

Chapter Twelve

USE INSPECTIONS AND FOLLOW-UP ENFORCEMENT

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USE INSPECTIONS & FOLLOW-UP ENFORCEMENT

AUTHORITY

FIFRA authorizes primary enforcement responsibility to states for pesticide use violations; see section 26 of FIFRA for more information.

Introduction

Use inspections and follow-up investigations are a necessary and indispensable element of pesticide use enforcement. While section 12(a)(2)(G) of FIFRA, as amended, makes it unlawful to use any registered pesticide in a manner inconsistent with its labeling, it does not give the federal inspector right of entry to conduct the inspection/investigation.

The Fourth Amendment of the U.S. Constitution states, in part: “the rights of the people to be secure in their persons, houses, papers, and effects, against unreasonable searches and seizures, shall not be violated...” To ensure lawful inspections, the Agency has developed procedures consistent with this provision and relevant court decisions.

Statutory Basis

FIFRA section 12(a)(2)(G) and section 2(ee) state that “it shall be unlawful for any person to use any registered pesticide in a manner inconsistent with its labeling.”

The phrase “to use any registered pesticide in a manner inconsistent with its labeling” means to use any registered pesticide in a manner not permitted by the labeling. This does not include:

- < Applying a pesticide at a rate, concentration, or frequency less than specified on the labeling, unless the labeling specifically prohibits deviation from the specified rate, concentration, or frequency.

- < Applying a pesticide against any target pest not specified on the labeling if the application is to the crop, animal or site specified on the labeling, unless the Administrator has required that the labeling specifically state that the pesticide may be used only for the pests specified on the labeling after the Administrator has determined that the use of the pesticide against other pests would cause an unreasonable adverse effect on the environment.
- < Employing any method of application not prohibited by the labeling.
- < Mixing a pesticide or pesticides with a fertilizer when such mixture is not prohibited by the labeling.
- < Any use of a pesticide in conformance with section 5, 18, or 24 of this Act.
- < Any use of a pesticide in a manner that the Administrator determines to be consistent with the purposes of the Act.

An advisory opinion was issued on March 3, 1981. It permits the use of less diluent than that specified on the label in ultra low volume (ULV) and low volume agricultural and forestry applications. This advisory opinion does not permit a discretionary choice of diluent different than that specified on the label, regardless of the recommendation by an authorized person or entity (see Federal Register Vol. 46, Number 41, March 3, 1981).

Consent

Entry to conduct use inspections/investigations is authorized pursuant to obtaining valid consent. To be considered valid, consent must be given freely and voluntarily and not as a result of duress, misrepresentation, or coercion (either expressed or implied). While the law does not require that a subject be advised of his/her right to refuse to give consent, if the inspector believes such knowledge may be helpful in validating the consent and in overcoming any taint of implied coercion, he may inform the consenting party of his/her right to refuse voluntary entry. In addition, the person granting the consent must be authorized to do so. The inspector must be certain that the consenting party has the premises under his/her control and has at least the apparent authority to give consent.

In the case of inspections that involve multiple instances of entry or sampling episodes, it is imperative that consent be gained for each entry or sampling unless prior consent has been obtained to cover all necessary entry and sampling. Accordingly, at the onset of an inspection, the inspector must seek to gain consent sufficient to authorize all entry and sampling activities he/she contemplates will be necessary to complete the inspection.

Open Fields

“Open fields” are areas where a land owner normally does not have a reasonable expectation of privacy. While the preferred procedure is to obtain valid consent prior to entry, the courts have established

that inspectors may enter open, private lands in the official performance of their duties. The inspectors may technically be trespassers on private property, but this fact will not prevent the lawful use of any evidence that is obtained in these open fields. This inspection authority does not extend to a residence or the area immediately surrounding a residence.

Exigent Circumstances

The law does not require a public official to stand by helplessly while a serious offense endangering human health or the public safety is occurring on private property. If there is insufficient time to procure a warrant before serious harm will occur and if consent to enter cannot be readily obtained, an inspector may enter the property to assist in preventing imminent harm to human life. Because of the heavy burden imposed on the Agency to show that its entry without authority was justified, this doctrine shall be used only in rare and emergency circumstances.

Plain View

The plain view doctrine is an acknowledgment by the courts that an inspector lawfully engaged in the course of his/her duties is not required to wear blinders or close his/her eyes to whatever is occurring around him/her. This principle applies regardless of the nature of the inspection (use, producer, marketplace, etc.). The following elements are required for a plain view observation:

- < **Lawfully Present.** The inspector must be justified in being where he/she is at the time the plain view observation is made. Lawful presence may be gained through such avenues as statutory authority, a valid search warrant, consent, or “open fields.”
- < **Inadvertent Discovery.** The inspector must discover the evidentiary items accidentally. The plain view doctrine will not apply if the inspector has probable cause to believe that an item is on certain premises and goes on those premises with the intention of searching for that item; such a discovery is not inadvertent.
- < **Apparently Incriminating Nature.** The inspector must have reasonable grounds to believe immediately, without further investigation, that the item in plain view constitutes evidence of a violation of the law.

