could be used since they were the only two examples listed. As long as the trace mineral is approved by FDA for use in feed supplements for the purpose of enrichment or fortification, the trace mineral is allowed under these regulations. Notwithstanding their allowed use in paragraph (d)(2), producers are also bound to comply with paragraphs (a) and (b) of § 205.237 dealing with livestock feed, including paragraph (b)(2) and (b)(6), which prohibit a producer from providing feed supplements or additives in amounts above those needed for adequate nutrition and health maintenance for the species at its specific stage of life or use feed additives and supplements in violation of the Federal Food, Drug, and Cosmetic Act. These livestock feed standards are also why we did not take the recommended changes of the second commenter that wanted a two-year period of use for minerals approved by the NOSB after a TAP review is conducted, and questioned NOP's policy with respect to trace minerals for animal feeds. This commenter cited an NOSB statement in 1995 that nutrients should come from organic sources, followed by non-synthetic sources if organic is unavailable, and only allowing synthetic sources of minerals if natural sources are unavailable. We believe that the regulations as written, especially § 205.237(a) addresses this concern by requiring feed to be 100 percent organic, with exceptions for nonsynthetic substances and synthetic substances as allowed under § 205.603(d).

Section 205.605 Nonagricultural (Nonorganic) Substances Allowed as Ingredients in or on Processed Products Labeled as "Organic" or "Made With Organic (Specified Ingredients or Food Groups)"

The proposed rule contained a typographical error, listing both nonsynthetic and synthetic lists as § 205.605(a). The synthetic nonagricultural substance list should be denoted as § 205.605(b).

(b) Synthetics allowed—Tartaric acid. As noted in the proposed rule, tartaric

acid was one of three materials that were inadvertently omitted from publication on the National List in the final regulations that were published on December 21, 2000, and the proposed rule would amend the National List to include tartaric acid in § 205.605(a). However, the NOSB pointed out in their comments that the NOSB had approved both synthetic and nonsynthetic forms of tartaric acid. Accordingly, § 205.605(a) and (b) are amended to include tartaric acid.

Ethylene—we received one comment asking why this is not in the list of synthetic materials approved for crop production, since it deals with ripening for fruit. However, its use is clearly intended for fruit that has left the farm and is enroute to final consumers and is more appropriately considered part of a processing function to prepare the fruit for final purchase. Three commenters opposed its addition to the National List, citing general concerns about adding more synthetic materials to the National List and degrading the status of organic products and one of those comments cited problems with European harmonization.

Congress recognized that synthetic materials might be necessary for organic production to develop and that is why the National List was created in the first place. Moreover, the process of adding a material to the National List is sufficiently rigorous that by itself, the process will provide a natural limit to the number of materials that may be added to the List.

The USDA is currently engaged in discussions with the European Union (EU) concerning harmonization and mutual recognition of our respective standards for organic production and processing, and we believe these issues will be addressed in those discussions.

Pursuant to 5 U.S.C. 553, it is found and determined that good cause exists for not postponing the effective date of this action until 30 days after publication in the *Federal Register*.

This rule reflects recommendations submitted to the Secretary by the NOSB. The ten substances proposed to be added to the National List were based on petitions from the industry and evaluated by the NOSB using criteria in the Act and the regulations. Because these substances are critical to organic production and handling operations, the National List should be amended as soon as possible.

List of Subjects in 7 CFR Part 205

Administrative practice and procedure, Agriculture, Animals, Archives and records, Imports, Labeling, Organically produced products, Plants,

Reporting and recordkeeping requirements, Seals and insignia, Soil conservation.

■ For the reasons set forth in the preamble, 7 CFR part 205, Subpart G is amended as follows:

PART 205—NATIONAL ORGANIC PROGRAM

■ 1. The authority citation for 7 CFR part 205 continues to read as follows:

Authority: 7 U.S.C. 6501–6522.

- 2. Section 205.601 is amended by:
 - a. Revising the introductory text.
 - b. Redesignating paragraphs (a)(3) and (a)(4) as paragraphs (a)(4) and (a)(7), respectively.
 - c. Adding new paragraphs (a)(3), (a)(5), and (a)(6).
 - d. Revising the word “demisters” in newly redesignated paragraph (a)(7) to read “demossers.”
 - e. Redesignating paragraphs (e)(3) through (e)(7) as paragraphs (e)(4) through (e)(8).
 - f. Adding a new paragraph (e)(3).
 - g. Revising paragraph (f).
 - h. Revising paragraph (i)(3).
 - i. Redesignating paragraphs (i)(7) through (i)(10) as paragraphs (i)(8) through (i)(11), respectively.
 - j. Adding a new paragraph (i)(7).
 - k. Revising paragraph (k).
 - l. Adding new paragraph (m)(2).

The revisions read as follows:

§ 205.601 Synthetic substances allowed for use in organic crop production.

In accordance with restrictions specified in this section, the following synthetic substances may be used in organic crop production: *Provided*, That, use of such substances do not contribute to contamination of crops, soil, or water. Substances allowed by this section, except disinfectants and sanitizers in paragraph (a) and those substances in paragraphs (c), (j), (k), and (l) of this section, may only be used when the provisions set forth in § 205.206(a) through (d) prove insufficient to prevent or control the target pest.

(a) * * *

(3) Copper sulfate—for use as an algicide in aquatic rice systems, is limited to one application per field during any 24-month period. Application rates are limited to those which do not increase baseline soil test values for copper over a timeframe agreed upon by the producer and accredited certifying agent.

* * * * *

(5) Ozone gas—for use as an irrigation system cleaner only.

(6) Peracetic acid—for use in disinfecting equipment, seed, and asexually propagated planting material.

* * * * *

(e) * * *

(3) Copper sulfate—for use as tadpole shrimp control in aquatic rice production, is limited to one application per field during any 24-month period. Application rates are limited to levels which do not increase baseline soil test values for copper over a timeframe agreed upon by the producer and accredited certifying agent.

* * * * *

(f) As insect management. Pheromones.

* * * * *

(i) * * *

(3) Hydrated lime.
(7) Peracetic acid—for use to control fire blight bacteria.

* * * * *

(k) As plant growth regulators. Ethylene gas—for regulation of pineapple flowering.

* * * * *

(m) * * *

(2) EPA List 3—Inerts of unknown toxicity—for use only in passive pheromone dispensers.

* * * * *

■ 3. Section 205.602 is revised to read as follows:

§ 205.602 Nonsynthetic substances prohibited for use in organic crop production.

The following nonsynthetic substances may not be used in organic crop production:

- (a) Ash from manure burning.
- (b) Arsenic.
- (c) Calcium chloride, brine process is natural and prohibited for use except as a foliar spray to treat a physiological disorder associated with calcium uptake.
- (d) Lead salts.
- (e) Potassium chloride—unless derived from a mined source and applied in a manner that minimizes chloride accumulation in the soil.
- (f) Sodium fluoaluminat (mined).
- (g) Sodium nitrate—unless use is restricted to no more than 20% of the crop's total nitrogen requirement; use in spirulina production is unrestricted until October 21, 2005.
- (h) Strychnine.
- (i) Tobacco dust (nicotine sulfate).
- (j)–(z) [Reserved]

■ 4. Section 205.603 is amended by:

- a. Revising paragraph (a).
- b. Revising the word “chlorohexidine” in paragraph (a)(4) to read “chlorhexidine”.

■ c. Redesignating paragraphs (b)(1) through (b)(5) as (b)(2) through (b)(6), respectively and redesignating paragraph (b)(6) as paragraph (b)(1).

■ d. Revising newly redesignated paragraph (b)(4).

■ e. Redesignating paragraphs (d)(1) and (d)(2) as paragraphs (d)(2) and (d)(3), respectively.

■ f. Adding a new paragraph (d)(1).

■ g. Revising newly redesignated paragraph (d)(2).

■ h. Revising the designation for paragraph (f) to read “(e)(1)”.

■ i. Reserving paragraphs (f)–(z).

The revisions and addition read as follows:

§ 205.603 Synthetic substances allowed for use in organic livestock production.

* * * * *

(a) As disinfectants, sanitizer, and medical treatments as applicable.

(1) Alcohols.

(i) Ethanol—disinfectant and sanitizer only, prohibited as a feed additive.

(ii) Isopropanol—disinfectant only.

(2) Aspirin—approved for health care use to reduce inflammation.

(3) Biologics—Vaccines.

(4) Chlorhexidine—Allowed for surgical procedures conducted by a veterinarian. Allowed for use as a teat dip when alternative germicidal agents and/or physical barriers have lost their effectiveness.

(5) Chlorine materials—disinfecting and sanitizing facilities and equipment. Residual chlorine levels in the water shall not exceed the maximum residual disinfectant limit under the Safe Drinking Water Act.

(i) Calcium hypochlorite.

(ii) Chlorine dioxide.

(iii) Sodium hypochlorite.

(6) Electrolytes—without antibiotics.

(7) Glucose.

(8) Glycerine—Allowed as a livestock teat dip, must be produced through the hydrolysis of fats or oils.

(9) Hydrogen peroxide.

(10) Iodine.

(11) Magnesium sulfate.

(12) Oxytocin—use in postparturition therapeutic applications.

(13) Parasiticides. Ivermectin—prohibited in slaughter stock, allowed in emergency treatment for dairy and breeder stock when organic system plan-approved preventive management does not prevent infestation. Milk or milk products from a treated animal cannot be labeled as provided for in subpart D of this part for 90 days following treatment. In breeder stock, treatment cannot occur during the last third of gestation if the progeny will be sold as organic and must not be used during the lactation period of breeding stock.

(14) Phosphoric acid—allowed as an equipment cleaner, *Provided*, That, no direct contact with organically managed livestock or land occurs.

(b) * * *

(4) Lime, hydrated—as external pest control, not permitted to cauterize physical alterations or deodorize animal wastes.

* * * * *

(d) * * *

(1) DL-Methionine, DL-Methionine—hydroxy analog, and DL-Methionine—hydroxy analog calcium—for use only in organic poultry production until October 21, 2005.

(2) Trace minerals, used for enrichment or fortification when FDA approved.

* * * * *

■ 5. Section 205.605 is revised to read as follows:

§ 205.605 Nonagricultural (nonorganic) substances allowed as ingredients in or on processed products labeled as “organic” or “made with organic (specified ingredients or food group(s)).”

The following nonagricultural substances may be used as ingredients in or on processed products labeled as “organic” or “made with organic (specified ingredients or food group(s))” only in accordance with any restrictions specified in this section.

(a) *Nonsynthetics allowed:*

Acids (Alginate; Citric—produced by microbial fermentation of carbohydrate substances; and Lactic).

Agar-agar.

Bentonite.

Calcium carbonate.

Calcium chloride.

Carageenan.

Colors, nonsynthetic sources only.

Dairy cultures.

Diatomaceous earth—food filtering aid only.

Enzymes—must be derived from edible, nontoxic plants, nonpathogenic fungi, or nonpathogenic bacteria.

Flavors, nonsynthetic sources only and must not be produced using synthetic solvents and carrier systems or any artificial preservative.

Kaolin.

Magnesium sulfate, nonsynthetic sources only.

Nitrogen—oil-free grades.

Oxygen—oil-free grades.

Perlite—for use only as a filter aid in food processing.

Potassium chloride.

Potassium iodide.

Sodium bicarbonate.

Sodium carbonate.

Tartaric acid.

Waxes—nonsynthetic (Carnauba wax; and Wood resin).

Yeast—nonsynthetic, growth on petrochemical substrate and sulfite waste liquor is prohibited (Autolysate; Bakers; Brewers; Nutritional; and Smoked—nonsynthetic smoke flavoring process must be documented).

(b) *Synthetics allowed:*

Alginates.

Ammonium bicarbonate—for use only as a leavening agent.

Ammonium carbonate—for use only as a leavening agent.

Ascorbic acid.

Calcium citrate.

Calcium hydroxide.

Calcium phosphates (monobasic, dibasic, and tribasic).

Carbon dioxide.

Chlorine materials—disinfecting and sanitizing food contact surfaces, *Except*,

That, residual chlorine levels in the water shall not exceed the maximum residual disinfectant limit under the Safe Drinking Water Act (Calcium hypochlorite; Chlorine dioxide; and Sodium hypochlorite).

Ethylene—allowed for postharvest ripening of tropical fruit and degreening of citrus.

Ferrous sulfate—for iron enrichment or fortification of foods when required by regulation or recommended (independent organization).

Glycerides (mono and di)—for use only in drum drying of food.

Glycerin—produced by hydrolysis of fats and oils.

Hydrogen peroxide.

Lecithin—bleached.

Magnesium carbonate—for use only in agricultural products labeled “made with organic (specified ingredients or food group(s))” prohibited in agricultural products labeled “organic”.

Magnesium chloride—derived from sea water.

Magnesium stearate—for use only in agricultural products labeled “made with organic (specified ingredients or food group(s))” prohibited in agricultural products labeled “organic”.

Nutrient vitamins and minerals, in accordance with 21 CFR 104.20, Nutritional Quality Guidelines For Foods.

Ozone.

Pectin (low-methoxy).

Phosphoric acid—cleaning of food-contact surfaces and equipment only.

Potassium acid tartrate.

Potassium tartrate made from tartaric acid.

Potassium carbonate.

Potassium citrate.

Potassium hydroxide—prohibited for use in lye peeling of fruits and vegetables.

Potassium iodide—for use only in agricultural products labeled “made

with organic (specified ingredients or food group(s))” prohibited in agricultural products labeled “organic”.

Potassium phosphate—for use only in agricultural products labeled “made with organic (specific ingredients or food group(s))” prohibited in agricultural products labeled “organic”.

Silicon dioxide.

Sodium citrate.

Sodium hydroxide—prohibited for use in lye peeling of fruits and vegetables.

Sodium phosphates—for use only in dairy foods.

Sulfur dioxide—for use only in wine labeled “made with organic grapes.”

Provided, That, total sulfite concentration does not exceed 100 ppm.

Tartaric acid.

Tocopherols—derived from vegetable oil when rosemary extracts are not a suitable alternative.

Xanthan gum.

(c)–(z) [Reserved]

■ 6. In § 205.607, paragraph (c) is revised to read as follows:

§ 205.607 Amending the National List.

* * * * *

(c) A petition to amend the National List must be submitted to: Program Manager, USDA/AMS/TMP/NOP, 1400 Independence Ave., SW., Room 4008–So., Ag Stop 0268, Washington, DC 20250.

* * * * *

Dated: October 27, 2003.

A.J. Yates,

Administrator, Agricultural Marketing Service.

[FR Doc. 03–27415 Filed 10–30–03; 8:45 am]

BILLING CODE 3410–02–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

18 CFR Parts 101, 141, 201, 260, 352, and 357

[Docket Nos. RM02–14–000 and RM02–14–001; Order No. 634–A]

Regulation of Cash Management Practices

October 23, 2003.

AGENCY: Federal Energy Regulatory Commission, Department of Energy.

ACTION: Final rule.

SUMMARY: The Federal Energy Regulatory Commission is amending its regulations to implement reporting requirements for FERC-regulated entities that participant in cash

Proposed Rules

Federal Register

Vol. 68, No. 73

Wednesday, April 16, 2003

This section of the FEDERAL REGISTER contains notices to the public of the proposed issuance of rules and regulations. The purpose of these notices is to give interested persons an opportunity to participate in the rule making prior to the adoption of the final rules.

DEPARTMENT OF AGRICULTURE

Agricultural Marketing Service

7 CFR Part 205

[Docket Number TM-02-03]

RIN # 0581-AA40

National Organic Program; Proposed Amendments to the National List of Allowed and Prohibited Substances

AGENCY: Agricultural Marketing Service, USDA.

ACTION: Proposed rule.

SUMMARY: This proposed rule would amend the U.S. Department of Agriculture's (USDA) National List of Allowed and Prohibited Substances (National List) to reflect recommendations submitted to the Secretary by the National Organic Standards Board (NOSB) from June 6, 2000 through October 20, 2002. Technical corrections have also been included in this proposed rule to clarify specific sections of the National List and adequately reflect previous NOSB recommendations. Consistent with recommendations from the NOSB, this proposed rule would: add ten substances, along with any restrictive annotations, to the National List, revise the annotations of two substances, and make eight technical revisions. In addition to amending the National List, this proposed rule would offer the opportunity for public comment on the use of ethylene in organic crop production.

DATES: Comments must be received by April 28, 2003.

ADDRESSES: Interested persons may comment on this proposed rule using the following procedures:

- **Mail:** Comments may be submitted by mail to: Richard H. Mathews, Program Manager, National Organic Program, USDA-AMS-TMP-NOP, 1400 Independence Ave., SW., Room 4008-So., Ag Stop 0268, Washington, DC 20250.

- **E-mail:** Comments may be submitted via the internet to: National.List@usda.gov.

- **Fax:** Comments may be submitted by fax to: (202) 205-7808.

- **Written comments** on this proposed rule should be identified with the docket number TMD-02-03. Commenters should identify the topic and section number of this proposed rule to which the comment refers.

- **Clearly indicate** if you are for or against the proposed rule or some portion of it and your reason for it. Include recommended language changes as appropriate.

- **Include a copy of articles or other references** that support your comments. Only relevant material should be submitted.

It is our intention to have all comments to this proposed rule, whether submitted by mail, E-mail, or fax, available for viewing on the NOP homepage. Comments submitted in response to this proposed rule will be available for viewing in person at USDA-AMS, Transportation and Marketing, Room 4008-South Building, 1400 Independence Ave., SW., Washington, DC, from 9 a.m. to 12 noon and from 1 p.m. to 4 p.m., Monday through Friday (except official Federal holidays). Persons wanting to visit the USDA South Building to view comments received in response to this proposed rule are requested to make an appointment in advance by calling (202) 720-3252.

FOR FURTHER INFORMATION CONTACT: Toni A. Strother, Agricultural Marketing Specialist, Telephone: (202) 720-3252; Fax: (202) 205-7808.

SUPPLEMENTARY INFORMATION:

I. Background

On December 21, 2000 the Secretary established, within the National Organic Standards (NOS) [7 CFR part 205], the National List (§§ 205.600 through 205.607). The National List is the Federal list that identifies synthetic substances and ingredients that are allowed and nonsynthetic (natural) substances and ingredients that are prohibited for use in organic production and handling. Since established, the National List has not been amended. However, under the authority of the Organic Foods Production Act of 1990 (OFPA), as amended (7 U.S.C. 6501 *et seq.*), the National List can be amended

by the Secretary based on proposed amendments developed by the NOSB.

This proposed rule would amend the National List to reflect recommendations submitted to the Secretary by the NOSB from June 6, 2000 through October 20, 2002. Between the specified time period, the NOSB has recommended that the Secretary add ten substances to §§ 205.601 through 205.603 of the National List based on petitions received from industry participants. These substances were evaluated by the NOSB using the criteria specified in OFPA (7 U.S.C. 6517 and 6518) and the NOS. The NOSB also recommended that the Secretary revise the annotations of two substances included within sections 205.602 and 205.605.

The NOSB has recommended that the Secretary add additional substances to sections 205.603 and 205.605 which have not been included in this proposed rule but are under review and, as appropriate, will be included in future rulemaking.

In addition to the amendments made based on June 6, 2000 through October 20, 2002 NOSB recommendations, this proposed rule would also make technical revisions to specific sections of the National List that provide clarity and adequately reflect the intent of the paragraphs identified within those sections.

II. Overview of Proposed Amendments

The following provides an overview of the proposed amendments made to designated sections of the National List:

Section 205.601 Synthetic Substances Allowed for Use in Organic Crop Production

This proposed rule would amend the introductory paragraph of § 205.601 by adding language which clarifies that synthetic substances used in crop production must be used in a manner which does not contribute to contamination of crops, soil, or water. The proposed amendment further clarifies that synthetic substances, except those in paragraphs (c), (j), (k), and (l), may only be used when the provisions of § 205.206(a) through (d) prove insufficient to prevent or control the target pest.

This proposed rule would amend paragraph (a) of § 205.601 (as algicide, disinfectants and sanitizers, including

irrigation cleaning systems) by adding the following materials:

Copper Sulfate, for use as an algicide, is limited to one application per field during any 24-month period.

Application rates are limited to those which do not increase baseline soil test values for copper over a timeframe agreed upon by the producer and accredited certifying agent.

Ozone Gas, for use as an irrigation system cleaner only; and

Peracetic acid, for use in disinfecting equipment, seed, and asexually propagated planting material.

Paragraph (a) is proposed to be further amended by correcting the spelling of the word "demisters" contained in subparagraph (a)(4) to "demossers."

This proposed rule would amend paragraph (e) of § 205.601 by adding the following material:

Copper Sulfate, for use as tadpole shrimp control in rice production, is limited to one application per field during any 24-month period.

Application rates are limited to levels which do not increase baseline soil test values for copper over a timeframe agreed upon by the producer and accredited certifying agent.

This proposed rule would amend paragraph (i) of § 205.601 (as plant disease control) by adding the following substance:

Peracetic acid, for use to control fire blight bacteria when approved by the Environmental Protection Agency (EPA) under a Special Local Need (24c) registration.

This proposed rule would revise paragraph (k) of § 205.601 (as plant growth regulators) by inserting the word "gas" behind "ethylene" to be consistent with the June 2000 NOSB recommendation for the substance. Section 205.601(k) will now read "As plant growth regulators—Ethylene gas, for regulation of pineapple flowering."

This proposed rule revises paragraph (m) of § 205.601 by inserting a new subpart (2) as follows:

(2) EPA List 3—Inerts of unknown toxicity—for use only in passive pheromone dispensers.

Section 205.602 Nonsynthetic Substances Prohibited for Use in Organic Crop Production

This proposed rule would amend § 205.602 by adding the following substance:

Calcium chloride, except as a brine-sourced foliar spray to treat physiological disorders associated with calcium uptake.

This proposed rule revises current paragraph (h) of § 205.602 by amending its annotation to read as follows:

Sodium nitrate—unless use is restricted to no more than 20% of the

crop's total nitrogen requirement; use in spirulina production is unrestricted until October 21, 2005.

Section 205.603 Synthetic Substances Allowed for Use in Organic Livestock Production

This proposed rule would revise current subparagraph (4) of § 205.603 (a) by correcting the spelling of the word "chlorohexidine" to "chlorhexidine."

This proposed rule would amend paragraph (d) of § 205.603 (as feed additives) by adding the following substances:

DL—Methionine, DL—Methionine—Hydroxy Analog, and DL—Methionine—Hydroxy Analog Calcium—for use only in organic poultry production until October 21, 2005.

This proposed rule would revise current subparagraph (1) of § 205.603 (d) by removing examples (i) and (ii), copper sulfate and magnesium sulfate, as they are both approved for use by FDA and do not need to be listed individually as examples. As currently published, subparagraphs § 205.603 (d) (1) (i) and (ii) may mislead readers to believe that the use of trace minerals are limited only to copper sulfate and magnesium sulfate. Therefore, the revision made in this proposed rule for current subparagraph (1) of § 205.603 (d) would read "Trace minerals, used for enrichment or fortification when FDA approved."

This proposed rule would amend current paragraph (e) of § 205.603 (As synthetic inert ingredients as classified by the Environmental Protection Agency (EPA), for use with nonsynthetic substances or synthetic substances listed in this section and used as active pesticide ingredients in accordance with any limitations on the use of such substances.) by redesignating current paragraph (f) of § 205.603 as new subparagraph (1) under § 205.603 (e). While drafting § 205.603 for final publication in the **Federal Register**, current paragraph (f) was intended to be designated as § 205.603 (e) (1), however, its designation was not properly assigned. Therefore, this proposed rule redesignates current paragraph (f) of § 205.603 as subparagraph (e) (1) of the same section.

Section 205.605 Nonagricultural (nonorganic) Substances Allowed as Ingredients In or On Processed Products Labeled as "Organic" or "Made with Organic (specified ingredients or food group(s))"

This proposed rule would amend current paragraph (a) of § 205.605 by adding agar-agar, carageenan and tartaric acid as technical corrections.

These substances were included on the National List proposed in the **Federal Register** on December 16, 1997, but were inadvertently removed from the National List published in the **Federal Register** on March 13, 2000, proposed rule and on December 21, 2000, Final Rule (7 CFR Part 205).

This proposed rule would revise current paragraph (b) (10) of § 205.605 by amending its annotation to read as follows:

Ethylene, allowed for postharvest ripening of tropical fruit and degreening of citrus.

III. Request for Public Comment on the Use of Ethylene

Ethylene, for organic crop production, was a substance that was petitioned and reviewed for inclusion onto the National List after promulgation of the proposed rule published in the **Federal Register** on March 13, 2000. The NOSB approved and recommended that ethylene gas be included on the National List with the annotation "for regulation of pineapple flowering." After receiving the NOSB recommendation for the material, the NOP, while finalizing the NOS, included the material on the National List without receiving public comment on the material through the Federal rulemaking process. As a result, this proposed rule requests public comment on the use of ethylene gas for regulation of pineapple flowering.

IV. Related Documents

Eight notices were published regarding the meetings of the NOSB and its deliberations on recommendations and substances petitioned for amending the National List. Substances and recommendations included in this proposed rule were announced for NOSB deliberation in the following **Federal Register** Notices: (1) 64 FR 54858, October 8, 1999 (Ethylene); (2) 65 FR 33802, May 25, 2000, (Ethylene gas); (3) 65 FR 64657, October 30, 2000, (Calcium borogluconate and Peracetic acid); (4) 66 FR 10873, February 20, 2001, (Poloxalene); (5) 66 FR 48654, September 21, 2001, (Calcium chloride, Copper sulfate, Methionine); (6) 67 FR 19375, April 19, 2002, (Potassium sorbate and Sodium propionate); (7) 67 FR 54784, August 26, 2002, (Ozone gas, Pheromones, Sodium (Chilean) nitrate, Propylene glycol, Magnesium hydroxide/Magnesium oxide, Kaolin pectin, Bismuth subsalicylate, Flunixin, Xylazine, Tolazoline, Butorphanol, Mineral oil, Activated charcoal, Epinephrine); and (8) 67 FR 62950,

October 9, 2002, (Potassium sulfate and Calcium propionate).

V. Statutory and Regulatory Authority

The Organic Foods Production Act of 1990 (OFPA), as amended (7 U.S.C. 6501 *et seq.*), authorizes the Secretary, at section 6517(d)(1), to make amendments to the National List based on proposed amendments developed by the NOSB. Sections 6518(k)(2) and 6518(n) of OFPA authorize the NOSB to develop proposed amendments to the National List for submission to the Secretary and establish a petition process by which persons may petition the NOSB for the purpose of having substances evaluated for inclusion onto or deletion from the National List. The National List petition process is implemented under § 205.607 of the NOS. The current petition process (65 FR 43259) can be accessed through the NOP Web site at <http://www.ams.usda.gov/nop>.

A. Executive Order 12866

This action has been determined to be non-significant for purposes of Executive Order 12866, and therefore, does not have to be reviewed by the Office of Management and Budget.

B. Executive Order 12988

Executive Order 12988 instructs each executive agency to adhere to certain requirements in the development of new and revised regulations in order to avoid unduly burdening the court system. The final rule was reviewed under this Executive Order and no additional related information has been obtained since then. This proposed rule is not intended to have a retroactive effect.

States and local jurisdictions are preempted under section 2115 of the Organic Foods Production Act (OFPA) (7 U.S.C. 6514) from creating programs of accreditation for private persons or State officials who want to become certifying agents of organic farms or handling operations. A governing State official would have to apply to USDA to be accredited as a certifying agent, as described in section 2115(b) of the OFPA (7 U.S.C. 6514(b)). States are also preempted under sections 2104 through 2108 of the OFPA (7 U.S.C. 6503 through 6507) from creating certification programs to certify organic farms or handling operations unless the State programs have been submitted to, and approved by, the Secretary as meeting the requirements of the OFPA.

Pursuant to section 2108(b)(2) of the OFPA (7 U.S.C. 6507(b)(2)), a State organic certification program may contain additional requirements for the production and handling of organically

produced agricultural products that are produced in the State and for the certification of organic farm and handling operations located within the State under certain circumstances. Such additional requirements must: (a) Further the purposes of the OFPA, (b) not be inconsistent with the OFPA, (c) not be discriminatory toward agricultural commodities organically produced in other States, and (d) not be effective until approved by the Secretary.

Pursuant to section 2120(f) of the OFPA (7 U.S.C. 6519(f)), this regulation would not alter the authority of the Secretary under the Federal Meat Inspection Act (21 U.S.C. 601 *et seq.*), the Poultry Products Inspections Act (21 U.S.C. 451 *et seq.*), or the Egg Products Inspection Act (21 U.S.C. 1031 *et seq.*), concerning meat, poultry, and egg products, nor any of the authorities of the Secretary of Health and Human Services under the Federal Food, Drug and Cosmetic Act (21 U.S.C. 301 *et seq.*), nor the authority of the Administrator of the Environmental Protection Agency (EPA) under the Federal Insecticide, Fungicide and Rodenticide Act (7 U.S.C. 136 *et seq.*).

Section 2121 of the OFPA (7 U.S.C. 6520) provides for the Secretary to establish an expedited administrative appeals procedure under which persons may appeal an action of the Secretary, the applicable governing State official, or a certifying agent under this title that adversely affects such person or is inconsistent with the organic certification program established under this title. The OFPA also provides that the U.S. District Court for the district in which a person is located has jurisdiction to review the Secretary's decision.

C. Regulatory Flexibility Act

The Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*) requires agencies to consider the economic impact of each rule on small entities and evaluate alternatives that would accomplish the objectives of the rule without unduly burdening small entities or erecting barriers that would restrict their ability to compete in the market. The purpose is to fit regulatory actions to the scale of businesses subject to the action.

Pursuant to the requirements set forth in the RFA, the Agricultural Marketing Service (AMS) performed an economic impact analysis on small entities in the final rule published in the **Federal Register** on December 21, 2000. AMS has also considered the economic impact of this action on small entities. Due to the changes reflected in this proposed rule that allow the use of

additional substances in agricultural production and handling, the Administrator of AMS certifies that this proposed rule will not have a significant economic impact on a substantial number of small entities. This action relaxes the regulations published in the final rule and provides small entities with more tools to use in day-to-day operations. Small agricultural service firms, which include producers, handlers, and accredited certifying agents, have been defined by the Small Business Administration (SBA) (13 CFR 121.201) as those having annual receipts of less than \$750,000 and small agricultural producers are defined as those having annual receipts of less than \$5,000,000.

The U.S. organic industry at the end of 2001 included nearly 6,600 certified crop and livestock operations, including organic production and handling operations, producers, and handlers. These operations reported certified acreage totaling more than 2.34 million acres, 72,209 certified livestock, and 5.01 million certified poultry. Data on the numbers of certified handling operations are not yet available, but likely number in the thousands, as they would include any operation that transforms raw product into processed products using organic ingredients. Growth in the U.S. organic industry has been significant at all levels. From 1997 to 2001, the total organic acreage grew by 74 percent; livestock numbers certified organic grew by almost 300 percent over the same period, and poultry certified organic increased by 2,118 percent over this time. Sales growth of organic products has been equally significant, growing on average around 20 percent per year. Sales of organic products were approximately \$1 billion in 1993, but are estimated to reach \$13 billion this year, according to the Organic Trade Association (the association that represents the U.S. organic industry). In addition, USDA has accredited 81 certifying agents who have applied to USDA to be accredited in order to provide certification services to producers and handlers. A complete list of names and addresses of accredited certifying agents may be found on the AMS NOP Web site, at <http://www.ams.usda.gov/nop>. AMS believe that most of these entities would be considered small entities under the criteria established by the SBA.

Additional regulatory flexibility analysis beyond the regulatory flexibility analysis published in the NOP final rule on December 21, 2000, is not required for the purposes of this proposed rule. Comments from small entities affected by parts of this

proposed rule will be considered in relation to the requirements of the RFA. These comments must be submitted separately and cite 5 U.S.C. 609 in the correspondence.

D. Paperwork Reduction Act

Pursuant to the Paperwork Reduction Act of 1995, the existing information collection requirements for the NOP are approved under OMB number 0581-0181. No additional collection or recordkeeping requirements are imposed on the public by this proposed rule. Accordingly, OMB clearance is not required by section 350(h) of the Paperwork Reduction Act, 44 U.S.C. 3501, *et seq.*, or OMB's implementing regulation at 5 CFR part 1320.

E. General Notice of Public Rulemaking

This proposed rule reflects recommendations submitted to the Secretary by the NOSB. The ten substances proposed to be added to the National List were based on petitions from the industry and evaluated by the NOSB using criteria in the Act and the regulations. Because these substances are critical to organic production and handling operations, producers and handlers should be able to use them in their operations as soon as possible. Accordingly, AMS believes that a 10-day period for interested persons to comment on this rule is appropriate.

List of Subjects in 7 CFR Part 205

Administrative practice and procedure, Agriculture, Animals, Archives and records, Imports, Labeling, Organically produced products, Plants, Reporting and recordkeeping requirements, Seals and insignia, Soil conservation.

For the reasons set forth in the preamble, 7 CFR Part 205, Subpart G is proposed to be amended as follows:

PART 205—NATIONAL ORGANIC PROGRAM

1. The authority citation for 7 CFR Part 205 continues to read as follows:

Authority: 7 U.S.C. 6501-6522.

2. Section 205.601 is amended by:

- a. Revising the introductory text.
- b. Redesignating paragraphs (a)(3) and (a)(4) as paragraphs (a)(4) and (a)(7), respectively.
- c. Adding new paragraphs (a)(3), (a)(5), and (a)(6).
- d. Revising the word "demisters" in newly redesignated paragraph (a)(7) to read "demossers".
- e. Redesignating paragraphs (e)(3) through (e)(7) as paragraphs (e)(4) through (e)(8).
- f. Adding a new paragraph (e)(3).

g. Redesignating paragraphs (i)(7) through (i)(10) as paragraphs (i)(8) through (i)(11), respectively.

h. Adding a new paragraph (i)(7).

i. Revising paragraph (k).

j. Adding new paragraph (m)(2).

The revisions read as follows:

§ 205.601 Synthetic substances allowed for use in organic crop production.

In accordance with restrictions specified in this section, the following synthetic substances may be used in organic crop production: Provided, That, use of such substances do not contribute to contamination of crops, soil, or water. Substances allowed by this section, except those in paragraphs (c), (j), (k), and (l) of this section, may only be used when the provisions set forth in § 205.206(a) through (d) prove insufficient to prevent or control the target pest.

(a) * * *

(3) Copper sulfate—for use as an algicide, is limited to one application per field during any 24-month period. Application rates are limited to those which do not increase baseline soil test values for copper over a timeframe agreed upon by the producer and accredited certifying agent.

* * * * *

(5) Ozone gas—for use as an irrigation system cleaner only.

(6) Peracetic acid—for use in disinfecting equipment, seed, and asexually propagated planting material.

* * * * *

(e) * * *

(3) Copper Sulfate—for use as tadpole shrimp control in rice production, is limited to one application per field during any 24-month period. Application rates are limited to levels which do not increase baseline soil test values for copper over a timeframe agreed upon by the producer and accredited certifying agent.

* * * * *

(i) * * *

(7) Peracetic acid—for use to control fire blight bacteria when approved by the Environmental Protection Agency (EPA) under a Special Local Need (24c) registration.

* * * * *

(k) As plant growth regulators. Ethylene gas—for regulation of pineapple flowering.

* * * * *

(m) * * *

(2) EPA List 3—Inerts of unknown toxicity—for use only in passive pheromone dispensers.

* * * * *

3. Section 205.602 is revised to read as follows:

§ 205.602 Nonsynthetic substances prohibited for use in organic crop production.

The following nonsynthetic substances may not be used in organic crop production:

- (a) Ash from manure burning.
 - (b) Arsenic.
 - (c) Calcium chloride, brine process is natural and prohibited for use except as a foliar spray to treat a physiological disorder associated with calcium uptake.
 - (d) Lead salts.
 - (e) Potassium chloride—unless derived from a mined source and applied in a manner that minimizes chloride accumulation in the soil.
 - (f) Sodium fluoaluminate (mined).
 - (g) Sodium nitrate—unless use is restricted to no more than 20% of the crop's total nitrogen requirement, or until October 21, 2005; for unrestricted use in spirulina production.
 - (h) Strychnine.
 - (i) Tobacco dust (nicotine sulfate).
 - (j)—(z) [Reserved]
4. Section 205.603 is amended by:
- a. Revising paragraph (a).
 - b. Revising the word "chlorohexidine" in paragraph (a)(4) to read "chlorhexidine".
 - c. Redesignating paragraphs (b)(1) through (b)(5) and (b)(6) as (b)(2) through (b)(6) and (b)(1), respectively.
 - (d) Redesignating paragraphs (d)(1) and (d)(2) as paragraphs (d)(2) and (d)(3), respectively.
 - e. Adding a new paragraph (d)(1).
 - f. Revising newly redesignated paragraph (d)(2).
 - g. Redesignating paragraph (f) as paragraph (e)(1) and reserving paragraph (e)(2);
 - h. Reserving paragraphs (f)—(z).
- The revisions and addition read as follows:

§ 205.603 Synthetic substances allowed for use in organic livestock production.

* * * * *

(a) As disinfectants, sanitizer, and medical treatments as applicable.

(1) Alcohols.

(i) Ethanol-disinfectant and sanitizer only, prohibited as a feed additive.

(ii) Isopropanol-disinfectant only.

(2) Aspirin—approved for health care use to reduce inflammation.

(3) Biologics-Vaccines.

(4) Chlorhexidine—Allowed for surgical procedures conducted by a veterinarian. Allowed for use as a teat dip when alternative germicidal agents and/or physical barriers have lost their effectiveness.

(5) Chlorine materials—disinfecting and sanitizing facilities and equipment. Residual chlorine levels in the water

shall not exceed the maximum residual disinfectant limit under the Safe Drinking Water Act.

- (i) Calcium hypochlorite.
- (ii) Chlorine dioxide.
- (iii) Sodium hypochlorite.
- (6) Electrolytes-without antibiotics.
- (7) Glucose.
- (8) Glycerine-Allowed as a livestock teat dip, must be produced through the hydrolysis of fats or oils.
- (9) Hydrogen peroxide.
- (10) Iodine.
- (11) Magnesium sulfate.
- (12) Oxytocin-use in postparturition therapeutic applications.
- (13) Parasiticides. Ivermectin—prohibited in slaughter stock, allowed in emergency treatment for dairy and breeder stock when organic system plan-approved preventive management does not prevent infestation. Milk or milk products from a treated animal cannot be labeled as provided for in subpart D of this part for 90 days following treatment. In breeder stock, treatment cannot occur during the last third of gestation if the progeny will be sold as organic and must not be used during the lactation period of breeding stock.
- (14) Phosphoric acid-allowed as an equipment cleaner, *Provided*, That, no direct contact with organically managed livestock or land occurs.

* * * * *

(d) * * *

(1) DL—Methionine, DL—Methionine—hydroxy analog, and DL—Methionine—hydroxy analog calcium—for use only in organic poultry production until October 21, 2005.

(2) Trace minerals, used for enrichment or fortification when FDA approved.

* * * * *

5. Section 205.605 is revised to read as follows:

§ 205.605 Nonagricultural (nonorganic) substances allowed as ingredients in or on processed products labeled as "organic" or "made with organic (specified ingredients or food group(s))."

The following nonagricultural substances may be used as ingredients in or on processed products labeled as "organic" or "made with organic (specified ingredients or food group(s))" only in accordance with any restrictions specified in this section.

(a) *Nonsynthetics allowed:*

- Acids (Alginic; Citric—produced by microbial fermentation of carbohydrate substances; and Lactic).
- Agar-agar.
- Bentonite.
- Calcium carbonate.

- Calcium chloride.
- Carageenan.
- Colors, nonsynthetic sources only.
- Dairy cultures.
- Diatomaceous earth—food filtering aid only.
- Enzymes—must be derived from edible, nontoxic plants, nonpathogenic fungi, or nonpathogenic bacteria.
- Flavors, nonsynthetic sources only and must not be produced using synthetic solvents and carrier systems or any artificial preservative.
- Kaolin.
- Magnesium sulfate, nonsynthetic sources only.
- Nitrogen—oil-free grades.
- Oxygen—oil-free grades.
- Perlite—for use only as a filter aid in food processing.
- Potassium chloride.
- Potassium iodide.
- Sodium bicarbonate.
- Sodium carbonate.
- Tartaric acid.
- Waxes—nonsynthetic (Carnauba wax; and Wood resin).
- Yeast—nonsynthetic, growth on petrochemical substrate and sulfite waste liquor is prohibited (Autolysate; Bakers; Brewers; Nutritional; and Smoked—nonsynthetic smoke flavoring process must be documented).

(a) *Synthetics allowed:*

- Alginates.
- Ammonium bicarbonate—for use only as a leavening agent.
- Ammonium carbonate—for use only as a leavening agent.
- Ascorbic acid.
- Calcium citrate.
- Calcium hydroxide.
- Calcium phosphates (monobasic, dibasic, and tribasic).
- Carbon dioxide.
- Chlorine materials—disinfecting and sanitizing food contact surfaces, *Except*, That, residual chlorine levels in the water shall not exceed the maximum residual disinfectant limit under the Safe Drinking Water Act (Calcium hypochlorite; Chlorine dioxide; and Sodium hypochlorite).
- Ethylene—allowed for postharvest ripening of tropical fruit and degreening of citrus.
- Ferrous sulfate—for iron enrichment or fortification of foods when required by regulation or recommended (independent organization).
- Glycerides (mono and di)—for use only in drum drying of food.
- Glycerin—produced by hydrolysis of fats and oils.
- Hydrogen peroxide.
- Lecithin—bleached.
- Magnesium carbonate—for use only in agricultural products labeled "made with organic (specified ingredients or food group(s))," prohibited in agricultural products labeled "organic".
- Magnesium chloride—derived from sea water.
- Magnesium stearate—for use only in agricultural products labeled "made with organic (specified ingredients or food group(s))," prohibited in agricultural products labeled "organic".

- Nutrient vitamins and minerals, in accordance with 21 CFR 104.20.
- Nutritional Quality Guidelines For Foods.
- Ozone.
- Pectin (low-methoxy).
- Phosphoric acid—cleaning of food-contact surfaces and equipment only.
- Potassium acid tartrate.
- Potassium tartrate made from tartaric acid.
- Potassium carbonate.
- Potassium citrate.
- Potassium hydroxide—prohibited for use in lye peeling of fruits and vegetables.
- Potassium iodide—for use only in agricultural products labeled "made with organic (specified ingredients or food group(s))," prohibited in agricultural products labeled "organic".
- Potassium phosphate—for use only in agricultural products labeled "made with organic (specific ingredients or food group(s))," prohibited in agricultural products labeled "organic".
- Silicon dioxide.
- Sodium citrate.
- Sodium hydroxide—prohibited for use in lye peeling of fruits and vegetables.
- Sodium phosphates—for use only in dairy foods.
- Sulfur dioxide—for use only in wine labeled "made with organic grapes," *Provided*, That, total sulfite concentration does not exceed 100 ppm.
- Tocopherols—derived from vegetable oil when rosemary extracts are not a suitable alternative.
- Xanthan gum.

(c)-(z) [Reserved]
6. In § 205.607, paragraph (c) is revised to read as follows:

§ 205.607 Amending the National List.

* * * * *

(c) A petition to amend the National List must be submitted to: Program Manager, USDA/AMS/TMP/NOP, 1400 Independence Ave., SW., Room 4008—So., Ag Stop 0268, Washington, DC 20250.

* * * * *

Dated: April 11, 2003.

A. J. Yates,
Administrator, Agricultural Marketing Services.

[FR Doc. 03-9412 Filed 4-15-03; 10:52 am]

BILLING CODE 3410-02-P

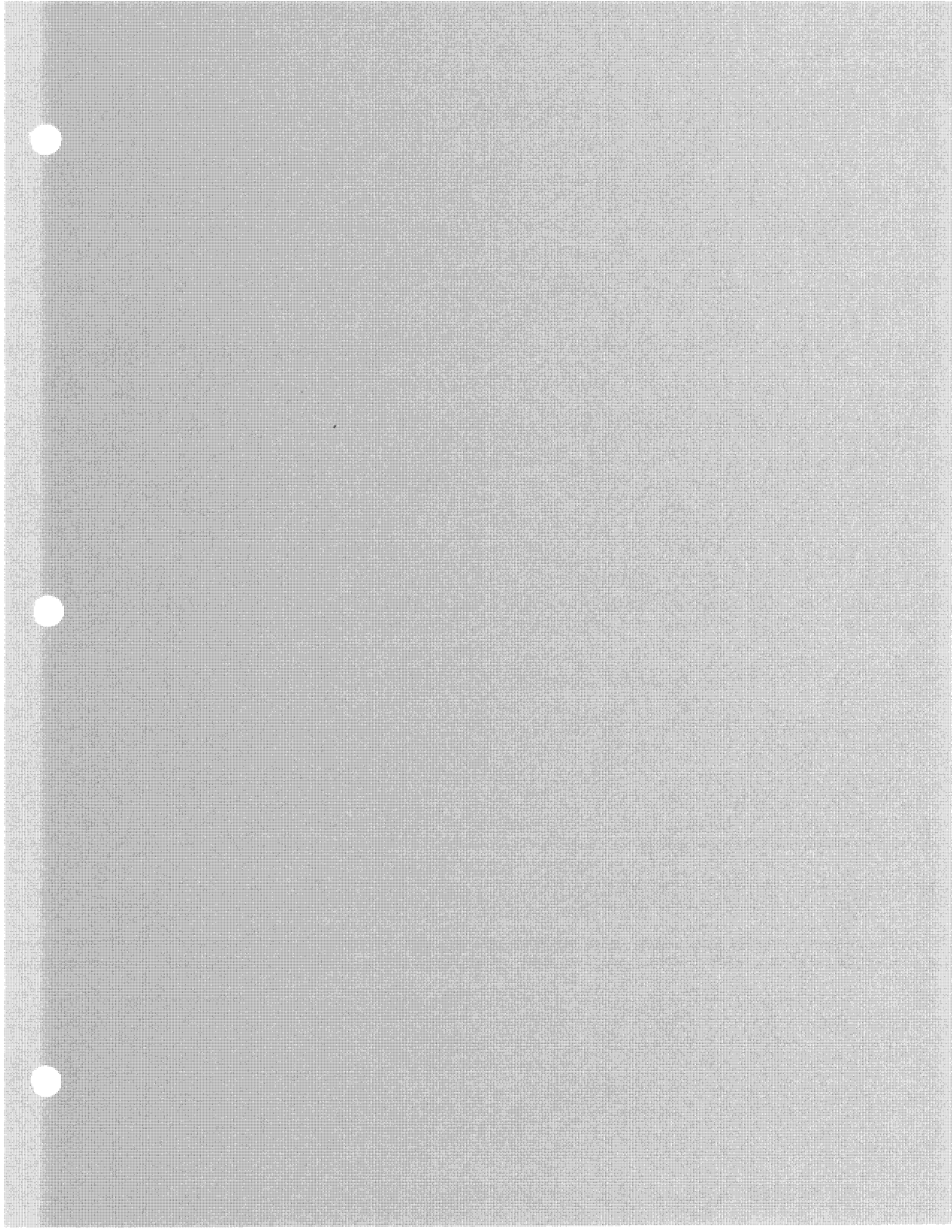
DEPARTMENT OF AGRICULTURE
Food Safety and Inspection Service

9 CFR Parts 317 and 381
[Docket No. 00-046P]

Nutrition Labeling: Nutrient Content Claims on Multi-Serve, Meal-Type Meat and Poultry Products

AGENCY: Food Safety and Inspection Service, USDA.

ACTION: Proposed rule.



Organic Materials Review Institute

Comments on USDA, National Organic Program Proposed Amendments to the National List of Allowed and Prohibited Substances 7 CFR Part 205, Docket No. TMD-02-03

April 28, 2003

OMRI appreciates the opportunity to comment on the proposed amendments to the USDA National List of Allowed and Prohibited Substances (National List), Docket Number TMD-02-03. OMRI supports the National Organic Program (NOP) for making technical corrections that were needed in the regulation and for incorporating recommendations of the National Organic Standards Board (NOSB). OMRI offers additional corrections for further improvements to the National List. Our goal is to bring attention to the intent of the public process as set out in the Organic Foods Production Act of 1990 (OFPA), particularly with respect to the advisory function of the NOSB for implementing and amending the National List.

Current NOSB recommendations reflect an extensive evaluation of issues raised in public NOSB meetings, by Technical Advisory Panels (TAP), and through the petition process. The absence of many NOSB recommendations from this Docket imposes delays on the development of a comprehensive National List. OMRI offers its comments both to clarify issues associated with the proposed amendments and to draw attention to the further improvements in the National List that can be implemented by better utilizing the statutory mission of NOSB. The strength of the NOP is in the public partnership that OFPA established between it and the NOSB. OMRI encourages a continued development of that partnership.

NOSB Recommendations Not Included

The Docket Background states that between June 6, 2000 and October 20, 2002, the NOSB recommended that the Secretary of Agriculture add ten substances to §§205.601-205.603 based on petitions received from industry participants (68 *Fed. Reg.* 18556). However, by our analysis, the NOSB has recommended 25 substances (See Table 1 of these comments, attached). We would appreciate a regulatory explanation for the absence of NOSB recommendations from the proposed amendments. Additionally, it would be helpful for NOP to issue a public statement as to its plans for addressing the hardships that may occur within the industry as a consequence of this delay in implementing NOSB recommendations. OMRI offers its own comments on these missing substances as follows.

The NOSB identified 13 high-priority livestock medications for expedited TAP reviews (Table 1). OMRI asks why these medications were not included in the proposed amendments, particularly given the urgency with which they were addressed by the NOSB. In October 2002, NOSB also recommended a specific allowance for excipients used in animal drugs to permit formulations of medical products containing approved active ingredients. All of these missing items should be added to the National List out of concern for prudent farm management and animal welfare.

The NOSB recommended 11 processing materials (Table 1) in the period between June 6, 2000 and October 20, 2002. The NOSB also made two recommendations for additions to §205.605 at the November 2000 meeting held in Washington DC, which were not incorporated in the Final Rule published on December 21, 2000. These recommendations included the animal-derived enzymes (rennet, bovine liver catalase, animal lipase, pancreatin, pepsin, trypsin) and peracetic acid. The current Docket added only three processing substances to §205.605 (agar-agar, carageenan, tartaric acid), all of which were based on NOSB recommendations dating to 1995.

NOSB recommendations were developed after lengthy deliberations in public meetings and with public comment. In addition to the abovementioned materials, the NOSB also submitted a list of proposed Technical Corrections in June 2001, which should be considered for future amendments to the National List. It is OMRI's view that adoption of NOSB recommendations should be undertaken in a timely manner. With operators now under the impact of a federally mandated certification system, the lack of an updated National List that incorporates NOSB recommendations poses potential hardships for producers.

Comments on §205.601

We support the revision of the introductory text that refers to relevant restrictions on use of materials as required in §205.203(c) and §205.206 (a-d). OMRI has based its own *Generic Materials List* restrictions (allowed or restricted designation) on these regulatory requirements as well as the specific limitations noted in annotations to the National List. This amended reference will remind producers to review use restrictions both stated in the supporting regulatory text and in the National List itself.

We do question, however, whether all the materials listed in §205.601(a) should be subject to the restrictions in §205.206(a-d). The §205.601(a) category includes algicides, disinfectants, and sanitizers, including irrigation cleaners. While algicides should be subject to the restrictions set out in §205.206 (i.e., preventive methods must be used before synthetic substances are applied), these restrictions should not broadly apply to materials such as alcohols used to clean pruning shears or ozone used to clean irrigation systems. OMRI suggests a revision that would organize the National List category in a more uniform way by moving the heading of "algicides" to §205.601(b) and include it there to read:

§205.601(b) As herbicides, weed barriers, and algicides/demossers, as applicable;

For consistency in the introductory sentence of §205.601, which exempts "(k)" - plant growth regulators, we suggest also including "(f)" - Pheromones, in the exemption from this restriction. Both of these materials, which are registered pesticides with the Environmental Protection Agency (EPA), have been reviewed and specifically added to the National List without restriction, with the recognition that there are few effective alternatives available. For further clarification of the exemptions allowed in §205.601, and consistent with our recommendation for the reassignment of algicides to §205.601(b), we also recommend adding "(a)" to the §205.601 introductory language as follows:

...Substances allowed by this section, except those in paragraphs (a) (c), (f), (j), (k), and (l) of this section, may only be used when the provisions set forth in §205.206(a) through (d) prove insufficient to prevent or control the target pest.

Pheromones: The NOSB recommended specific language to amend the annotation for pheromones to correct their inaccurate designation as “insect attractants.” Pheromones are commonly used for insect mating disruption, or mass confusion technique, which is not synonymous with “insect attraction.” In its current form, the proposed amendments deal only indirectly with pheromones by changing the annotation for inert ingredients. Although the proposed addition of List 3 inerts to §205.601(m)(2) for use in passive pheromone dispensers does accomplish the intent of the NOSB recommendation, it does not fully qualify their EPA regulatory status. In addition to asking NOP to reconsider the original NOSB List 3 inert recommendation, OMRI recommends that the proposed NOSB annotation, which was based on EPA recommendations, be adopted as an explanatory policy guidance statement for §205.601(m)(2) to read as follows:

Pheromones -includes only EPA-exempt pheromone products, EPA-registered pheromone products with no additional synthetic toxicants unless listed in this section, and any inert ingredients used in such pheromone formulations that are not on EPA List 1 (Inerts of toxicological concern) or EPA List 2 (Potentially toxic inerts), *Provided* the pheromone products are limited to passive dispensers. Pheromone products containing only pheromones, active ingredients listed in this section, and List 4 inerts may be applied without restriction.

The point of this lengthy annotation was to clarify that List 3 inerts can be used in pheromone formulations that are EPA-registered, as well as in those that are exempt from EPA registration, provided that all active ingredients are approved and the pheromone is used in a passive dispenser (trap). According to the current proposed amendment language of §205.601(m)(2), inert ingredients in pheromone formulations may be interpreted to imply their use only in EPA-registered pheromones.

We also suggest that §205.601(f) should be changed to:

“for insect management – Pheromones”

Hydrated Lime: The NOSB and OMRI both commented in June 2001 that the annotation in §205.601(i)(3) for hydrated lime is incorrect: “-must be used in a manner that minimizes copper accumulation in the soil.” Hydrated lime was approved for crop use by the NOSB in 1995 in the context of a review of Bordeaux mix (copper sulfate plus hydrated lime). We suggest either deleting the annotation as currently written or revising it to “for use with copper sulfate which must be used in a manner that minimizes copper accumulation in the soil.”

Peracetic acid: Although based on a NOSB recommendation, the proposed annotation in §205.601(i)(7), which states “for use to control fire blight bacteria when approved by the EPA under a Special Local Need (24c) registration,” is redundant. Pesticidal use of peracetic is subject to EPA’s regulatory authority. Currently, there are no products registered with EPA for

this use¹, although they may be developed and registered in the future. This proposed National List language also implies that only products with a Special Local Need (24c) registration may be used for fire blight control. Use for product development research would more likely occur under an Experimental Use Permit, (EPA Section 5 registration) as NOSB noted, thereby encouraging alternatives to antibiotic use for fireblight control.² In either case, EPA has regulatory jurisdiction for all pesticidal uses of peracetic acid. Thus, it is not necessary to specify the EPA status in the NOP regulation. We suggest the following correction to §205.601(i)(7):

~~"for use to control fire blight bacteria when approved by the Environmental Protection Agency (EPA) under a Special Local Need (24c) registration."~~

The NOSB also recommended peracetic acid as an approved material for post-harvest handling of crops. In this respect, the broader language of our recommended wording for §205.601(i)(7) is consistent with NOSB recommendations.

Comments on §205.603 – Livestock

As noted above, the 13 livestock medications approved by NOSB are not included in the proposed amendments although a temporary allowance for the feed additive DL-Methionine is included in §205.603(d)(1). Should the NOSB annotations for extended withdrawal periods for many of these medications be of concern, we would like to note that the current listings in §205.603 for ivermectin, lidocaine, and procaine all contain specific withdrawal time restrictions. We suggest that the NOSB recommendations be addressed consistently with implementation of *all* the NOSB livestock recommendations in these proposed amendments to the National List, with priority given to substances needed to alleviate animal suffering and to provide protection of animal welfare.

Forms of minerals

OMRI would also like to comment on the revision of the listings for, and the deletion of, **copper sulfate** (21 CFR §582.80) and **magnesium sulfate** (21 CFR §582.5443). Both minerals were the only two for which a TAP review was conducted. NOSB recommended their addition to the National List in November 1995. It also recommended that other minerals as well as synthetic vitamins should be allowed for two years after which TAP reviews would be scheduled (Addendum 18, October 31, 1995). While the December 21, 2000 regulation includes a categorical allowance for "trace minerals, used for enrichment or fortification when FDA approved," NOP has offered no clarification as to the FDA-approved status of minerals. While we agree that FDA has authority over trace minerals for animal feeds under 21 CFR Part 582 and 21 CFR Part 573, NOP's policy is not clear with respect to the determination of approved mineral additives for the National List as authorized under OFPA. This absence of a clear regulatory program is particularly troublesome for minerals not found in 21 CFR and presents questions as to NOP's intended regulatory handling of synthetic minerals for organic production.

¹ <http://www.cdpr.ca.gov/docs/epa/epachem.htm>

² TAP review- Peracetic acid, Crops. http://www.omri.org/peracetic_acid.pdf see p. 7

In the absence of further clarification of approved forms of minerals and vitamins from NOP, OMRI interprets NOP's use of "FDA approved" for livestock use to apply only to those vitamins and minerals listed in 21 CFR Parts 582 and 573. As suggested in our comments dated January 24, 2002, OMRI believes that additional TAP reviews are needed to clarify which synthetic forms of vitamins and minerals are permitted, which forms are necessary, and which forms are compliant with OFPA for use in organic production.

In 1995, the NOSB clearly stated its policy that nutrients should first and mostly come from organically produced agricultural sources, non-synthetic vitamins and minerals should be used when available, and synthetically produced vitamins and minerals should be used only if natural sources are unavailable. This policy was reaffirmed in the April 11, 2002 NOSB Livestock Committee proposal:

"The NOSB continues to support an allowance for specific synthetic vitamins and minerals as warranted by the conditions and circumstances specified in an approved organic system plan. Synthetic supplements should not be used as a substitute for a balanced feed ration including access to pasture for ruminants and exposure to direct sunlight for all livestock.

Furthermore, Section 2115(c)(1)(B)(ii) of the Organic Foods Production Act (OFPA) requires that a synthetic substance only be allowed when a wholly natural substitute product is not available. The importance of organically produced agricultural products and direct sunlight in organic livestock production and the availability of many natural sources of vitamins and minerals dictate that the allowance for synthetic forms of these nutrients should be carefully proscribed. At this time, the NOSB recommends that the allowance for synthetic vitamins and minerals contained in Sections 205.603(d)(1) and (2) include materials either listed for such use in the CFR or in Sections 57 or 90 of the AAFCO Official Publication...."

The NOSB final recommendation from May 8, 2002 also states:

"The NOSB recognizes the need to review the following materials and recommends a TAP review to determine if the following materials should be prohibited:

Ammonium sulfate, ethylenediamine dihydroiodide (*sic*), metal amino acid complex, metal (*sic*) (specific amino acid) complex, metal amino acid chelate, metal protinate (*sic*), ammonium polyphosphate solution, diammonium phosphate, monoammonium phosphate, zinc chloride diammine (*sic*) complex, and menadione forms."

Materials in this recommended TAP review list contain synthetic nitrogen or sulfites that are prohibited in organic feed or handling by OFPA. On the advice of its Advisory Council of scientific and technical experts, OMRI considers these materials to be prohibited until TAP reviews find otherwise and provide justification for their addition to the National List. OMRI recommends maintaining copper sulfate and magnesium sulfate on the National List until the TAP reviews for other synthetic vitamins and minerals are completed and clarification of appropriate forms of vitamins and minerals is made.

With respect to the current proposed amendment language, OMRI recommends deleting the term "trace" because magnesium is considered a macro-element in animal nutrition by the National Academy of Sciences, as are calcium, phosphorous, sodium, potassium, sulfur and chlorine.

OMRI would also like to note that the May 2002 NOSB recommendations on other feed additives have not been adopted by NOP in these proposed amendments.

Additional comments on §205.603 – Livestock

OMRI appreciates the deletion of the **inert ingredients** language from §205.603(f) and its move to (e)(1). This is an important clarification that EPA List 4 inert ingredients are permitted only in pesticides approved for organic livestock use.

In November 2000, NOSB recommended a change in the annotation for **ivermectin** to add: “slow release formulations such as the SR (slow release) bolus are prohibited.” OMRI again brings this important recommendation to the attention of NOP and requests that the NOSB language be added to the annotation in §205.603(a)(13).

The question of **excipients** should also be addressed. OMRI supports the October 2002 NOSB recommendation for a suggested language change in §205.603(a) to read as follows:

§205.603(a) excipients, for use in livestock drugs, except:
(i) reserved [any specific substances that may be prohibited]

Another correction is still needed in §205.603(b)(3) **Lime, hydrated**. The regulation continues to state “(bordeaux mixes), not permitted to cauterize physical alterations or deodorize animal wastes.” OMRI and the NOSB have both commented that the regulatory use of “Bordeaux mix” here is incorrect. Bordeaux mix is a crop protection material, not a livestock material. We suggest the following language change:

§205.603(b)(3): lime, hydrated, ~~(bordeaux mixes)~~, as external pest control, not permitted to cauterize physical alterations or deodorize animal wastes.

Comments on §205.605

As OMRI and NOSB have commented previously in requests for technical corrections, the NOSB did not review **natural colors** for use in organic food processing. We urge the Secretary to immediately remove “colors, non-synthetic” from §205.605 because any further delay or confusion in addressing this issue will be increasingly costly to remedy. The National List is not clear as to which coloring agents this section refers, nor does FDA, in its regulatory authority over colors used in processed foods, have a standard of identity for “natural colors.”

OMRI notes the addition of **agar-agar, carageenan, and tartaric acid** to the National List as recommended by the NOSB in 1995. Since tartaric acid was approved by NOSB from both synthetic (made from malic acid) and nonsynthetic sources (made from grapes), OMRI recommends that it also be added to §205.605(b) to allow use of its synthetic form.

We would like to draw attention to processing materials recently recommended by NOSB but omitted from the proposed amendments. **Calcium sulfate** and **glucono delta-lactone** were both approved, in 2001 and 2002 respectively, and are widely used as the preferred coagulants for certain styles of organic tofu. These two materials were reviewed carefully, a clear need was demonstrated, and NOSB determined that they are clearly functional food additives that meet

statutory and regulatory criteria for processing. We respectfully request that NOP reconsider the NOSB recommendations for calcium sulfate and glucono delta-lactone.

Another unexplained omission of a NOSB processing recommendation deals with **potassium hydroxide**. The proposed amendments leave standing the current annotation in §205.605(b). In 2001, the NOSB approved an additional use of this substance for peeling peaches used in the individual quick freezing process. The un-amended annotation prohibits potassium hydroxide for this special use, contrary to the expectations of the organic industry, and jeopardizes the certification and labeling of these products.

Please note a typographical error: §205.605(a) Synthetics allowed – should be numbered as §205.605**(b)** Synthetics allowed.

Comments on §205.606

Gelatin and **orange shellac** were both recommended by the NOSB to be added to §205.606, yet neither appear in this docket. The NOSB described these two materials as agricultural ingredients that are subject to the commercial availability clause in this section. The NOP's decision making to not include these two substances in the proposed amendments should be explained. As nonorganically produced agricultural products, gelatin and orange shellac cannot be used at present, despite the lengthy petition and review process that found them both suitable for organic production. Given the extensive evaluation supporting the NOSB recommendations, these two substances should be placed on the National List.

Conclusion

OMRI commends the NOP on its efforts in administering the National List and in initiating the implementation of the regulatory program supervising organic production. A great deal of progress has been made by the NOP and NOSB in building a viable, workable National List from a complex set of materials issues relating to a wide spectrum of agricultural commodities that includes field, vegetable and livestock crops as well as processed food. The industry is aware of the limited resources currently available to the NOP in conducting its statutory mission. As an industry service arm developed to handle materials review, OMRI offers its expertise to assist in any way possible to help craft a strong and functional National List that reflects the consensus of the organic community and serves the goals of preserving and improving organic integrity. We look forward to the finalization of this Docket, and future amendments that we trust will include the adoption of all of the NOSB recommendations.

Respectfully submitted,

Dr. Laura Morrison
Executive Director
Organic Materials Review Institute
P.O. Box 11558
Eugene, Oregon 97440

Table 1

National List Recommendations Made by National Organic Standards Board from April 1995- October 2002, Compared to the Federal Register Docket TM-02-03

Substances included in Federal Register

Material	NOSB Recommended category	NOSB Date of vote	NOSB recommendation and annotation	NOP Docket language 68 Fed Reg 18556, April 16, 2003 7 CFR 205 (additions and changes to December 21, 2000 Rule)
CROPS				
1,4 dimethyl-naphthalene		10-20-02	Prohibited synthetic (reviewed as sprout inhibitor)	Not added
calcium chloride, (from brine process)	205.602	10-01	Nonsynthetic, prohibited, except as a foliar spray to treat a physiological disorder associated with calcium uptake	205.602(c) Calcium chloride, brine process is natural and is prohibited for use except as a foliar spray to treat a physiological disorder associated with calcium uptake.
calcium oxide		5-07-02	Prohibited (considered for fertilizer use)	Not added
calcium hydroxide		5-07-02	Prohibited (considered for fertilizer use)	Not added
copper sulfate	205.601	10-01	Synthetic. Amend annotation to add: allowed only with documented need for algicide and tadpole shrimp control in aquatic rice systems, not to exceed one application per 2-year interval; used in a manner to minimize accumulation of copper in the soil and water systems.	205.601(a)(3) Copper sulfate--for use as an algicide, is limited to one application per field during any 24-month period. Application rates are limited to those which do not increase baseline soil test values for copper over a timeframe agreed upon by the producer and accredited certifying agent. 205.601(e)(3)--Copper sulfate for use as tadpole shrimp control in rice production, is limited to one application per field during any 24-month period. Application rates are limited to levels which do not increase baseline soil test values for copper

Material	NOSB Recommended category	NOSB Date of vote	NOSB recommendation and annotation	NOP Docket language 68 Fed Reg 18556, April 16, 2003 7 CFR 205 (additions and changes to December 21, 2000 Rule)
ethylene gas	205.601	06-06-2000	synthetic, allowed for regulation of pineapple flowering. see pheromones	over a timeframe agreed upon by the producer and accredited certifying agent.
Inert ingredients of unknown toxicity				205.601(k) ethylene gas--for regulation of pineapple flowering. 205.601(m)(2) EPA List 3--Inerts of unknown toxicity--for use only in passive pheromone dispensers.
Oils, narrow range (petroleum distillates)		11-01-95	Allowed as suffocating or stilet oils on foliage and as inert ingredients.	Not added as inert ingredients.
ozone	205.601	9-18-02	Allowed with the annotation: To clean irrigation lines only	205.601(a)(5) ozone gas--for use as an irrigation system cleaner only.
peracetic acid	205.601	9-00	Synthetic. Allowed to disinfect equipment. Allowed to disinfect seed and asexually propagated planting material (i.e., bulb, corm, tubers) used for planting crops. Allowed for fireblight control only with an Experimental Use Permit with documentation that alternatives including biocontrols have been tried.	205.601(a)(6) peracetic acid--for use in disinfecting equipment, seed, and asexually propagated planting material. 205.601(i) (7) peracetic acid--for use to control fire blight bacteria when approved by the Environmental Protection Agency (EPA) under a Special Local Need (24c) registration.
pheromones (TAP was done for Butylated hydroxy-toluene (BHT))	205.601(f)	10-20-02	Allowed, changed annotation as follows: As-insect-attractants--Pheromones -includes only EPA exempt pheromone products, EPA registered pheromone products with no additional toxicants unless listed in this section, and any inert ingredients used in such pheromone formulations that are not on EPA List 1 (Inerts of toxicological concern) or EPA List 2 (Potentially toxic inerts), <i>Provided</i> the pheromone products are limited to passive dispensers. Pheromone products containing only	No change, see Inert ingredients 205.601 (f) As insect attractants - pheromones

Comments on NOP Proposed Amendments to the National List, Docket No. TMD-02-03

Material	NOSB Recommended category	NOSB Date of vote	NOSB recommendation and annotation	NOP Docket language 68 Fed Reg 18556, April 16, 2003 7 CFR 205 (additions and changes to December 21, 2000 Rule)
			pheromones, active ingredients listed in this section, and List 4 inerts may be applied without restriction.	
potassium sorbate		5-7-02	Prohibited, considered for seed treatment	Not added.
potassium sulfate		10-20-02	Prohibited from synthetic sources (nonsynthetic mimed sources remain allowed)	Not added.
sodium chloride	205.602	9-96	Nonsynthetic, prohibited, except for use in cotton production to comply with emergency spray programs or to prevent immediate loss of crop.	Not added.
sodium nitrate	205.602(h)	9-19-02	Non-synthetic and prohibited: annotation changed: <u>unless use is restricted to no more than 20% of the crop's total nitrogen requirement; OR for unrestricted use in <i>Spirulina</i> production until October 21st, 2005.</u>	205.602(g) Sodium nitrate—unless use is restricted to no more than 20% of the crop's total nitrogen requirement, or until October 21, 2005, for unrestricted use in <i>spirulina</i> production.
sodium propionate		5-07-02	Prohibited, considered for seed treatment	Not added.
spinosad	Nonsynthetic	5-07-02	Nonsynthetic, allowed (will not appear on National List)	Not added.
Livestock				
activated carbon	205.603(a)	9-18-02	Allowed from vegetative sources only.	Not added.
bismuth subsalicylate	205.603(a)	9-18-02	Allowed.	Not added.
butorphanol	205.603(a)	9-18-02	Allowed with the annotations: <u>withhold time shall be double the FDA requirement</u>	Not added.
calcium borogluconate	205.603(a)	11-00	Allowed for milk fever	Not added.
calcium propionate	205.603(a)	9-18-02	Allowed with the annotation: <u>for treatment of milk fever only.</u>	Not added.
cell wall carbohydrates	Nonsynthetic	9-18-02	Allowed [Not added to the National List]	Not added.
chlorhexidine	205.603(a)	9-96	Allowed	205.603(a)(4)—Allowed for surgical procedures conducted by a veterinarian. Allowed for use as a teat dip when alternative germicidal agents and/or physical barriers have lost
chlorhexidine				

Comments on NOP Proposed Amendments to the National List, Docket No. TMD-02-03

Material	NOSB Recommended category	NOSB Date of vote	NOSB recommendation and annotation	NOP Docket language 68 Fed Reg 18556, April 16, 2003 7 CFR 205 (additions and changes to December 21, 2000 Rule) their effectiveness.
<u>DL-methionine</u>	205.603(d)	10-01	Allowed with annotation: for interim use by the organic poultry industry until October 21, 2005.	205.603(d) <u>DL-Methionine, DL--Methionine--hydroxy analog, and DL--Methionine--hydroxy analog calcium--for use only in organic poultry production until October 21, 2005.</u>
epinephrine/ adrenaline	205.604	9-18-02	[prohibited nonsynthetic] except for emergency treatment of anaphylactic shock.	Not added.
flunixin	§205.603(a):	10-20-02	Allowed with the annotation: withhold time shall be double the FDA requirement	Not added.
glycerine glycerin		9-99		205.603(a)(8) Glycerine--Allowed as a livestock teat dip, must be produced through the hydrolysis of fats or oils.
heparin		9-19-02	Prohibited	Not added.
ivermectin	205.603(a)(12)	11-00	Amend annotation to add: slow release formulations such as the SR (slow release) bolus are prohibited.	Not added. Renumbered as 205.603(a) (13)
kaolin pectin	205.603(a):	9-18-02	Allowed [for healthcare]	Not added.
magnesium oxide / magnesium hydroxide	205.603(a)	9-18-02	Allowed [for healthcare]	Not added.
mineral oil	205.603(a)	9-18-02	Allowed for healthcare.	Not added to 205.603(a) for internal use. Renumbers 205.603(b)(4) to 205.603(b)(5), remains only for topical (external) use
peracetic acid	205.603(a)	11-00	Allowed with annotation: For facility and processing equipment sanitation (barns milking parlors, pipelines, processing areas)	Not added to 205.603 for livestock use.
pheromones -- livestock	205.603	10-20-02	Allowed [Same annotation as for crops]	Not added.
poloxalone	Livestock	03-01	Synthetic. Allowed for emergency treatment of	Not added.

Comments on NOP Proposed Amendments to the National List, Docket No. TMD-02-03

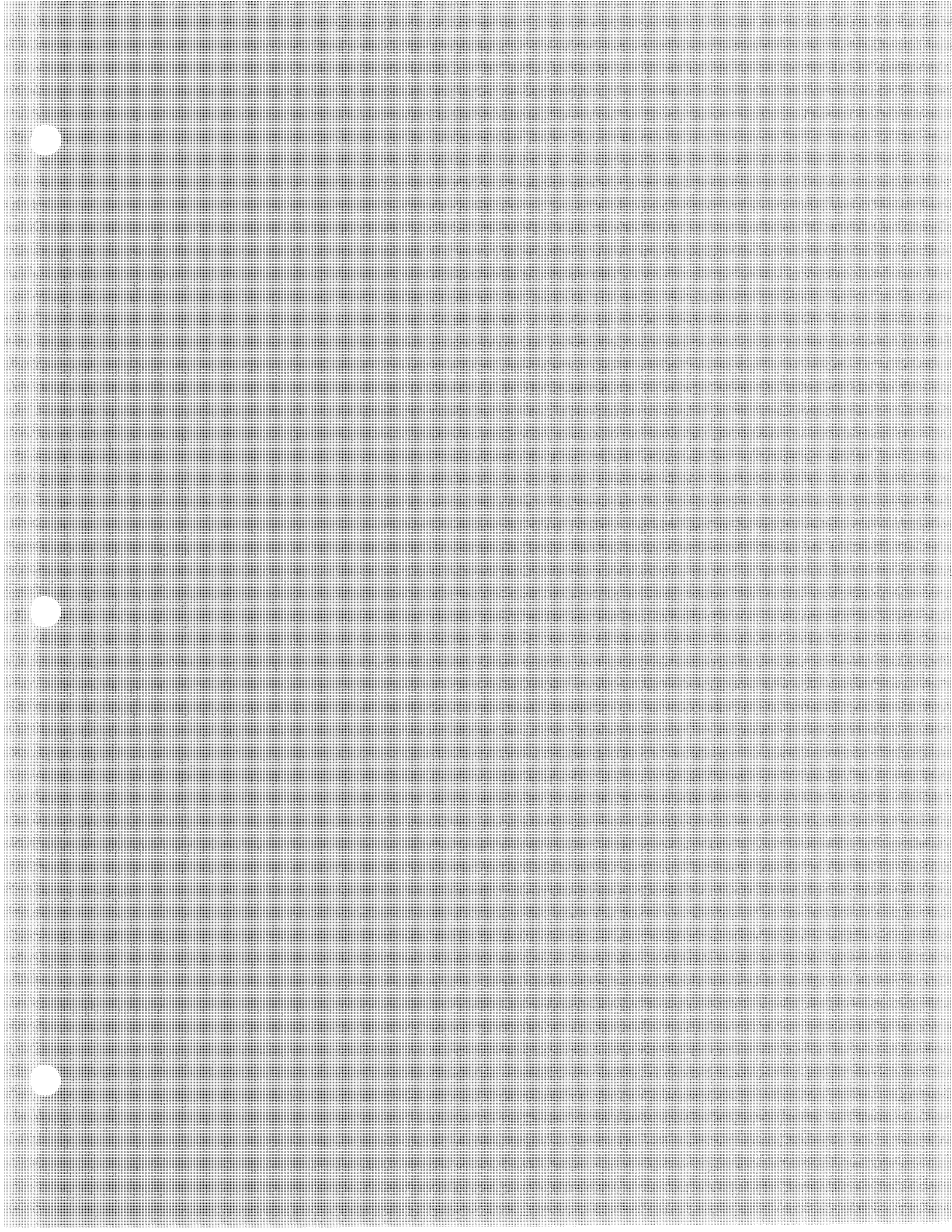
Material	NOSB Recommended category	NOSB Date of vote	NOSB recommendation and annotation	NOP Docket language 68 Fed Reg 18556, April 16, 2003 7 CFR 205 (additions and changes to December 21, 2000 Rule)
	205.603(a)		<u>biolat.</u>	
potassium sorbate	205.603(a), (b), (d)?	9-18-02	Allowed with the annotation: <u>only for use in aloe vera products for livestock production</u>	Not added.
propylene glycol	205.603(a)	9-19-02	Allowed with the annotation: <u>only for treatment of acute ketosis.</u>	Not added.
tolazoline	205.603(a):	9-19-02	Allowed with the annotation: <u>For emergency use only, as antidote to xylazine, withhold time shall be double FDA requirements.</u>	Not added.
trace minerals	205.603(d)	10-31-95	Synthetic, allowed until reviewed.	205.603(d) Trace minerals, used for enrichment or fortification when FDA approved, including: (i) Copper sulfate; (ii) Magnesium sulfate.
xylazine	205.603(a):	9-19-02	Allowed with the annotation: <u>for emergency use only, withhold time shall be double FDA requirements.</u>	Not added.
yeast derivatives	Nonsynthetic	9-19-02	Allowed. [Not added to the National List]	Not added.
Processing agar-agar	205.605(a)	4-95	Non-synthetic, allowed.	205.605(a) <u>Agar-agar.</u>
activated carbon	205.605(b)	9-19-02	Allowed with the annotation: <u>from vegetative sources only for use as filtering aid</u>	Not added.
ammonium hydroxide	205.605(b)	10-01	Synthetic, allowed. For use as a boiler additive only until Oct. 21, 2005	Not added.
calcium sulfate	205.605(a)	05-01	Nonsynthetic. Allowed from nonsynthetic sources only.	Not added.
calcium stearate		9-19-02	Prohibited for organic and made with organic	Not added.
carageenan	205.605(a)	04-95	Non-synthetic, allowed.	205.605(a) <u>Carageenan.</u>
cellulose	205.605(b)	10-01	Synthetic, allowed. For use in regenerative casings, as anti-caking agent (non-chlorine bleached) and filtering aid.	Not added.
cyclohexylamine	205.605(b)	10-01	Synthetic, allowed. For use only as boiler water additive for packaging sterilization only.	Not added.

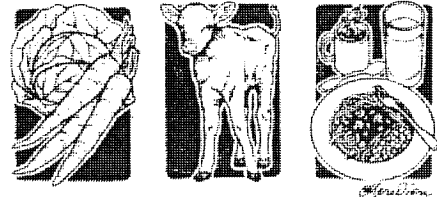
Comments on NOP Proposed Amendments to the National List, Docket No. TMD-02-03

Material	NOSB Recommended category	NOSB Date of vote	NOSB recommendation and annotation	NOP Docket language 68 Fed Reg 18556, April 16, 2003 7 CFR 205 (additions and changes to December 21, 2000 Rule)
diethylamino-ethanol	205.605(b)	05-07-02	Synthetic, allowed. For use only as boiler water additive for packaging sterilization only.	Not added.
enzymes, animal derived	205.605(a)	11-00	Nonsynthetic, allowed. Rennet (animal derived); catalase (bovine liver); animal lipase; pancreatin; pepsin; trypsin.	Animal sources not added.
ethylene	205.605(b)	11-01	Synthetic, annotation amended. For post harvest ripening of tropical fruit and degreening of citrus	205.605(a) Ethylene--allowed for post harvest ripening of tropical fruit and degreening of citrus. [section-numbering error: the "(a) Synthetics allowed;" should be "(b) Synthetics allowed."]
gelatin	205.606	05-07-02	Approved as agricultural, must be from organic source when commercially available	Not added.
glycerol monooleate		9-19-02	Synthetic, Prohibited (petition withdrawn)	Not added.
glucono delta-lactone	205.605(a)	9-19-02	Nonsynthetic, Allowed with the annotation: produced through microbial fermentation of carbohydrates only.	Not added.
hydroxypropyl methylcellulose (HPMC)		9-19-02	Prohibited, for use in Made with Organic category and Organic	Not added.
octadecylamine	205.605 (b)	10-01	Synthetic, allowed. For use only as boiler water additive for packaging sterilization only.	Not added.
peracetic acid	205.605(b)	11-00	Synthetic, allowed. For direct food contact only in wash and/or rinse water. Allowed as sanitizer on surfaces in contact with organic food.	Not added.
potassium hydroxide	205.605(b)(27)	10-01	Synthetic, allowed. Amend annotation to read: Prohibited for lye peeling of fruits and vegetables except when used for peeling peaches during the individually quick frozen production process.	Not changed. Annotation still reads: Prohibited for use in lye peeling of fruits and vegetables.
shellac, orange, unbleached	205.606	05-07-02	Approved as agricultural, must be organic when available	Not added.

Comments on NOP Proposed Amendments to the National List, Docket No. TMD-02-03

Material	NOSB Recommended category	NOSB Date of vote	NOSB recommendation and annotation	NOP Docket language
tartaric acid	205.605(a-b)	11-95	Nonsynthetic (made from grapes), Allowed. Synthetic, made from malic acid, Allowed.	68 Fed Reg 18556, April 16, 2003 <u>7 CFR 205 (additions and changes to December 21, 2000 Rule)</u> 205.601(a) Tartaric acid. [natural source only; synthetic form not added]
tetrasodium pyrophosphate	205.603(b)	9-19-02	Allowed with the annotation: <u>for use only in textured meat analog products</u>	Not added.





January 14, 2004

Charles Chandler
TETRA Technologies Inc.
25025 I-45 North
The Woodlands, TX 77380

Dear Mr. Chandler,
Thank you for your inquiry by telephone on January 13, 2004. As I said on the call, I would like to apologize about the delay in notifying you about the change in calcium chloride's status as a consequence of an amendment to the National Organic Program (NOP) Rule that was published in the *Federal Register* on October 31, 2003. OMRI was delayed in sending correspondence to suppliers affected by this Rule change as a consequence of major organizational changes in Board membership and staffing. Additionally, the holidays have further delayed our schedules.

The product, HI-CAL, as reviewed by the OMRI Review Panel on October 17, 2002 has an OMRI Listed™ status of **Regulated**. This status of the product remains unchanged.

OMRI offers product review and evaluation using the *OMRI Generic Materials List (GML)*, which is based on the NOP Rule. The **Regulated** status was assigned to the product because it contained a restricted substance as defined in the *GML* (April 21, 2002 version). The entry for calcium chloride on page 11 states that the material is allowed from "nonsynthetic sources only. (1)"

The footnote advises the reader of pending changes to this material. Under the "See NOSB (National Organic Standards Board) Appendix," one finds the text and the date of the NOSB recommendation and annotation. This entry states (page 93):

Calcium chloride (brine process)—nonsynthetic, prohibited. Prohibited except as used for foliar sprays to treat physiological disorders associated with calcium uptake. [All non-brine sources are synthetic and prohibited.]

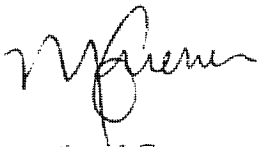
The *GML* was mailed to you at TETRA Technologies Inc. as part of the OMRI Brand Name Review application kit in May 21, 2002. In this respect, the information concerning a potential Rule amendment that further restricted the use of calcium chloride in organic production was available to you at the time of your product application. OMRI also notified subscribing certifiers of the Rule change in early November 2003. According to the regulatory framework for organic certification, it is the certifiers who are responsible for informing their clients of Rule changes.

As I mentioned on the telephone, this NOSB recommendation was adopted as an amendment to the Rule. Accordingly, use of the Tetra Technologies Inc. product HI-CAL on certified organic operations is limited to usage that complies with the above language, i.e. as a foliar application to treat physiological disorders associated with calcium uptake.

In April 2004, OMRI plans to publish a new version of the *GML* that will include these changes made to the NOP Rule. Please note that as stated in the *OMRI Operating Manual*, OMRI may change the status of any given generic material or listed brand name product at any time. In the case of NOP Rule changes, given the status of the *GML* as an NOP-compliant list, incorporation of Rule amendments is automatic.

We regret our delay in corresponding with you on this matter and will ensure that a more speedy process is implemented in the future.

With best regards,

A handwritten signature in black ink, appearing to read 'Miguel Guerrero', written in a cursive style.

Miguel Guerrero
Product Review Coordinator

Reporting and recordkeeping requirements, Seals and insignia, Soil conservation.

■ For the reasons set forth in the preamble, 7 CFR part 205, Subpart G is amended as follows:

PART 205—NATIONAL ORGANIC PROGRAM

■ 1. The authority citation for 7 CFR part 205 continues to read as follows:

Authority: 7 U.S.C. 6501-6522.

■ 2. Section 205.601 is amended by:

- a. Revising the introductory text.
- b. Redesignating paragraphs (a)(3) and (a)(4) as paragraphs (a)(4) and (a)(7), respectively.
- c. Adding new paragraphs (a)(3), (a)(5), and (a)(6).
- d. Revising the word "demisters" in newly redesignated paragraph (a)(7) to read "demisters."
- e. Redesignating paragraphs (c)(3) through (c)(7) as paragraphs (c)(4) through (c)(8).
- f. Adding a new paragraph (c)(3).
- g. Revising paragraph (f).
- h. Revising paragraph (i)(1).
- i. Redesignating paragraphs (i)(7) through (i)(10) as paragraphs (i)(8) through (i)(11), respectively.
- j. Adding a new paragraph (i)(7).
- k. Revising paragraph (k).
- l. Adding new paragraph (m)(2).

The revisions read as follows:

§ 205.601 Synthetic substances allowed for use in organic crop production.

In accordance with restrictions specified in this section, the following synthetic substances may be used in organic crop production: *Provided*, That, use of such substances do not contribute to contamination of crops, soil, or water. Substances allowed by this section, except disinfectants and sanitizers in paragraph (a) and those substances in paragraphs (c), (j), (k), and (l) of this section, may only be used when the provisions set forth in § 205.206(a) through (d) prove insufficient to prevent or control the target pest.

- (a) * * *
- (1) Copper sulfate for use as an algicide in aquatic rice systems, is limited to one application per field during any 24-month period. Application rates are limited to those which do not increase baseline soil test values for copper over a timeframe agreed upon by the producer and accredited certifying agent.

- (5) Ozone gas¹ for use as an irrigation system cleaner only.

- (6) Peroxyacetic acid¹ for use in disinfecting equipment, seed, and asexually propagated planting material.

- (a) * * *
- (3) Copper sulfate for use as tadpole shrimp control in aquatic rice production, is limited to one application per field during any 24-month period. Application rates are limited to levels which do not increase baseline soil test values for copper over a timeframe agreed upon by the producer and accredited certifying agent.

- (f) As insect management. Pheromones.

- (i) * * *
- (3) Hydrated lime.
- (7) Peroxyacetic acid¹ for use to control fire blight bacteria.

- (k) As plant growth regulators. Ethylene gas¹ for regulation of pineapple flowering.

- (m) * * *
- (2) EPA List 3 Inerts of unknown toxicity for use only in passive pheromone dispensers.

■ 3. Section 205.602 is revised to read as follows:

§ 205.602 Nonsynthetic substances prohibited for use in organic crop production.

The following nonsynthetic substances may not be used in organic crop production:

- (a) Ash from manure burning.
- (b) Arsenic.
- (c) Calcium chloride, brine process is natural and prohibited for use except as a foliar spray to treat a physiological disorder associated with calcium uptake.
- (d) Lead salts.
- (e) Potassium chloride unless derived from a mined source and applied in a manner that minimizes chloride accumulation in the soil.
- (f) Sodium fluoaluminat (mined).
- (g) Sodium nitrate unless use is restricted to no more than 20% of the crop's total nitrogen requirement; use in spirulina production is unrestricted until October 21, 2005.
- (h) Strychnine.
- (i) Tobacco dust (nicotine sulfate).
- (j) (z) [Reserved]

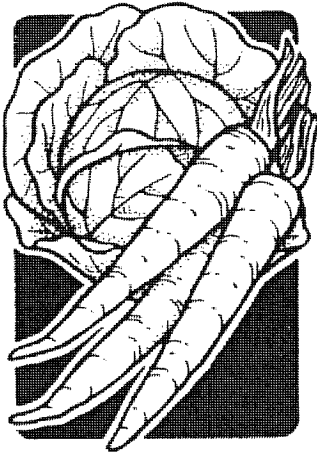
■ 4. Section 205.603 is amended by:

- a. Revising paragraph (a).
- b. Revising the word "chlorhexidine" in paragraph (3)(4) to read "chlorhexidine."

- c. Redesignating paragraphs (b)(1) through (b)(5) as (b)(2) through (b)(6), respectively and redesignating paragraph (b)(6) as paragraph (b)(1).
 - d. Revising newly redesignated paragraph (b)(4).
 - e. Redesignating paragraphs (d)(1) and (d)(2) as paragraphs (d)(2) and (d)(3), respectively.
 - f. Adding a new paragraph (d)(1).
 - g. Revising newly redesignated paragraph (d)(2).
 - h. Revising the designation for paragraph (f) to read (e)(1).
 - i. Reserving paragraphs (f), (z).
- The revisions and addition read as follows:

§ 205.603 Synthetic substances allowed for use in organic livestock production.

- (a) As disinfectants, sanitizer, and medical treatments as applicable.
 - (1) Alcohols.
 - (i) Ethanol disinfectant and sanitizer only, prohibited as a feed additive.
 - (ii) Isopropanol disinfectant only.
 - (2) Aspirin approved for health care use to reduce inflammation.
 - (3) Biologics Vaccines.
 - (4) Chlorhexidine Allowed for surgical procedures conducted by a veterinarian. Allowed for use as a teat dip when alternative germicidal agents and/or physical barriers have lost their effectiveness.
 - (5) Chlorine materials disinfecting and sanitizing facilities and equipment. Residual chlorine levels in the water shall not exceed the maximum residual disinfectant limit under the Safe Drinking Water Act.
 - (i) Calcium hypochlorite.
 - (ii) Chlorine dioxide.
 - (iii) Sodium hypochlorite.
 - (6) Electrolytes without antibiotics.
 - (7) Glucose.
 - (8) Glycerine Allowed as a livestock teat dip, must be produced through the hydrolysis of fats or oils.
 - (9) Hydrogen peroxide.
 - (10) Iodine.
 - (11) Magnesium sulfate.
 - (12) Oxytocin use in postparturition therapeutic applications.
 - (13) Parasiticides. Ivermectin prohibited in slaughter stock, allowed in emergency treatment for dairy and breeder stock when organic system plan-approved preventive management does not prevent infestation. Milk or milk products from a treated animal cannot be labeled as provided for in subpart D of this part for 90 days following treatment. In breeder stock, treatment cannot occur during the last third of gestation if the progeny will be sold as organic and must not be used during the lactation period of breeding stock.

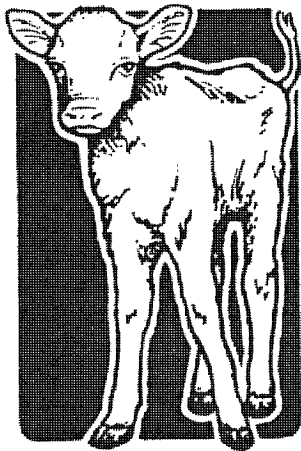


OMRI

L i s t e d

Organic Materials Review Institute
Box 11558 • Eugene, OR 97440-3758 USA
541-343-7600 • Fax: 541-343-8971
info@omri.org • www.omri.org

OMRI has reviewed the following material based on the *OMRI Generic Materials List*, the *OMRI Operating Manual for Review of Brand Name Products*, and documentation provided by the manufacturer or distributor to support the product application.



Product Name

HI-CAL

OMRI Status*

Regulated

OMRI Product Nr.

tet-9840

OMRI Generic Category*

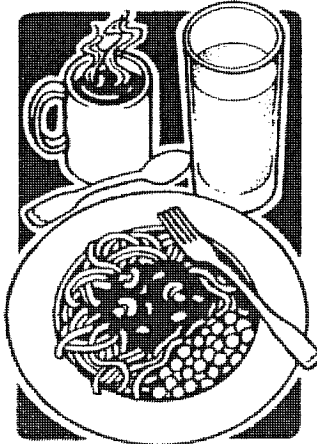
calcium chloride (CaCl₂)†

OMRI Class*

Fertilizer (F)

Supplier

TETRA Technologies Inc
Jim Funke
PO Box 73087, Houston, TX 77273
voice 281-367-1983, fax 281-298-7150




Meridian

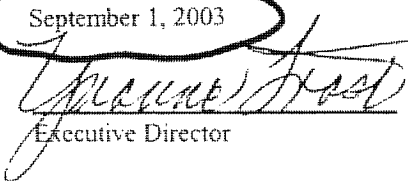
Issue Date

October 3, 2002

Expires

September 1, 2003


Product Review Coordinator


Executive Director

This listing is not OMRI certification or endorsement and cannot be construed as certification or listing by any of OMRI's subscribing certifiers. Final decisions regarding the acceptability of use of the product and any restrictions on its use under any particular certifier's program are made by the certifier that still has the right to decline OMRI's recommendation. Producers and handlers still need to contact their certifiers for information as to whether or not this material may be used in organic production or handling.

* See the most current *OMRI Generic Materials List* for more information plus annotations and restrictions.

October 18, 2002

Mr. Funke
TETRA Technologies Inc
PO Box 73087
Houston, TX 77273

Dear Mr. Funke:

Thank you for applying to the Organic Materials Review Institute for brand name product review.

The OMRI Review Panel has reviewed TETRA Technologies Inc's product, HI-CAL, and has determined it is Regulated for use in organic production in the category of calcium chloride. Calcium chloride may be used to treat physiological disorders associated with calcium uptake. This listing indicates that your product meets organic standards based on OMRI's most current *Generic Materials List* and *Operating Manual*, as well as good faith acceptance of the documentation provided to support your application.

Subscribing certifiers, state programs, individuals, and businesses will receive information regarding the OMRI status of HI-CAL in the next quarterly update. This listing is not OMRI certification or endorsement, and cannot be construed as certification or listing by any of the subscribing certifiers. Final decisions regarding the acceptability of use of the product, and any restrictions on its use under any particular certifier's program, are made by that certifier who has the right to decline OMRI's recommendation. Producers and handlers still need to contact their certifiers for information as to whether or not this material may be used in organic production or handling. OMRI is not responsible for any losses that may occur as a result of this listing or the actions of OMRI subscribers as the result of this listing. Also, OMRI listing does not imply that the product has been registered for use by the appropriate state or Federal agencies.

Enclosed are OMRI's seal and wording options to use on labeling and promotional literature to promote a listed product plus a document showing the product's listing with OMRI. Any use of OMRI's name outside of this sanctioned policy may result in a product being removed from the list or further action against the company that violates that policy. OMRI reserves the right to remove any product from its list at any time. Also enclosed is information on subscribing to OMRI. With a subscription, you receive the most current *Generic Materials List* and *Brand Name Products List* and all updates to these lists.

This letter serves as the Final Response Letter to TETRA Technologies Inc regarding the status of HI-CAL. If TETRA Technologies Inc wishes to appeal this decision, please refer to the "Appeals" section in the most current *OMRI Operating Manual*.

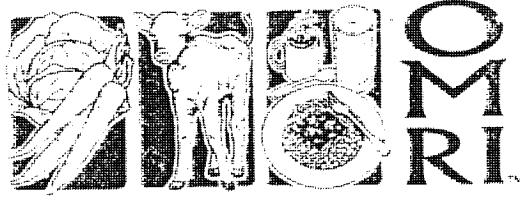
TETRA Technologies Inc needs to annually renew HI-CAL for that product to remain on the *OMRI Brand Name Products List*. The annual listing period starts with the date of this letter. OMRI sends renewal reminder packets during the last quarter of the product listing. See the most current *OMRI Operating Manual* for more details.

Again, thank you for your participation in the OMRI Materials Review Program. Please let us know if we can be of any further assistance.

Sincerely,



Cindy Douglas
Product Review Coordinator



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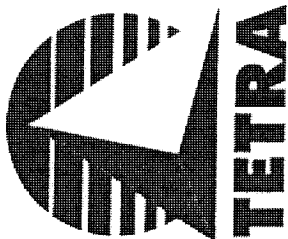
Tim Sullivan, J.D.
*Mississippi River Basin
Alliance*
Minneapolis, MN

Joran Viers
*New Mexico Organic
Commodity Commission*
Albuquerque, NM

Bill Wolf
Wolf & Associates, Inc.
New Castle, VA

Affiliations listed for identification

2 of 6



TETRA Technologies, Inc.

HI-CAL

For calcium nutrition in liquid fertilizer mixes and soil and water amendment

Information regarding the contents and level of metals in this product is available on the internet at <http://www.wa.gov/agr/>

RECOMMENDED APPLICATION RATES

FOR DRIP IRRIGATION:

Apply 10 gallons of HI-CAL per acre inch up to a maximum of 140 gallons of HI-CAL per acre foot of applied irrigation water per year.

FOR SOIL AMENDMENT:

Apply 25 gallons per acre of HI-CAL for every ton of gypsum required up to a maximum of 140 gallons of HI-CAL per acre per year.

FOR WATER RUN:

Apply 40 gallons HI-CAL for every acre foot of applied water up to a maximum of 140 gallons of HI-CAL per acre per year.

TO SUPPLEMENT GYPSUM:

Apply 10-15 gallons HI-CAL per acre for every ton of gypsum used up to a maximum of 140 gallons of HI-CAL per acre per year.

Net Weight: Bulk
Wt. Per Gallon = 11.5 lbs

GUARANTEED ANALYSIS

Calcium (Ca).....12%

Derived from Calcium Chloride

CAUTION
Keep Out of Reach of Children

CONDITIONS OF SALE:

- Seller warrants that this product consists of the ingredients specified and is reasonably fit for the purpose stated on this label when used in accordance with direction under normal conditions of use. No one, other than an officer of Seller is authorized to make any warranty, guarantee or direction concerning this product.
- Because the time, place, rate of application and other conditions of use are beyond Seller's control, Seller's liability from handling, storage and use of this product is limited to replacement of product or refund of purchase price.

Contact Sales & Tech. Support
for specific recommendations

Guaranteed by:

TETRA Technologies, Inc.

General Office: 25025 I-45 N., The Woodlands, TX 77380

Phone: (281) 367 1983



DO NOT MIX WITH PHOSPHATE OR SULFUR CONTAINING SOLUTIONS

STORAGE AND USE PRECAUTIONS:

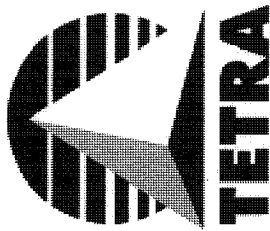
Avoid mixing with phosphorous or sulfur containing materials as precipitation may occur.
Store in polyolefin or polyethylene storage tanks.
Do not store for extended periods in mild steel tanks.
If fiberglass is used, consult manufacturer for compatibility.
Although stainless steel tanks are less prone to corrosion than mild steel, they are not recommended for extended storage.
Do not use nylon fittings and valves.
PVC or polypropylene valves and fittings are recommended.

WARNING:

Harmful if swallowed.
Avoid breathing spray mist.
May cause irritation of nose, throat, and/or skin.
Avoid contact with eyes, skin and clothing.

If swallowed: If victim is conscious, have victim drink water or milk. Never give anything by mouth to an unconscious person. Get medical attention.

If in eyes: Wash eyes with plenty of clear water for at least 15 minutes. Get medical attention.



TETRA Technologies, Inc.

HI-CAL

For calcium nutrition in liquid fertilizer mixes and soil
and water amendment

RECOMMENDED APPLICATION RATES

Mix any proportion of HI-CAL with urea or urea containing solution. Apply the mixture in the same manner as you now apply nitrogen solution. Use rates and methods of application that are consistent with normal nitrogen practices. The rates may be varied according to the recommendation for individual crops. For more information consult with your local agricultural agent and manufacturer's representative.

FOR DRIP IRRIGATION:

Apply 10 gallons of HI-CAL per acre inch up to a maximum of 140 gallons of HI-CAL per acre foot of applied irrigation water per year.

FOR SOIL AMENDMENT:

Apply 25 gallons per acre of HI-CAL for every ton of gypsum required up to a maximum of 140 gallons of HI-CAL per acre per year.

FOR WATER RUN:

Apply 40 gallons HI-CAL for every acre foot of applied water up to a maximum of 140 gallons of HI-CAL per acre per year.

TO SUPPLEMENT GYPSUM:

Apply 10-15 gallons HI-CAL per acre for every ton of gypsum used up to a maximum of 140 gallons of HI-CAL per acre per year.

Net Weight: Bulk

Wt. Per Gallon = 11.5 lbs

GUARANTEED ANALYSIS

Calcium (Ca).....12%
Derived from Calcium Chloride
Chlorine (Cl) maximum.....26%

CAUTION

Keep Out of Reach of Children

CONDITIONS OF SALE:

- Seller warrants that this product consists of the ingredients specified and is reasonably fit for the purpose stated on this label when used in accordance with direction under normal conditions of use. No one, other than an officer of Seller is authorized to make any warranty, guarantee or direction concerning this product. Because the time, place, rate of application and other conditions of use are beyond Seller's control, Seller's liability from handling, storage and use of this product is limited to replacement of product or refund of purchase price.

Contact Sales & Tech. Support
for specific recommendations

(F1480)

Guaranteed by:

TETRA Technologies, Inc.

General Office: 25025 I-45 N., The Woodlands, TX 77380

Phone: (281) 367-1983

DO NOT MIX WITH PHOSPHATE OR SULFUR CONTAINING SOLUTIONS

STORAGE AND USE PRECAUTIONS:

Avoid mixing with phosphorous or sulfur containing materials as precipitation may occur.
Store in polyolefin or polyethylene storage tanks.
Do not store for extended periods in mild steel tanks.
If fiberglass is used, consult manufacturer for compatibility.
Although stainless steel tanks are less prone to corrosion than mild steel, they are not recommended for extended storage.
Do not use nylon fittings and valves.
PVC or polypropylene valves and fittings are recommended.

WARNING:

Harmful if swallowed.
Avoid breathing spray mist.
May cause irritation of nose, throat, and/or skin.
Avoid contact with eyes, skin and clothing.

If swallowed: If victim is conscious, have victim drink water or milk. Never give anything by mouth to an unconscious person. Get medical attention.

If in eyes: Wash eyes with plenty of clear water for at least 15 minutes. Get medical attention.



HI-CAL[®] Liquid
12% Calcium 0-0-0-12Ca

PRODUCT SPECIFICATION

TYPICAL PHYSICAL PROPERTIES

Color Clear to Straw pH 7.0
Weight 11.5 lbs. per gallon

TYPICAL CHEMICAL ANALYSIS

Derived from Calcium Chloride

Typical Analysis Calcium (Ca) 12-13%	Lead (Pb) < 10 ppm
GUARANTEED Analysis ... Calcium (Ca) 12%	Mercury (Hg) < 10 ppm
Chloride (Cl) 24-26%	Molybdenum (Mo) < 10 ppm
Arsenic (As) < 10 ppm	Nickel (Ni) < 10 ppm
Cadmium (Cd) < 10 ppm	Selenium (Se) < 10 ppm
Cobalt (Co) < 10 ppm	Zinc (Zn) < 10 ppm

PACKAGING OPTIONS

• Bulk Liquid

SHIPPING POINTS

Contact TETRA Technologies
1-800-327-7817



This MSDS Sheet complies with the style format specified by ANSI Z400 1-1993

SECTION 1: CHEMICAL PRODUCT - COMPANY IDENTIFICATION

TETRA Technologies, Inc. (281) 367-1983
 25025 I-45 North (800) 327-7817
 The Woodlands, Texas 77380

(800) 424-9300 CHEMTREC (24 Hour Emergency Response)
(800) 222-1222 POISON CONTROL

PRODUCT: HI-CAL™
 CHEMICAL FAMILY: Inorganic Salt
 MSDS CREATION DATE: 07 OCT 97
 MSDS REVISION DATE: 24 SEP 02

SECTION 2: COMPOSITION, INFORMATION ON INGREDIENTS

The composition of this product is proprietary. This product is not hazardous as defined in 29 CFR 1910.1200. In the event of a medical emergency, compositional information will be revealed to a physician or nurse.

COMPONENTS	CAS NUMBER	RTECS NUMBER	PERCENTAGE
Calcium Chloride	10043-52-4	EV9800000	Proprietary
Proprietary	Proprietary	Proprietary	Proprietary

PROBABLE CONTAMINANTS: Calcium Carbonate, Calcium Hydroxide, Calcium Oxide, Alkali Metal Chlorides, Alkaline Earth Metal Chlorides

SECTION 3: HAZARDS IDENTIFICATION

NFPA RATINGS: (SCALE 0-4): HEALTH=1 FIRE=0 REACTIVITY=0
 EMERGENCY OVERVIEW: Odorless, clear to amber liquid. May cause skin, respiratory tract, and eye irritation.
 POTENTIAL HEALTH EFFECTS:
 INHALATION, SKIN CONTACT, EYE CONTACT: May cause minor irritation.
 INGESTION: May cause nausea.

SECTION 4: FIRST AID MEASURES

SKIN CONTACT: Remove contaminated clothing and shoes. Wash affected area with soap or mild detergent.
 EYE CONTACT: Flush eyes with water or normal saline solution.
 INGESTION: Get medical attention.

SECTION 5: FIRE FIGHTING MEASURES

FIRE AND EXPLOSION HAZARD: Negligible fire hazard.
 HAZARDOUS COMBUSTION PRODUCTS: Not applicable.

SECTION 6: ACCIDENTAL RELEASE MEASURES

OCCUPATIONAL SPILL: For small spills, take up with sand or other absorbent material and place in containers for disposal. For larger spills, dike far ahead of spill for later disposal.

This MSDS Sheet complies with the style format specified by ANSI Z400 1-1993

SECTION 7: HANDLING AND STORAGE

Observe all federal, state and local regulations when storing this product. Store in a tightly closed container. Store away from incompatible materials.

SECTION 8: EXPOSURE CONTROLS, PERSONAL PROTECTION

EXPOSURE LIMITS: No occupational exposure limits established by OSHA/ACGIH/NIOSH.
VENTILATION: Provide local exhaust ventilation system.
EYE PROTECTION: Wear safety glasses with splash shields or safety goggles/shield.
CLOTHING: Wear normal work clothing. Leather work boots and/or leather products will dehydrate with resultant shrinkage and possible destruction.
GLOVES: Wear appropriate protective gloves.

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

DESCRIPTION: Odorless, colorless to light yellow or amber liquid.
MOLECULAR FORMULA: Proprietary
MOLECULAR WEIGHT: Proprietary
BOILING POINT: Proprietary
SPECIFIC GRAVITY: Proprietary
pH: 6.0 - 9.0
WATER SOLUBILITY: Miscible with water in all proportions.
SOLVENT SOLUBILITY: Miscible in alcohol, acetic acid and acetone

SECTION 10: STABILITY AND REACTIVITY

REACTIVITY: Stable under normal temperatures and pressures.
INCOMPATIBILITIES: Strong oxidizing agents.
HAZARDOUS DECOMPOSITION: None, under normal conditions.
POLYMERIZATION: Does not occur under normal temperatures and pressures.
CONDITIONS TO AVOID: None

SECTION 11: TOXICOLOGICAL INFORMATION

TOXICITY DATA (ANHYDROUS CALCIUM CHLORIDE):
TD_{Lo}: 112g/kg, oral, 20 weeks, rat
LD_{Lo}: 274 mg/kg, subcutaneous, dog
LD₅₀: 1000 mg/kg, oral, rat
LD₅₀: 264 mg/kg, intraperitoneal, rat
Mutagenic data and tumorigenic data—see Registry of Toxic Effects of Chemical Substances (RTECS) file.
CARCINOGEN STATUS: None.
LOCAL EFFECTS: Eye, mucous membrane and skin irritant.
ACUTE TOXICITY LEVEL: Moderately toxic by ingestion, slightly toxic by dermal absorption.

SECTION 12: ECOLOGICAL INFORMATION

DEGRADABILITY: Product will not biodegrade or bioaccumulate.

SECTION 13: DISPOSAL INFORMATION

Observe all federal, state and local regulations when disposing of this substance.

This MSDS Sheet complies with the style format specified by ANSI Z400 1-1993

SECTION 14: TRANSPORT INFORMATION

DOT Shipping Name-ID Number: Non-regulated.

SECTION 15: REGULATORY INFORMATION

TSCA STATUS:	Yes
DSL STATUS:	Yes
EINECS STATUS:	Yes
OTHER TSCA ISSUES:	None
CALIFORNIA PROPOSITION 65:	No ingredients found on the Propositions 65 list
SARA SECTIONS 311 CLASSIFICATION:	Acute Hazard

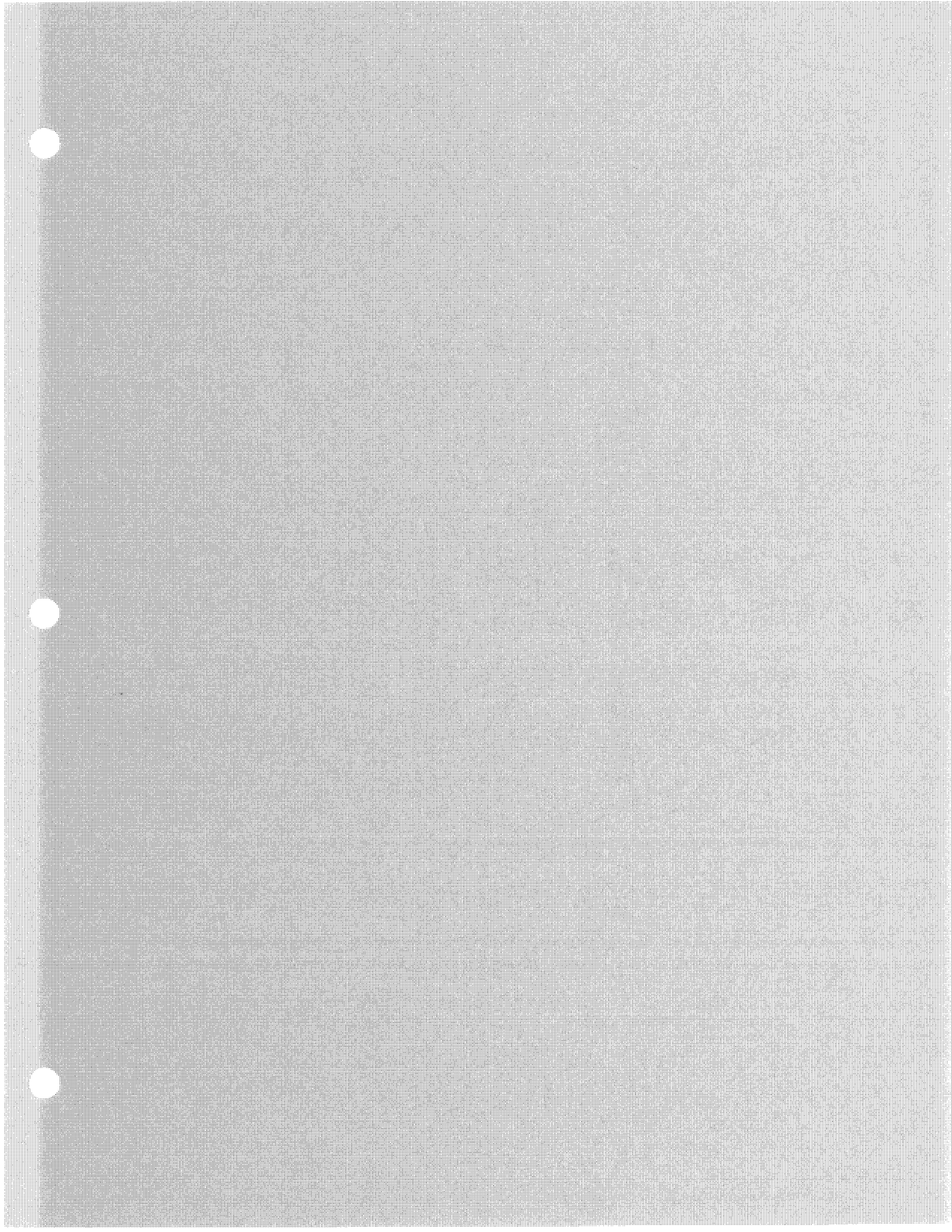
SECTION 16: OTHER INFORMATION

Individuals handling this product should be informed of the recommended safety precautions and should have access to this information.

This information relates to the specific product designated and may not be valid for such product used in combination with any other materials or in any other processes. Such information is to the best of our knowledge and belief, accurate and reliable as of the date compiled. However, no representation, warranty or guarantee is made as to its accuracy, reliability, or completeness. It is the users' responsibility to satisfy themselves as to the suitability and completeness of such information for their own particular use. We do not accept liability for any loss or damage that may occur from the use of this information nor do we offer warranty against patent infringement.

TETRA Technologies, Inc. reserves the right to refuse shipment of this product to any consumer who fails to demonstrate the ability to consistently handle and use it safely and in compliance with all applicable laws, rules and regulations. Such demonstration may require on-site inspection of any or all storage, processing, packaging and other handling systems that come in contact with it.

Customers are responsible for compliance with local, state and federal regulations that may be pertinent in the storage, application and disposal of this product.





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Chemical References

CALCIUM CHLORIDE, DIHYDRATE

CAS #10035-04-8

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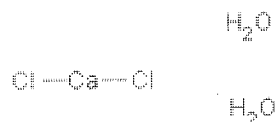
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NAME: Calcium chloride [USAN:JAN]
RN: 10035-04-8



MW: 147.014
[Enlarge Structure](#)

Basic Information

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[Code of Federal Regulations]
[Title 21, Volume 3]
[Revised as of April 1, 2004]
From the U.S. Government Printing Office via GPO Access
[CITE: 21CFR184.1193]

[Page 491-492]

TITLE 21--FOOD AND DRUGS

CHAPTER I--FOOD AND DRUG ADMINISTRATION, DEPARTMENT OF HEALTH AND HUMAN SERVICES (CONTINUED)

PART 184 DIRECT FOOD SUBSTANCES AFFIRMED AS GENERALLY RECOGNIZED AS SAFE--Table of Contents

Subpart B Listing of Specific Substances Affirmed as GRAS

Sec. 184.1193 Calcium chloride.

(a) Calcium chloride ($\text{CaCl}_2 \cdot 2\text{H}_2\text{O}$), CAS Reg. No. 10035-04-8) or anhydrous calcium chloride (CaCl_2), CAS Reg. No. 10043-52-4) may be commercially obtained as a byproduct in the ammonia-soda (Solvay) process and as a joint product from natural salt brines, or it may be prepared by substitution reactions with other calcium and chloride salts.

(b) The ingredient meets the specifications of the Food Chemicals Codex, 3d Ed. (1981), p. 47, which is incorporated by reference. Copies are available from the National Academy Press, 2101 Constitution Ave. NW., Washington, DC 20418, or available for inspection at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC 20408.

(c) The ingredient is used as an anticaking agent as defined in Sec. 170.3(o)(1) of this chapter; antimicrobial agent as defined in Sec. 170.3(o)(2) of this chapter; curing or pickling agent as defined in Sec. 170.3(o)(5) of this chapter; firming agent as defined in Sec. 170.3(o)(10) of this chapter; flavor enhancer as defined in Sec. 170.3(o)(11) of this chapter; humectant as defined in Sec. 170.3(o)(16) of this chapter; nutrient supplement as defined in Sec. 170.3(o)(20) of this chapter; pH control agent as defined in Sec. 170.3(o)(23) of this chapter; processing aid as defined in Sec. 170.3(o)(24) of this chapter; stabilizer and thickener as defined in Sec. 170.3(o)(28) of this chapter; surface-active agent as defined in Sec. 170.3(o)(29) of this chapter; synergist as defined in Sec. 170.3(o)(31) of this chapter; and texturizer as defined in Sec. 170.3(o)(32) of this chapter.

(d) The ingredient is used in foods at levels not to exceed current good manufacturing practices in accordance

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with Sec. 184.1(b)(1). Current good manufacturing practices result in a maximum level, as served, of 0.3 percent for baked goods as defined in Sec. 170.3(n)(1) of this chapter and for dairy product analogs as defined in Sec. 170.3(n)(10) of this chapter; 0.22 percent for nonalcoholic beverages and beverage bases as defined in Sec. 170.3(n)(3) of this chapter; 0.2 percent for cheese as defined in Sec. 170.3(n)(5) of this chapter and for processed fruit and fruit juices as defined in Sec. 170.3(n)(35) of this chapter; 0.32 percent for coffee and tea as defined in Sec. 170.3(n)(7) of this chapter; 0.4 percent for condiments and relishes as defined in Sec. 170.3(n)(8) of this chapter; 0.2 percent for gravies and sauces as defined in Sec. 170.3(n)(24) of this chapter; 0.1 percent for commercial jams and jellies as defined in Sec. 170.3(n)(28) of this chapter; 0.25 percent for meat products as defined in Sec. 170.3(n)(29) of this chapter; 2.0 percent for plant protein products as defined in Sec. 170.3(n)(33) of this chapter; 0.4 percent for processed vegetables and vegetable juices as defined in

Sec. 170.3(n)(36) of this chapter; and 0.05 percent for all other food categories.

(e) Prior sanctions for this ingredient different from the uses established in this section do not exist or have been waived.

[47 FR 27808, June 25, 1982, as amended at 61 FR 14247, Apr. 1, 1996]

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Calcium Supplements (Systemic)


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Contents of this page:

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Brand Names

Some commonly used brand names are:

In the U.S.—

- [Alka-Mints](#)²
- [Amitone](#)²
- [Calcarb 600](#)²
- [Calci-Chew](#)²
- [Calciday 667](#)²
- [Calcilac](#)²
- [Calci-Mix](#)²
- [Calcionate](#)⁵
- [Calcium 600](#)²
- [Calglycine](#)²
- [Calphosan](#)⁶
- [Cal-Plus](#)²
- [Caltrate 600](#)²
- [Caltrate Jr](#)²
- [Chooz](#)²
- [Citracal](#)⁴
- [Citracal Liquitabs](#)⁴
- [Dicarbosil](#)²
- [Gencalc 600](#)²
- [Liquid-Cal](#)²
- [Liquid Cal-600](#)²
- [Maalox Antacid Caplets](#)²
- [Mallamint](#)²
- [Neo-Caiglucon](#)⁵
- [Nephro-Calci](#)²
- [Os-Cal 500](#)²
- [Os-Cal 500 Chewable](#)²
- [Oysco](#)²
- [Oysco 500 Chewable](#)²
- [Oyst-Cal 500](#)²
- [Oystercal 500](#)²
- [Posture](#)¹²
- [Rolaids Calcium Rich](#)²
- [Titalac](#)²
- [Tums](#)²
- [Tums 500](#)²
- [Tums E-X](#)²

In Canada—

- [Apo-Cal](#)²
- [Calciject](#)³
- [Calcite 500](#)²
- [Calcium-Sandoz](#)⁵
- [Calcium-Sandoz Forte](#)¹⁰
- [Caltrate 600](#)²
- [Gramcal](#)¹⁰
- [Nu-Cal](#)²
- [Os-Cal](#)²
- [Os-Cal Chewable](#)²

- Calcium Stanley⁶
- Calsan²
- Tums Extra Strength²
- Tums Regular Strength²

Note: For quick reference, the following calcium supplements are numbered to match the corresponding brand names.

This information applies to the following:

- | | |
|--|--|
| <ol style="list-style-type: none"> 1. Calcium Acetate (KAL-see-um ASa-tate)† 2. Calcium Carbonate (KAL-see-um KAR-boh-nate)‡ 3. Calcium Chloride (KAL-see-um KLOR-ide)‡ 4. Calcium Citrate (KAL-see-um SIH-trayt)‡‡ 5. Calcium Glubionate (KAL-see-um gloo-BY-oh-nate)§ 6. Calcium Gluceptate and Calcium Gluconate (KAL-see-um gloo-SEP-tate and KAL-see-um GLOO-coh-nate)* 7. Calcium Gluconate (KAL-see-um GLOO-coh-nate)‡ | <ol style="list-style-type: none"> 8. Calcium Glycerophosphate and Calcium Lactate (KAL-see-um gliss-er-o-FOS-fate and KAL-see-um LAK-tate)‡ 9. Calcium Lactate (KAL-see-um LAK-tate)‡ 10. Calcium Lactate-Gluconate and Calcium Carbonate (KAL-see-um LAK-tate GLOO-coh-nate and KAL-see-um KAR-boh-nate)* 11. Dibasic Calcium Phosphate (dy-BAY-sic KAL-see-um FOS-fate)‡‡ 12. Tribasic Calcium Phosphate (try-BAY-sic KAL-see-um FOS-fate)† 13. Calcium Gluceptate (KAL-see-um gloo-SEP-tate)‡‡ |
|--|--|

‡ Generic name product may be available in the U.S.

§ Generic name product may be available in Canada

* Not commercially available in the U.S.

† Not commercially available in Canada

Category

- Antacid –Calcium Carbonate
- Antihyperkalemic –Calcium Chloride ; Calcium Gluconate Injection
- Antihypermagnesemic – Calcium Chloride; Calcium Gluceptate; Calcium Gluconate Injection
- Antihyperphosphatemic –Calcium Carbonate ; Calcium Citrate
- Antihypocalcemic –Calcium Acetate ; Calcium Carbonate; Calcium Chloride; Calcium Citrate; Calcium Glubionate; Calcium Gluceptate; Calcium Gluconate; Calcium Glycerophosphate and Calcium Lactate; Calcium Lactate; Calcium Lactate-Gluconate and Calcium Carbonate; Calcium Phosphate, Dibasic; Calcium Phosphate, Tribasic
- Cardiotonic –Calcium Chloride; Calcium Gluconate Injection
- Electrolyte replenisher –Calcium Acetate; Calcium Chloride; Calcium Gluceptate; Calcium Gluconate Injection
- Nutritional supplement, mineral –Calcium Carbonate; Calcium Citrate; Calcium Glubionate, Oral ; Calcium Gluceptate and Calcium Gluconate ; Calcium Gluconate, Oral; Calcium Lactate; Calcium Lactate-Gluconate and Calcium Carbonate; Calcium Phosphate, Dibasic; Calcium Phosphate, Tribasic

Description

Calcium supplements are taken by individuals who are unable to get enough calcium in their regular diet or who have a need for more calcium. They are used to prevent or treat several conditions that may cause hypocalcemia (not enough calcium in the blood). The body needs calcium to make strong bones. Calcium is also needed for the heart, muscles, and nervous system to work properly.

The bones serve as a storage site for the body's calcium. They are continuously giving up calcium to the bloodstream and then replacing it as the body's need for calcium changes from day to day. When there is not enough calcium in the blood to be used by the heart and other organs, your body will take the needed calcium from the bones. When you eat foods rich in calcium, the calcium will be restored to the bones and the balance between your blood and bones will be maintained.

Pregnant women, nursing mothers, children, and adolescents may need more calcium than they normally get from eating calcium-rich foods. Adult women may take calcium supplements to help prevent a bone disease called osteoporosis. Osteoporosis, which causes thin, porous, easily broken bones, may occur in women after menopause, but may sometimes occur in elderly men also. Osteoporosis in women past menopause is thought to be caused by a reduced amount of ovarian estrogen (a female hormone). However, a diet low in

calcium for many years, especially in the younger adult years, may add to the risk of developing it. Other bone diseases in children and adults are also treated with calcium supplements.

Calcium supplements may also be used for other conditions as determined by your health care professional.

Injectable calcium is administered only by or under the supervision of your health care professional. Other forms of calcium are available without a prescription.

Calcium supplements are available in the following dosage forms:

Oral

- Calcium Carbonate
 - Capsules (U.S. and Canada)
 - Oral suspension (U.S.)
 - Tablets (U.S. and Canada)
 - Chewable tablets (U.S. and Canada)
- Calcium Citrate
 - Tablets (U.S.)
 - Tablets for solution (U.S.)
- Calcium Glubionate
 - Syrup (U.S. and Canada)
- Calcium Gluceptate and Calcium Gluconate
 - Oral solution (Canada)
- Calcium Gluconate
 - Tablets (U.S. and Canada)
 - Chewable tablets (U.S.)
- Calcium Lactate
 - Tablets (U.S. and Canada)
- Calcium Lactate-Gluconate and Calcium Carbonate
 - Tablets for solution (Canada)
- Dibasic Calcium Phosphate
 - Tablets (U.S.)
- Tribasic Calcium Phosphate
 - Tablets (U.S.)

Parenteral

- Calcium Acetate
 - Injection (U.S.)
- Calcium Chloride
 - Injection (U.S. and Canada)
- Calcium Glubionate
 - Injection (Canada)
- Calcium Gluceptate
 - Injection (U.S.)
- Calcium Gluconate
 - Injection (U.S. and Canada)
- Calcium Glycerophosphate and Calcium Lactate
 - Injection (U.S.)

A calcium "salt" contains calcium along with another substance, such as carbonate or gluconate. Some calcium salts have more calcium (elemental calcium) than others. For example, the amount of calcium in calcium carbonate is greater than that in calcium gluconate. To give you an idea of how different calcium supplements vary in calcium content, the following chart explains how many tablets of each type of supplement will provide 1000 milligrams of elemental calcium. When you look for a calcium supplement, be sure the number of milligrams on the label refers to the amount of elemental calcium, and not to the strength of each tablet.

Calcium supplement	Strength of each tablet (in milligrams)	Amount of elemental calcium per tablet (in milligrams)	Number of tablets to provide 1000 milligrams of calcium
Calcium carbonate	625	250	4
	650	260	4
	750	300	4

	835	334	3
	1250	500	2
	1500	600	2
Calcium citrate	950	200	5
Calcium gluconate	500	45	22
	650	58	17
	1000	90	11
Calcium lactate	325	42	24
	650	84	12
Calcium phosphate, dibasic	500	115	9
Calcium phosphate, tribasic	800	304	4
	1600	608	2

Importance of Diet

For good health, it is important that you eat a balanced and varied diet. Follow carefully any diet program your health care professional may recommend. For your specific dietary vitamin and/or mineral needs, ask your health care professional for a list of appropriate foods. If you think that you are not getting enough vitamins and/or minerals in your diet, you may choose to take a dietary supplement. The daily amount of calcium needed is defined in several different ways.

For U.S.—

- Recommended Dietary Allowances (RDAs) are the amount of vitamins and minerals needed to provide for adequate nutrition in most healthy persons. RDAs for a given nutrient may vary depending on a person's age, sex, and physical condition (e.g., pregnancy).
- Daily Values (DVs) are used on food and dietary supplement labels to indicate the percent of the recommended daily amount of each nutrient that a serving provides. DV replaces the previous designation of United States Recommended Daily Allowances (USRDA).

For Canada—

- Recommended Nutrient Intakes (RNIs) are used to determine the amounts of vitamins, minerals, and protein needed to provide adequate nutrition and lessen the risk of chronic disease.

Normal daily recommended intakes in milligrams (mg) for calcium are generally defined as follows:

Persons	U.S. (mg)	Canada (mg)
Infants and children Birth to 3 years of age	400–800	250–550
4 to 6 years of age	800	600
7 to 10 years of age	800	700–1100
Adolescent and adult males	800–1200	800–1100
Adolescent and adult females	800–1200	700–1100
Pregnant females	1200	1200–1500
Breast-feeding females	1200	1200–1500

Getting the proper amount of calcium in the diet every day and participating in weight-bearing exercise (walking, dancing, bicycling, aerobics, jogging), especially during the early years of life (up to about 35 years of age) is most important in helping to build and maintain bones as dense as possible to prevent the development of osteoporosis in later life.

The following table includes some calcium-rich foods. The calcium content of these foods can supply the daily RDA or RNI for calcium if the foods are eaten regularly in sufficient amounts.

Food (amount)	Milligrams of calcium
Nonfat dry milk, reconstituted (1 cup)	375
Lowfat, skim, or whole milk (1 cup)	290 to 300

Yogurt (1 cup)	275 to 400
Sardines with bones (3 ounces)	370
Ricotta cheese, part skim (½ cup)	340
Salmon, canned, with bones (3 ounces)	285
Cheese, Swiss (1 ounce)	272
Cheese, cheddar (1 ounce)	204
Cheese, American (1 ounce)	174
Cottage cheese, lowfat (1 cup)	154
Tofu (4 ounces)	154
Shrimp (1 cup)	147
Ice milk (¾ cup)	132

Vitamin D helps prevent calcium loss from your bones. It is sometimes called "the sunshine vitamin" because it is made in your skin when you are exposed to sunlight. If you get outside in the sunlight every day for 15 to 30 minutes, you should get all the vitamin D you need. However, in northern locations in winter, the sunlight may be too weak to make vitamin D in the skin. Vitamin D may also be obtained from your diet or from multivitamin preparations. Most milk is fortified with vitamin D.

Do not use bonemeal or dolomite as a source of calcium. The Food and Drug Administration has issued warnings that bonemeal and dolomite could be dangerous because these products may contain lead.

Before Using This Medicine

If you are taking this dietary supplement without a prescription, carefully read and follow any precautions on the label. For calcium supplements, the following should be considered:

Pregnancy—It is especially important that you are receiving enough calcium when you become pregnant and that you continue to receive the right amount of calcium throughout your pregnancy. The healthy growth and development of the fetus depend on a steady supply of nutrients from the mother. However, taking large amounts of a dietary supplement during pregnancy may be harmful to the mother and/or fetus and should be avoided.

Breast-feeding—It is especially important that you receive the right amount of calcium so that your baby will also get the calcium needed to grow properly. However, taking large amounts of a dietary supplement while breast-feeding may be harmful to the mother and/or baby and should be avoided.

Children—Problems in children have not been reported with intake of normal daily recommended amounts. Injectable forms of calcium should not be given to children because of the risk of irritating the injection site.

Older adults—Problems in older adults have not been reported with intake of normal daily recommended amounts. It is important that older people continue to receive enough calcium in their daily diets. However, some older people may need to take extra calcium or larger doses because they do not absorb calcium as well as younger people. Check with your health care professional if you have any questions about the amount of calcium you should be taking in each day.

Other medicines—Medicines or other dietary supplements

Although certain medicines or dietary supplements should not be used together at all, in other cases they may be used together even if an interaction might occur. In these cases, your health care professional may want to change the dose, or other precautions may be necessary. When you are taking calcium supplements, it is especially important that your health care professional know if you are taking any of the following:

- Calcium-containing medicines, other—Taking excess calcium may cause too much calcium in the blood or urine and lead to medical problems
- Cellulose sodium phosphate (e.g., Calcibind)—Use with calcium supplements may decrease the effects of cellulose sodium phosphate
- Digitalis glycosides (heart medicine)—Use with calcium supplements by injection may increase the chance of irregular heartbeat
- Etidronate (e.g., Didronel)—Use with calcium supplements may decrease the effects of etidronate; etidronate should not be taken

within 2 hours of calcium supplements

- Gallium nitrate (e.g., Ganite)—Use with calcium supplements may cause gallium nitrate to not work properly
- Magnesium sulfate (for injection)—Use with calcium supplements may cause either medicine to be less effective
- Phenytoin (e.g., Dilantin)—Use with calcium supplements may decrease the effects of both medicines; calcium supplements should not be taken within 1 to 3 hours of phenytoin
- Tetracyclines (medicine for infection) taken by mouth—Use with calcium supplements may decrease the effects of tetracycline; calcium supplements should not be taken within 1 to 3 hours of tetracyclines

Other medical problems—The presence of other medical problems may affect the use of calcium supplements. Make sure you tell your health care professional if you have any other medical problems, especially:

- Diarrhea or
- Stomach or intestinal problems—Extra calcium or specific calcium preparations may be necessary in these conditions
- Heart disease—Calcium by injection may increase the chance of irregular heartbeat
- Hypercalcemia (too much calcium in the blood) or
- Hypercalciuria (too much calcium in the urine)—Calcium supplements may make these conditions worse
- Hyperparathyroidism or
- Sarcoidosis—Calcium supplements may increase the chance of hypercalcemia (too much calcium in the blood)
- Hypoparathyroidism—Use of calcium phosphate may cause high blood levels of phosphorus which could increase the chance of side effects
- Kidney disease or stones—Too much calcium may increase the chance of kidney stones

Proper Use of This Medicine

Dosing—

The amount of calcium needed to meet normal daily recommended intakes will be different for different individuals. The following information includes only the average amounts of calcium.

- For oral dosage form (capsules, chewable tablets, lozenges, oral solution, oral suspension, syrup, tablets, extended-release tablets, tablets for solution):
 - To prevent deficiency, the amount taken by mouth is based on normal daily recommended intakes (Note that the normal daily recommended intakes are expressed as an actual amount of calcium. The salt form [e.g., calcium carbonate, calcium gluconate, etc.] has a different strength):
 - For the U.S.*
 - Adults and teenagers—800 to 1200 milligrams (mg) per day.
 - Pregnant and breast-feeding females—1200 mg per day.
 - Children 4 to 10 years of age—800 mg per day.
 - Children birth to 3 years of age—400 to 800 mg per day.
 - For Canada*
 - Adult and teenage males—800 to 1100 mg per day.
 - Adult and teenage females—700 to 1100 mg per day.
 - Pregnant and breast-feeding females—1200 to 1500 mg per day.
 - Children 7 to 10 years of age—700 to 1100 mg per day.
 - Children 4 to 6 years of age—600 mg per day.
 - Children birth to 3 years of age—250 to 550 mg per day.
 - To treat deficiency:
 - Adults, teenagers, and children—Treatment dose is determined by prescriber for each individual based on

severity of deficiency.

Drink a full glass (8 ounces) of water or juice when taking a calcium supplement. However, if you are taking calcium carbonate as a phosphate binder in kidney dialysis, it is not necessary to drink a glass of water.

This dietary supplement is best taken 1 to 1½ hours after meals, unless otherwise directed by your health care professional. However, patients with a condition known as achlorhydria may not absorb calcium supplements on an empty stomach and should take them with meals.

For individuals taking *the chewable tablet form* of this dietary supplement:

- Chew the tablets completely before swallowing.

For individuals taking *the syrup form* of this dietary supplement:

- Take the syrup before meals. This will allow the dietary supplement to work faster.
- Mix in water or fruit juice for infants or children.

Take this dietary supplement only as directed. Do not take more of it and do not take it more often than recommended on the label. To do so may increase the chance of side effects.

Missed dose—

If you are taking this dietary supplement on a regular schedule and you miss a dose, take it as soon as possible, then go back to your regular dosing schedule.

Storage—

To store this dietary supplement:

- Keep out of the reach of children.
- Store away from heat and direct light.
- Do not store in the bathroom, near the kitchen sink, or in other damp places. Heat or moisture may cause the dietary supplement to break down.
- Keep the liquid form of this dietary supplement from freezing.
- Do not keep outdated dietary supplements or those no longer needed. Be sure that any discarded dietary supplement is out of the reach of children.

Precautions While Using This Medicine

If this dietary supplement has been ordered for you by your health care professional and you will be taking it in large doses or for a long time, your health care professional should check your progress at regular visits. This is to make sure the calcium is working properly and does not cause unwanted effects.

Do not take calcium supplements within 1 to 2 hours of taking other medicine by mouth. To do so may keep the other medicine from working properly.

Unless you are otherwise directed by your health care professional, to make sure that calcium is used properly by your body:

- *Do not take other medicines or dietary supplements containing large amounts of calcium, phosphates, magnesium, or vitamin D unless your health care professional has told you to do so or approved.*
- *Do not take calcium supplements within 1 to 2 hours of eating large amounts of fiber-containing foods, such as bran and whole-grain cereals or breads, especially if you are being treated for hypocalcemia (not enough calcium in your blood).*
- *Do not drink large amounts of alcohol or caffeine-containing beverages (usually more than 8 cups of coffee a day), or use tobacco.*

Some calcium carbonate tablets have been shown to break up too slowly in the stomach to be properly absorbed into the body. If the calcium carbonate tablets you purchase are not specifically labeled as being "USP," check with your pharmacist. He or she may be able to help you determine which tablets are best.

Side Effects of This Medicine

Side Effects of This Dietary Supplement Along with its needed effects, a dietary supplement may cause some unwanted effects. Although the following side effects occur very rarely when the calcium supplement is taken as recommended, they may be more likely to occur if:

- It is taken in large doses.
- It is taken for a long time.
- It is taken by patients with kidney disease.

Check with your health care professional as soon as possible if any of the following side effects occur:

- *More common (for injection form only)*
 - Dizziness; flushing and/or sensation of warmth or heat; irregular heartbeat; nausea or vomiting; skin redness, rash, pain, or burning at injection site; sweating; tingling sensation
- *Rare*
 - Difficult or painful urination; drowsiness; nausea or vomiting (continuing); weakness
- *Early signs of overdose*
 - Constipation (severe); dryness of mouth; headache (continuing); increased thirst; irritability; loss of appetite; mental depression; metallic taste; unusual tiredness or weakness
- *Late signs of overdose*
 - Confusion; drowsiness (severe); high blood pressure; increased sensitivity of eyes or skin to light; irregular, fast, or slow heartbeat; unusually large amount of urine or increased frequency of urination

Other side effects not listed above may also occur in some patients. If you notice any other effects, check with your health care professional.

Additional Information

Once a medicine or dietary supplement has been approved for marketing for a certain use, experience may show that it is also useful for other medical problems. Although this use is not included in product labeling, calcium supplements are used in certain patients with the following medical condition:

- Hyperphosphatemia (too much phosphate in the blood)

Other than the above information, there is no additional information relating to proper use, precautions, or side effects for this use.

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Salt Affected Soil: Problems and Solutions

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Introduction

A substantial percentage of agricultural land around the world is salt affected. However, adverse role of salt in soil is frequently misunderstood. In terms of the role of sodium and chloride in the crop physiology, while sodium is toxic to crops, chloride is a micronutrient. In fact, plants may take up as much chloride as they do secondary elements such as sulfur. However, the salt problem in soil is mistakenly labeled as the chloride problem and not a sodium problem, which is the real culprit. This misrepresentation possibly could be attributed to the chemical analytical practices. Until recently, the analysis of sodium in a substrate or liquid phase has been a tedious task. For an accurate measurement, one needs a more expensive and sophisticated analytical instruments to measure sodium content. In soil, other elements present in chloride form, such as calcium and magnesium, are much easier to measure. Measurement of chloride, on the other hand, is even simpler and relatively cheap. Portable analytical tools for chloride measurement have also been available for some time. To estimate the extent of salt damage to the soil, it had, therefore, become customary to measure the chloride content. May be due to this reason chloride is frequently misunderstood being the problem for the soil.

In this article the problems associated with the salt affected soil are discussed. Treatment of such soil is recommended for bringing it back to the state that will allow the healthy growth of crops.

How is Salt Present in Soil and Its Effect on Crops?

Salt affected soils are as a result of arid environment, frequent use of irrigation water that has high salt concentration, high salt containing fertilizers and also due to accidental spills of high salt containing fluids from mining or oil/gas field operations. In the aqueous environment of soil, salt is present in its dissociated form, as Na^+ and Cl^- ions. The behavior of these ions in soil is influenced by their affinity to the soil particles. Soil, in general, is composed of sand, silt, humus and clays. In the agricultural environment, these soil components are negatively charged. Of these, clay and humus also have high cationic exchange capacity (CEC), which represents the total quantity of negative charge available to attract positively charged ions present in the solution. It is expressed in terms of milliequivalent of negative charge per 100 g of oven dried soil (meq/100g). The CEC also represents the total meq/100 g of cations that can be held on the negative charge sites of the soil particles.

In such environment, invariably, it is the Na^+ ions that tend to adsorb into the soil structure, particularly in to the clay structure. Cl^- ions, being like charged to the surface of the soil forming components, remain free, and move with the movement of moisture. This means, with adequate irrigation, they can be flushed out of the soil cross section to lower levels.

Salt contaminated soil can be classified into three groups: *saline*, *sodic* and *saline/sodic*.

Saline Soils have saturated Extract Conductivity (EC_{se}) > 4 mmhos (or mS)/cm, $\text{pH} < 8.5$, and $\text{ESP} < 15\%$. This means that most of salt in the soil is still in the Free State, and sodium has not adsorbed into the soil structure as yet. However, the presence of the soluble salt in soil is sufficient to interfere with vegetation or plant growth. In such case, depending on the CEC value of the soil, the excessive soluble salts may be removed by leaching through irrigation and the soil again can become normal. If the CEC value of the soil is low, irrigation with fresh water can alone resolve the problem. However, if the CEC value of the soil is high and attracts the Na^+ ions from the salt solution, the adsorbed Na^+ ions would need to be replaced by more preferred ions.

Saline soils are often recognized by the presence of white crusts of salts on the surface. The damage to vegetation or plants in saline soil is primarily attributed to its high EC_{se} , which imparts high osmotic pressure of the soil solution that keeps moisture away from the root structure. This, in turn, could produce devastation on vegetation or plants.

Sodic Soils occur when $\text{ESP} > 15\%$, $\text{EC}_{\text{se}} < 4$ mmhos/cm, and $\text{pH} > 8.5$. This is the state after a certain period of soil being exposed to the salt solution, and the CEC value of the soil is adequate to adsorb Na^+ ions into its structure. In such case, the adsorption of sodium disperses the colloidal fraction of the soil structure and makes the soil more impermeable to moisture or air. The presence of sodium in the soil structure in the sodic soil creates nutritional disorder in most plants and vegetation. In contrast to saline soil, in the sodic soil, when free salt is leached out of its structure, the exchangeable sodium hydrolyses and there is increase of pH. In this case, as the free salt is leached out of the soil structure, the EC_{se} value is lower than the saline soil.

Sodic soils are primarily found at the sites which were exposed to salt in the past. In the soil structure, sodium ions are adsorbed into the colloidal clay particles. Due to it being like charged to the soil particles, the fate of the chloride ions is to drain out of the soil system and to follow the movement of water. However, due to the dispersion of colloidal clay particles in the soil structure soil becomes increasingly impermeable. The free chloride ions are also physically entrapped in to the impermeable soil structure. These entrapped chloride ions can be removed from the soil structure by replacing the sodium ions with preferred ions. Adsorption of these preferred ions also destabilizes (flocculate) the soil particles, making the soil structure more permeable.

Saline/Sodic Soils is combination of the two states, which has high salt concentration with $EC_{se} > 4$ mmhos/cm and high ESP $> 15\%$. However, it has $pH < 8.5$. This is a typical case of periodic occurrence of salt spills to the soil that has been exposed to salt for some time. Although, the return of the soluble salt to the soil that has achieved the sodic state may lower the pH, the management of this soil continues to be a problem until the excess salts and exchangeable sodium are removed from the plant or vegetation root zone and favorable physical condition of soil is restored.

The high EC_{se} value of soil due to high concentration of salt increases the osmotic pressure of the soil solution. The roots of plants and vegetation under this environment are unable to overcome the osmotic pressure of the soil, and they die from the lack of water.

As there is a statistical relationship between EC_{se} and osmotic pressure, on the basis of easily measurable EC_{se} potential damage for the crops can be estimated. Apart from the lack of water being available to the roots in the high EC_{se} environment, high salt concentration in the soil solution also reduces the availability of essential plant nutrients. This results in drop in plant yields, and in many cases there is total devastation.

There is no one threshold salinity level for all plants or vegetation. Generally, vegetables are more sensitive to salts than grains and grasses. A general crop tolerance levels to salt has been developed by the US Salinity Laboratory (1954) as given in Table 1, which indicates no effect on the plant yields at EC_{se} lower than 2 mmhos/cm.

Table 1
General Crop Response as a Function of EC_{se}

<u>EC_{se} (mmhos/cm)</u>	<u>Effect on Crop Yield</u>
0 – 2	None
2 – 4	Slight
4 – 8	Many crops affected
8 – 16	Only tolerant crops yield well
> 16	Only very tolerant crops yield well

At higher EC_{se} value than 16 mmhos/cm, either there is drastic reduction in plant yield or there is a complete devastation. Sodidity or ESP of the soil or high sodium content of the soil also influences the crop yield, as shown in Table 2.

Table 2
Reduction in Crop Yield as a Function of Soil ESP

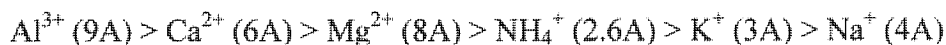
<u>Type of Soil</u>	<u>ESP</u>	<u>Average % Reduction in Crop Yield</u>
Slightly Sodic	7 – 15	20 – 40
Moderately Sodic	15 – 20	40 – 60
Very Sodic	20 – 30	60 – 80
Extremely Sodic	> 30	> 80

Remediation of Salt Affected Soil

Principles: The mode of adsorption of the ionic species that are present in the soil or that are introduced to it could be attributed primarily to the ion exchange phenomenon or to the physical or chemical adsorption of the ions to the soil structure. While cation exchange in soil is considered to be the major factor influencing the adsorption of the available ions in the system, adsorption of cations at the predominantly negatively charged surface of the soil forming particles is also possible.

The major exchangeable or adsorbing cations in soil are Al^{3+} , Ca^{2+} , Mg^{2+} , K^+ , Na^+ and H^+ . Other exchangeable cations, which are minor components of soil but have nutrient values are Cu^{2+} , Fe^{3+} , Zn^{2+} , Mn^{2+} and NH_4^+ . Among these, Ca^{2+} , Mg^{2+} , K^+ and Na^+ are the dominant cations in most soils, and they are frequently measured for the evaluation of soil condition.

Valence is the major factor affecting the likelihood that a cation can be adsorbed. A trivalent Al^{3+} is more likely to adsorb than a divalent Ca^{2+} , which is more strongly adsorbed than a monovalent Na^+ . However, for cations of similar valence, smaller cations with greater charge density per unit volume adsorb more strongly. The diameter of these ions includes the water molecules that are adsorbed onto them, forming a hydrated layer. It is the hydrated diameter of the cations that are involved in the adsorption at the particle surfaces. For this reason, Ca^{2+} with hydrated ionic radius of 6A adsorbs with much stronger energy than Mg^{2+} with hydrated radius of 8A. Similarly, NH_4^+ or K^+ with their respective radii of 2.6A and 3A adsorbs with much stronger energy than Na^+ with hydrated radius of 4A. The general order of selectivity or replace ability of some important exchangeable hydrated cations (hydrated radius of each ion is given in parenthesis) is as follows:



Among the above hydrated cations, Al^{3+} though has the largest hydrated radius but due to its higher valence can adsorb most strongly. However, at pH values higher than 4.0 as aluminum starts precipitating as aluminum hydroxide there is drastic reduction in the concentration of Al^{3+} ions in the soil environment. As most of plants or

vegetation sustain only at pH values higher than 5.0, use of an aluminum electrolyte is not an option for soil amendment. Consequently, calcium is the most effective element that could be used for soil amendment. It could be classified as the preferred cation that was referred to earlier in this text.

The CEC of a soil is strongly influenced by the nature and amount of mineral and organic compounds present. Soil containing high clay and organic matters have higher cationic exchange capacity than sandy soils that are low in organic matter content. The CEC of soil with different textures are given in Table 3

Table 3
CEC Values of Different Soil Textures

<u>Soil Textures</u>	<u>CEC (meq/100 g)</u>
Sands (light colored)	3 – 5
Sands (dark colored)	10 – 20
Loams	10 – 15
Silt Loams	15 – 25
Clayey Loams and Clay	20 – 50
Organic Soils	50 – 100

It is evident that a soil with high clay content or organic matters has high CEC value, and will tend to adsorb a larger amount of cationic species. However, the capacity for the adsorption of cations will also depend on the base saturation of the soil, which is defined as *the percentage of total CEC occupied by base cations, e.g. Ca²⁺, Mg²⁺, K⁺ and Na⁺*. The percentage base saturation is expressed as follows:

$$\% \text{ Base Saturation} = [\text{total bases (meq/100g)} / \text{CEC (meq/100g)}] * 100 \quad (1)$$

As the presence of Na⁺ in the soil structure is critical to its fertility, it is important that they are replaced by more desirable cations. There is a direct relationship between the *Exchangeable Sodium Percentage (ESP)* of the soil and its CEC value. This can be expressed as follows:

$$\text{ESP} = [\text{Exchangeable Na (meq/100g)} / \text{CEC (meq/100g)}] * 100 \quad (2)$$

In soils, ESP is the most prevalent criteria to assess the sodium hazard. However, ESP does not apply to irrigation water since water does not have CEC sites. Instead of ESP, criteria used for irrigation water to quantify sodium induced hazard is *Sodium Adsorption Ratio (SAR)*. Traditional means of assessing Na status is to determine the quantity of Na, Ca and Mg in irrigation water and report it as the SAR as follows:

$$\text{SAR} = \text{Na} / [(\text{Ca} + \text{Mg}) / 2]^{0.5} \quad (3)$$

Where the concentrations of Na, Ca and Mg are expressed in meq/L.

On empirical basis, for soil, a relationship between soil ESP and its SAR (saturated paste extract) has been determined as follows:

$$ESP = (1.475 * SAR) / (1 + 0.0147 * SAR) \quad (4)$$

The ESP value that may possibly cause the damage to the soil fertility depends on the soil composition. For example, soil that may contain kaolinite clay (prevalent in the south eastern USA) with its relatively low CEC value may require as high as 40% Na saturation in its cationic exchangeable structure before damage can be noted. On the other hand, soil containing montmorillonite clay (prevalent in the mid-south USA) with its high CEC value may require only 15% Na saturation before the soil is damaged. However, in general, soil with low clay content are subjected to less of problems as they have a low cationic exchange capacity and are also water and air permeable. It is, therefore, important that when a soil is evaluated along with ESP value its CEC is also determined.

Treatment: It is important that the fates of Na^+ and Cl^- species in the soil structure are clearly understood. The general chemical environment of most of natural soils is such that Cl^- species do not adsorb at the particles. They remain free. However, Na^+ species do adsorb at the predominantly negatively charged surface of the soil particles. Once the soil that is dispersed due to the adsorption of Na^+ species is destabilized through amendment, its permeability and, therefore, the drainage property is improved. This results in the removal of Cl^- species that are mechanically entrapped in the soil structure to further lower level. If adequate amount of soil amendment and irrigation are applied, adsorbed Na^+ species and free Na^+ species that are mechanically entrapped in the soil structure along with Cl^- species can be liberated and removed from the soil cross section to a lower level. Soil at the root zone, thus, can be restored to the state of fertility.

Amendment of salt affected soil through cationic exchange is postulated in Fig. 1. Due to the adsorption of Na^+ species the soil particles, particularly the clay fractions, are dispersed. The parallel plate like arrangement of the dispersed clay particles impedes the movement of moisture in the soil structure. As shown in Fig. 1 (A), the Na^+ while is adsorbed into the clay structure, the negatively charged Cl^- ions remain free but entrapped mechanically in the dispersed clay system. The excess Na^+ ions that are not adsorbed in the clay structure and are free could also be mechanically entrapped in this system. When this soil is analyzed, it will show high Na^+ and Cl^- ions. Nature of the presence of Na^+ can only be determined through the measurement of the ESP of the soil in question.

Figure 1: Soil Amendment Postulate

Once the cationic additives are added to the salt affected soil for its amendment, the replacement of the adsorbed Na^+ species in the clay structure with more preferred cations, such as Ca^{2+} , would liberate Na^+ from the system. The adsorption of Ca^{2+} ions also aggregates (flocculates) otherwise dispersed particles. This results in better drainage of moisture in the soil. With adequate irrigation, both mechanically and chemically liberated Na^+ and Cl^- from the system will drain to a lower level, as shown in Fig. 1 (B). Removal of these species from the plant or vegetation root zone restores the fertility of soil. At this stage, if Na^+ and Cl^- were measured at the root zone, significant reduction in their concentrations would be noted.

As discussed earlier, due to it being divalent with small hydrated ionic radius and its favorable solution chemistry (calcium being predominantly present in Ca^{2+} form at pH up to 11.0) calcium remains preferred cationic species for the amendment of salt affected soil. There are a number of calcium compounds that are available for use. However, their effectiveness is based on the amount of calcium that could be available for cationic exchange in the soil structure. The availability of calcium in these compounds for such use depends on their water solubility. Limestone, lime, gypsum, and dolomite have been used for soil amendment. Yet, their effectiveness is grossly limited by their poor water solubility. Consequently, the amount of these materials that is needed to achieve the required degree of amendment can be very large. This could be restrictive, particularly in the regions where there are low rainfalls and artificial irrigation is expensive. Calcium chloride, due to its high water solubility, is a preferred additive for soil amendment. The effectiveness of these additives can be compared in terms of their solubility products that determine their water solubility, as shown in Table 4.

Table 4
Solubility Products of Some Soil Amendment
Additives with Calcium Source (at 25°C)

<u>Amendment</u> <u>Additives</u>	<u>Ca Content</u> <u>(wt%)</u>	<u>Solubility</u> <u>Product (K_{sp})</u>	<u>Water</u> <u>Solubility</u> <u>(g/100g)</u>
Limestone, CaCO ₃	40	9.95 x 10 ⁻⁹	0.0007
Lime, Ca(OH) ₂	54	7.88 x 10 ⁻⁶	0.147
Gypsum, CaSO ₄ .2H ₂ O	29.4	1.2 x 10 ⁻⁶	0.0149
Dolomite*, CaMg(CO ₃) ₂	21.7	5.26 x 10 ⁻⁶	0.0423
Calcium Chloride**, CaCl ₂	36	8,883.66	82.0

* Calculated based on the K_{sp} of CaCO₃ and MgCO₃

** Calculated using the solubility data on CaCl₂

Among the amendment additives in Table 4, though limestone and lime have higher calcium content than calcium chloride, they are very insoluble in water. Lime having higher solubility than limestone is restricted to its use in acidic soil. Its use in the alkaline or moderately acidic soil would render the soil undesirably alkaline. Gypsum, though often used in soil amendment, is more forgiving from the soil pH point of view, its effectiveness in soil amendment is restricted by its extremely low water solubility. When compared against these additives, calcium chloride being highly soluble in water is the preferred additive in soil amendment. Readily available calcium speeds up the rate of remediation.

The speed at which soil restoration can be achieved by calcium chloride is demonstrated by this example. In this case, the salt spillage occurred due to a storage tank into a pasture land. Soil was classified as clayey loam. At this site, tilling was possible at the time of N-Cal[®] application. In this case, following the application of N-Cal, the site was immediately irrigated with water. To evaluate the quick action of the additive, from the top 6-in. of the surface, a set of samples were taken after only three hours of treatment. They were analyzed for sodium content and for SAR and ESP values.

Table 5
Remediation of Salt Contaminated Site at Kilgore, Texas

<u>Sample</u>	<u>Na (mg/kg)</u>			<u>SAR</u>			<u>ESP</u>		
	<u>Before</u>	<u>After</u>	<u>% Red</u>	<u>Before</u>	<u>After</u>	<u>% Red</u>	<u>Before</u>	<u>After</u>	<u>%Red</u>
1	5626	1950	65	44	14.5	67	75.5	4.6	94
2	3993	1516	62	27.5	2.6	91	41.3	8.7	79

Test results are summarized in Table 5, which indicate that within the short period of 3 hrs. there were dramatic reductions in sodium content, SAR (by 67 to 91%) and ESP (by 79 to 94%) values of the treated soil. This behavior suggests rapid rate of interaction between the cations of N-Cal and the soil system.

Concluding Remarks

Problems associated with salt affected soil are primarily attributed to the Na^+ and not the Cl^- . Adsorption of Na^+ in the soil structure, mainly clays, while disperses and drastically impedes the moisture permeability of the soil, it is also toxic to plants and vegetation. Most effective method of amending such soil is through the replacement of undesirable Na^+ with other cations that functions as nutrient to plants and vegetation. Ca^{2+} is the most effective cations for this role. As water is the workhorse for the cationic exchange process in the soil, solubility of the calcium containing chemical is critical to its effectiveness. Calcium chloride being highly water soluble, which allows calcium to be readily available, is the most effective chemical additive that is used for the amendment of the salt affected soil.

Hi-Cal and Potassium Chloride: A Comparative Study

By
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Introduction:

Calcium chloride (CaCl_2) and potassium chloride (KCl) are sources of two essential nutrients for plants, calcium and potassium. Both being electrolytes (compounds that dissociate in aqueous environment into their cationic and anionic species), they have readily available sources of their cations and anions. Chloride is the common nutrient in these electrolytes.

Both are highly soluble in water. Solubility of CaCl_2 (74.5 g/100 g water) is significantly greater than that of KCl (34.4 g/100 g water). This means, at room temperature (73°F), CaCl_2 remains in solution up to a concentration of 42.7 wt%. On the other hand, KCl solubility is only 25.6 wt%.

Commercial Production of CaCl_2 and KCl

Both, CaCl_2 and KCl, have mineral origins. They are either naturally found in the form of brine that needs to be processed to separate these compounds from the undesirable materials, or are manufactured from naturally occurring minerals.

Naturally occurring brine may contain CaCl_2 , MgCl_2 , KCl and NaCl in different concentrations. With these salts having different solubility in water, they can be separated by the well established technique of fractional crystallization. Calcium chloride from the Mojave Desert of California is produced by this process. Potassium chloride of sylvinites, a mixture of rock salt (NaCl) and sylvite (KCl), is also separated from sodium chloride component of this mineral by the same fractional crystallization process.

CaCl_2 is also produced from naturally occurring limestone by reacting it with hydrochloric acid. On the other hand, minerals such as carnallite ($\text{KCl} \cdot \text{MgCl}_2 \cdot 6\text{H}_2\text{O}$), kainite ($\text{KCl} \cdot \text{MgSO}_4 \cdot 3\text{H}_2\text{O}$) and hartsalz (a mixture of carnallite, sylvite and kieserite, $\text{MgSO}_4 \cdot \text{H}_2\text{O}$) are the raw materials that are used in manufacturing of potassium chloride.

How is Chloride a Problem?

It is interesting to note that both KCl and CaCl₂ are used for foliar applications in organic agriculture. However, for soil applications, only KCl is allowed to be used with the proviso that it should be used only in the manner that will minimize chloride accumulation in the soil. The concern is genuine, as excessive amount of chloride in the soil can be toxic to many crops. With potassium being a monovalent cation, it can disperse soil particles with a resulting reduced permeability of the soil structure. Although, anionic chloride does not adsorb at the negatively charged soil particle surfaces but in the dispersed condition of soil it can be mechanically entrapped into the soil cross section. Irrigation water is unable to reach and wash the chloride out of the root zone. By gradually accumulating in the soil structure in this manner, chloride ions can reach the toxic level for crops. The concern from the regulating authority for chloride of KCl is valid.

Unlike the monovalent potassium ion of KCl, the divalent cation of CaCl₂ flocculates the soil structure and makes it more water permeable. This improves the drainage characteristic of the soil. Consequently, when CaCl₂ is used in soil application chloride ions does not get entrapped in the soil structure. This minimizes the danger of accumulating chloride in soil to a toxic level. It becomes obvious that, if chloride accumulation in the soil structure is a major concern, it is safer to use CaCl₂ than KCl. Apart from this, by improving the drainage characteristics of the soil and consequently improving the air uptake by the soil structure, for the microorganism's habitat of the soil CaCl₂ is preferred additive over KCl.

Concluding Remarks

- Calcium, potassium and chloride are essential nutrients for crops.
- KCl is permitted to be used in soil application of organically grown crops, and CaCl₂ is not.
- When KCl is used, potassium ions can disperse the soil particles, which can allow chloride in the soil structure to accumulate to a toxic level.
- Calcium ions of CaCl₂ flocculate soil particles that, in turn, improve drainage of chloride ions in the soil structure and move it away from the crop root zone.
- To minimize the danger of chloride toxicity and for better wellbeing of the microorganisms of the soil, in soil application, CaCl₂ is much preferred over KCl.
- Both calcium chloride and potassium chloride have natural origins.

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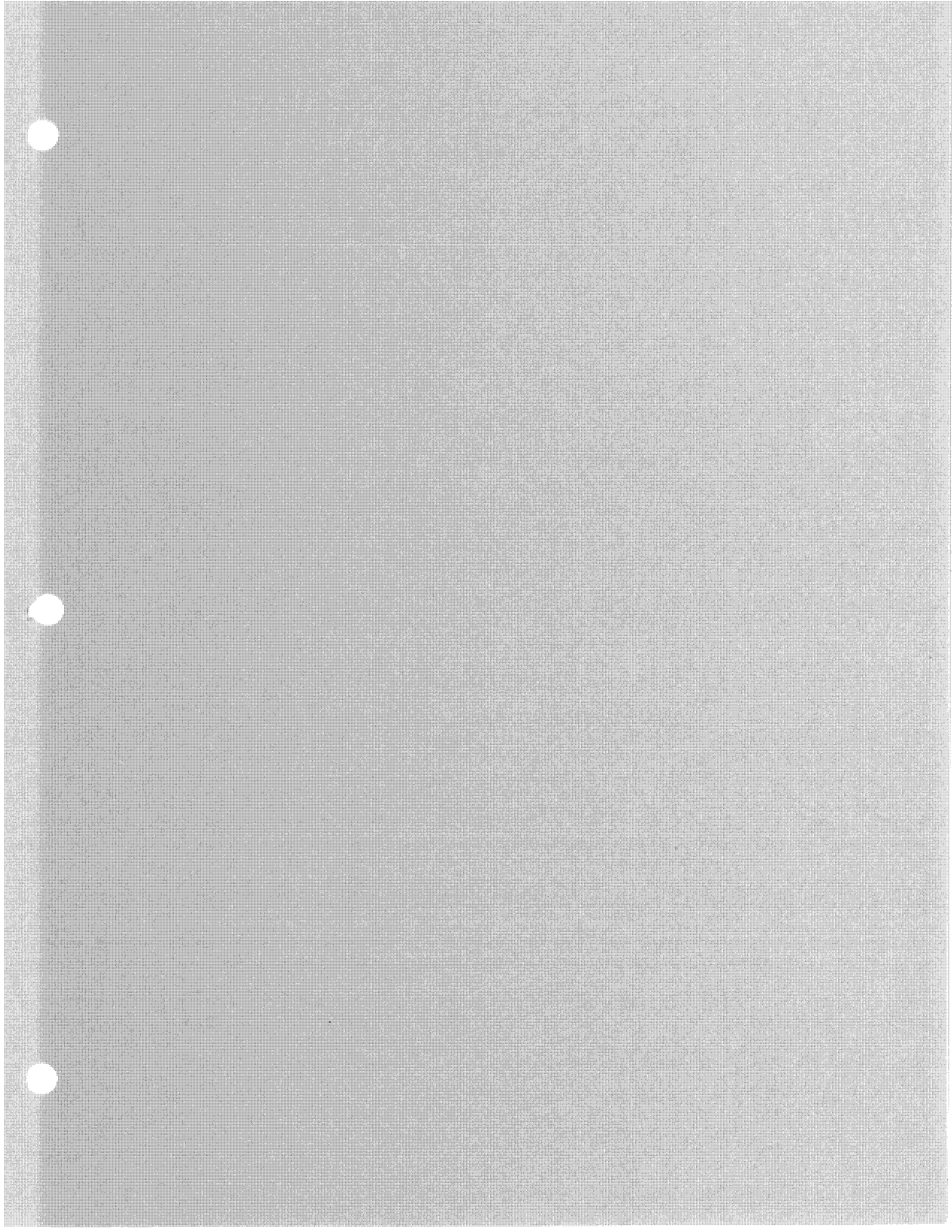
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Suren Mishra
10/18/04



However, we must remember, normal chloride applications are not a problem for any form of agriculture. Some sensitive plants such as all of the berry family and avocados are very sensitive to high chloride. Avocados have such high sensitivity they are harmed by fog from the ocean (as occurs in my back yard in Los Osos where we can see the ocean). Potatoes have a poor development of starch solidification when chloride is high. Tobacco has a harsh burning quality with high chloride. Other than these exceptions, plants can benefit from some chloride application to the soil.

I have identified nine major points about the use of calcium chloride I feel are pertinent to use in organic agriculture.

One: Chloride is recognized as being absolutely essential for plant growth. This has been known for half a century. Sea breezes often bring in enough chloride to supply the crop need by raining out the sodium chloride salt from the entrapped winds blowing off any ocean. However, in the past several years, wheat growers in Kansas have begun the application of magnesium chloride as a chloride supplement. This is because these farmers have mined out all of the soil chloride during over 150 years of extensive farming. Only trace levels of chloride are essential for normal crop production.

Two: Enhanced chloride nutrition has been identified as the major factor causing a decrease in disease incidence for a variety of diseases (mainly fungal). The original research attributed this effect to potassium. However, upon the realization the researchers used KCl (potassium chloride) in all of the original research and ignored the chloride effect, they now realize it is the chloride which provides the disease resistance. A level of about 50 to 100 pounds of chloride per acre is required to provide an adequate level of chloride for plants to maintain their ability to resist various plant pathogenic diseases. The chloride functions in this regard by increasing the osmotic pressure and thus the turgor pressure of the plant root and leaf cells. When the plant cells maintain full turgor, then they are much better able to prevent fungal mycelium from penetrating into the plant cell surface layer. Soil use of calcium chloride would provide the same benefit as would potassium chloride. This is true because the chloride is the ion providing the benefit for the plant.

Three: Increasingly, we are realizing the importance of having some level of soluble ions in the soil solution. This has become a critical problem in the management of western soils where they are irrigated with snow melt water. The same thing happens in soils dependent upon only rain water. Thus, irrigation water can be too pure for good use in agriculture. The soil can have so much good quality water (Electrical Conductivity $EC < 0.20$ mmhos/cm or < 0.20 dS/m) this lack of salts causes the clay particles to swell up and to disperse, causing soil sealing and water penetration problems. This problem can be overcome by the application of various salts to raise the soil EC to > 0.20 . This higher salt level allows the soil clay particles to flocculate and to maintain good soil aggregation. This promotes good drainage and optimizes water, air and root movement through the soil. This is a key use for calcium chloride in western agriculture.

Four: We recognize it is critical to have some soluble salts in the soil to allow the cations [+ charged ions mainly calcium (Ca^{2+}), magnesium (Mg^{2+}), potassium (K^+), sodium (Na^+), and ammonium (NH_4^+)] to move from the soil CEC (Cation Exchange Capacity) sites into the soil solution. The CEC has a negative charge and holds these ions. Unless the soil solution has an adequate amount of negatively charged ions (Anions), the soil can not effectively release these essential cations into the solution. It is critical for these cations to be in the soil solution so they can be able to move to the root by mass flow of soil water compensating for the transpiration loss of water out the plant leaves. In addition, these ions must be free in the soil solution for absorption by the plant roots. Because of its high water solubility, calcium chloride is an excellent source of calcium cations. In fact, calcium chloride is more soluble and has a quicker effect than does the use of gypsum (calcium sulfate dihydrate) in this regard.

Five: A foliar application of either calcium or potassium is critical for rapid correction of a potential deficiency of these two ions. This foliar absorption can be enhanced by spraying the leaves with a light application of calcium chloride or potassium chloride or other soluble salts of these ions. Again, one can easily overdue these applications. Common sense will dictate the appropriate levels needed.

Six: The level of soluble potassium and calcium in the soil solution appears to be the most limiting factor determining the plant availability of these ions. The rate of release of these ions from the CEC sites (due to clay and organic matter or humus) is the critical rate factor. However, this rate depends upon having sufficient soluble salts in the soil solution for this release process to occur from the clay or humus surface into the soil solution. The potassium release rate has been shown to be a key limiting factor in some soils. Likewise, I believe the calcium release rate is a major limiting factor in some soils (although this has not been established in the public literature). I have an on going research project investigating this rate for calcium release. Soils having a very high level of extractable calcium by the soil test may have a calcium limitation due to a slow release rate of movement from the CEC sites to the solution. This is contrary to much of the previous belief about calcium nutrition for plant roots.

Seven: The drainage of soil is critical for all conditions in agriculture. One of the most critical problems I am seeing in both acidic soils with rainfall and snow melt water, or normal irrigation water is their application to the soil is creating problems of poor drainage. The irrigation water containing bicarbonate (HCO_3^-) is the problem. This bicarbonate ion must be eliminated before it contacts the soil. If the grower does **not** eliminate the bicarbonate, then this bicarbonate reacts with the soluble soil calcium to form insoluble calcium carbonate (CaCO_3 lime) as a precipitate inside the soil pores at the soil surface. This precipitate gradually accumulates and clogs these soil pores. Eventually, the water movement through the soil is strongly reduced. This is the major problem causing hidden difficulties of poor soil drainage. It is becoming an increasingly severe problem worldwide.

This problem can only be eliminated by appropriate use of an acidic compounds to the irrigation water. I believe sulfur dioxide (SO_2) should be permitted for organic agricultural purposes as well as for all agricultural uses. Other strong acids create some other problems. If the grower uses calcium chloride, but irrigates with high bicarbonate water, then they create more calcium carbonate (CaCO_3) as lime. This actually would accentuate the problem if they did not acidify the water when adding any form of soluble calcium.

Eight: The problems of the seventh point have a further concern. If the soluble salt level is low, then this will increasingly create a more severe problem due to changing the Sodium Adsorption Ratio (SAR). When the soluble calcium in the soil is converted into insoluble calcium carbonate (CaCO_3) lime, the SAR value increases. The sodium level and the magnesium level are not affected, but the loss of soluble calcium can have a very harmful effect upon the soil. The higher the SAR in the soil, the greater the problem becomes. Usually, the problem becomes noticeable when the SAR value is above 6. It is very severe when the value exceeds 15. However, this overlooks the very real problem of the **very surface** of the soil. In the top one half inch, this reaction can occur causing increasing SAR values to 15 or 20 when the soluble calcium is depleted as indicated in item seven. Addition of calcium chloride through soil use will help remedy this problem especially when acidity has been added to keep this calcium soluble and active in the soil.

Nine: The use of calcium chloride is important as a method for increasing good water infiltration. The calcium goes onto the CEC and strongly flocculates the clay and humus particles. This actually enhances the soil's ability to transmit extra water deeper into the soil. Thus, calcium chloride can improve water infiltration, water percolation and water drainage if initial drainage exists. This does assume the soil has good water drainage in the subsoil. If good drainage does not occur, then it would not be appropriate to use a high chloride material.

I fully recognize the concern for not adding "chemical" compounds to a natural system. However, all organic systems are inherently "chemical". These natural systems are just the same "chemicals" as the synthetic chemicals. Certainly, I do not believe we should be applying synthetic organic pesticides, herbicides, or other products and should not allow biotechnology products to be used in organic agriculture.

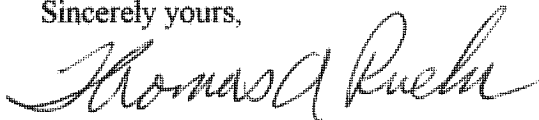
Organic agriculture has so few effective products, it is important to recognize what products can be allowed with a reasonable recognition of what is "chemical". Calcium chloride, potassium chloride, sulfur and sulfur dioxide are all natural chemicals or mineral sources. These substances can function effectively in an organic agricultural system without threatening the organic system. Calcium chloride can be applied to soil "in a manner minimizing chloride accumulation in the soil."

As I indicated previously, I realize any inappropriate use of any substance can be a problem. My Ph. D. involved a study of applying beef cattle feedlot manure at varying rates. We used high rates which did create harmful conditions. Likewise, excessive application of any of these inorganic or organic materials can create problems. However, normal levels have no adverse conditions for crop production for most crops (other than berries, avocados, potatoes, or tobacco).

I welcome any questions you may have about my comments and interpretations on the use of several potential substances for approval for use in organic agriculture. Soil use of calcium chloride should be allowed in organic agriculture similar to the approved use of potassium chloride. For the reasons previously described, soil use of calcium chloride provides numerous benefits which cannot be achieved through only the foliar use currently allowed under the NOP. Logically, one should treat all chloride materials similarly since they are all mineral sources and essentially perform as indicated in the nine points previously cited.

If you have any questions, please contact me by phone at 805-756-2552 (work) or 805-528-0151 (home where I am until mid-September), or by e-mail at truehr@calpoly.edu or by FAX 805-756-5412.

Sincerely yours,

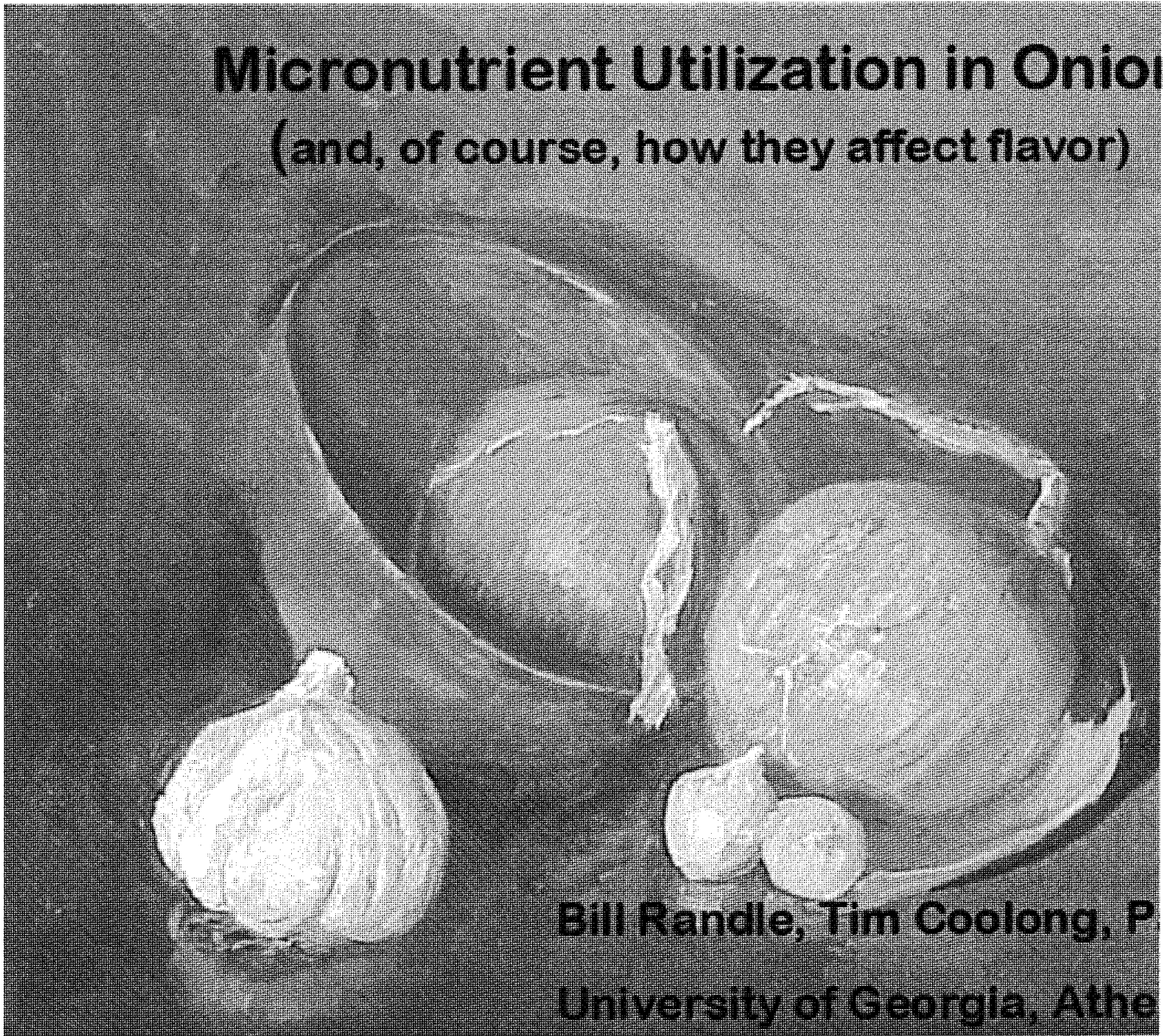


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Micronutrient Utilization in Onion

(and, of course, how they affect flavor)



Notes:

2004 National Allium Research Conference Oral Presentation - Flavor

MICRONUTRIENT UTILIZATION IN ONION (AND, OF COURSE, HOW THEY AFFECT FLAVOR)

W.M. Randle, T.W. Coolong, and P. Chang

Department of Horticulture, University of Georgia, Athens, GA 30606 USA Email: wrandle@uga.edu

The absorption and utilization of chloride (Cl) and zinc (Zn) were investigated in onion to better understand their requirements and tolerances, and to determine their effects on onion growth and subsequent flavor development. Chloride was varied from 0 to 500 ppm as CaCl₂ in a greenhouse experiment. The plants were grown to maturity, the bulbs weighed and later analyzed for different flavor attributes. It was determined that the Cl requirement for onion is very high, and with adequate availability, Cl can be the fourth most utilized essential element in onion. As CaCl₂ increased in the nutrient solutions, bulb weight increased by a factor of two, bulb S accumulation decreased by 45%, and bulb pungency decreased by 35%. Manipulating Cl may be thought of as a useful tool for managing high S environments for producing low pungency onion because of its strong effect on decreasing S uptake. In a separate experiment, Zn was supplied to onion seedlings at concentrations ranging from 10 to 150 ppm to investigate the rate of uptake in onion. Zinc uptake and accumulation occurred rapidly and proportional to the concentration in the nutrient environment when compared to S uptake. Within 24 h of applying the higher Zn rates, over 1200 ppm Zn measured in onion leaves on a dry weight basis. The concept of nutrient pulsing onions as a way of fortifying food for human consumption will be discussed.



to the 2004 National Allium Research Conference Home Page

August 10, 2004

CAL POLY

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National Organic Standards Board
c/o Robert Pooler
Agricultural Marketing Specialist
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Ag Stop 0268
P.O. Box 96456
Washington, DC 20090-6456

Subject: Petition for Calcium Chloride Use as Soil Application and Removal From “Prohibited” Status Except As a Foliar Application

Dear Mr. Pooler,

Allow me to introduce myself. I have taught courses in introductory soil science plus fertilizers and plant nutrition and soil microbiology and biochemistry plus team teaching fertigation for the past 30 years at Cal Poly. I have taught the soil and water chemistry course and have taught the graduate course on advanced soil fertility for many years. In addition, I have taught Human Values in Agriculture in the College of Liberal arts for 17 years and have team taught the course Organic Agriculture for the past 4 years. The last course is team taught with Dr. John Phillips (Horticulture and Crop Sciences Department). I have been presenting agronomic and soil fertility and water treatment talks throughout the state and nationally for the past decade. I am a member of the Soil Science Society of America, the American Society of Agronomy, the American Association for the Advancement of Science, the American Chemical Society and the American Society for Microbiology.

I will address what I understand to be the aspects of calcium chloride and potassium chloride use relative to organic agriculture. As I understand, soil use of potassium chloride is allowed as long as it is “applied in a manner minimizing chloride accumulation in the soil.” Foliar use of calcium chloride is allowed, but not soil use. For logical and scientific consistency, soil use of calcium chloride should be allowed similar to soil use of potassium chloride. The same annotation (i.e. applied in a manner minimizing chloride accumulation in the soil) still applies. In fact, very heavy soil applications of potassium chloride do create problems if not managed properly. Whereas, the same application of calcium chloride will not have the same detrimental effect. Potassium in high concentration can cause soil dispersion, whereas calcium will only flocculate the soil clay and humus particles. Applying calcium chloride could counteract an excess of potassium chloride if good drainage exists and proper management is followed.

As with any chemical material (manure, compost, natural mineral, etc.), these can be used appropriately or inappropriately. I am assuming people have enough sense to use all of these materials sensibly.

Certainly, excessive applications of chlorides in any form can be harmful to agriculture. One of the most common ways this can occur in organic agriculture is the over application of kelp, sea weed and other organic materials of marine origin. The total amount of chloride and of soluble salts should be carefully monitored by all organic farmers by determining the chloride level and soluble salts (Electrical Conductivity) levels of their soils periodically.

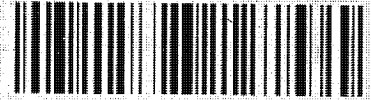
The chloride can cause severe chloride toxicity or excessive salt resulting in an excessive osmotic pressure condition in the root zone causing plants to wilt and inhibiting nutrient absorption by the plant roots.

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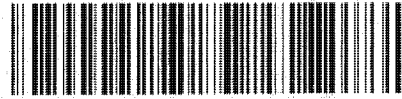
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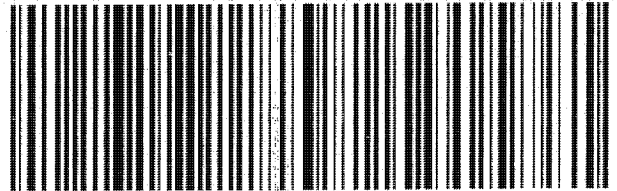
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