OBJECTIVES

The objectives of use inspections and follow-up investigations are to:

- < Protect health and the environment.
- < Determine compliance with FIFRA.

- < Collect information for use by the Agency to determine the need for pesticide label and labeling changes.

POLICY

Primarily in states without primacy, and federal and tribal lands, the Agency will conduct (1) a routine inspection program and (2) follow-up of reported cases of misuse and suspected pesticide-related incidents with investigations. Additionally, EPA will conduct inspections where states have waived their section 26(b) authority or where states have not acted in a timely manner (section 27), or at the request of states/tribes.

USE INSPECTIONS

Use inspections encompass a wide variety of pesticide use circumstances and inspection sites. Although many aspects of pesticide compliance are involved, the primary focus is on use inconsistent with the label and the Worker Protection Standard. Inspection opportunities include, but are not limited to the following areas of pesticide use:

- < Agricultural (commercial and private)
 - Field crops
 - Planting times (and plant back restrictions)
 - Orchards/groves
 - Greenhouses/nurseries
 - Sod farms
 - Forests
 - Vegetable and specialty crops
- < Nonagricultural (commercial, public, and not-for-hire)
 - Residential sites
 - Structures
 - Rights-of-way
 - Aquatic environments
 - Hospitals/nursing homes/clinics
 - Veterinarians
 - Lawns, ornamentals, and golf courses
 - Grain elevators

Use inspections can be initiated at either the site of application or the applicator's place of business.

Use includes storage, handling, mixing/loading, transportation, application, and disposal.

Use inspections may be performed during application or during any "use" activity (see above). Use inspections may also occur where pesticides have previously been applied, including inspection at the end of a growing season when the crops are being harvested.

Note: At all times during Use/Misuse Inspections, the inspector should be aware of bio-security. See Exhibit 12-4 for guidelines to be followed when entering and exiting farms, ranches, etc.

Inspector Obligations and Procedures

The inspector must seek the most responsible individual available at the inspection site and present his/her credentials to that person. Before beginning any use inspection, the owner, operator, or agent in charge must be issued a written Notice of Use/Misuse Inspection (EPA Form 3540-25) (Exhibit 12-1). The notice must include the reason for the inspection and any suspected violations. The Notice of Use/Misuse Inspection form contains a "consent" statement that the inspector shall read to the person from whom consent is sought. The form also bears a space for the person to sign so as to provide a written record of the authorization to enter and/or sample based on consent.

If entry is refused, the inspector must immediately notify his/her supervisor.

Use Inspection Procedures

The collection of records of use and application are an essential part of every use/misuse inspection and investigation. These records document use and, in addition, can be used to either contradict or corroborate statements regarding how pesticides were used and the circumstances surrounding their use. These records should be identified as exhibits and attached either to the report or to the appropriate statement.

The inspector must obtain the relevant information necessary to complete a narrative report of the inspection. This information includes, but is not limited to the following:

Persons Interviewed:

- < Name, address, and telephone number of facility.
- < Name, address, and telephone number of inspection site, if different from above.
- < Owner, operator, and/or agent-in-charge of facility.
- < Owner of inspection site, if different from above.
- < Certification, license, or permit number of applicator.

Description of Facility:

Physical description and location of the inspection site, i.e. hospital, aerial applicator, golf course, etc. including address, telephone number, and contact person.

Pesticide(s) Inspected:

- < Name, EPA Registration Number, EPA Establishment Number, and classification of pesticide(s) used (i.e., general or restricted use).
- < Note types of pesticides in storage, i.e. restricted, canceled, suspended, etc.
- < Collect a physical of the product if a problem is suspected with product chemistry or a documentary sample of the product label if a misuse is suspected.
- < The inspection report, as appropriate, shall also include a thorough review of the label(s) encountered and contain written documentation that the pesticide(s) was/were used as specified by the label. Specific areas of pesticide use to be addressed should include:
 - Crop, area, or object treated
 - Method and rate of application
 - Disposal (rinsate/containers)
 - Mixing/loading instructions
 - Diluent/additives
 - Worker Protection Standard
 - Protective clothing and equipment
 - Precautionary statements
 - Environmental precautions
 - Transportation/storage
 - Pre-harvest intervals
 - Spray intervals
 - Classification
 - Relevant weather restrictions
 - Groundwater protection restrictions
 - Endangered species protection restrictions

Note: Specific pesticide labels vary greatly. The above list is not meant to be inclusive. Individual labels should be examined in each inspection and relevant or suspected areas should be investigated in accordance with established procedures.

Records Review:

Review records required under federal and/or State regulations.

Storage Facility Conditions:

Inspect storage area for leaking containers, security of restricted use pesticides, etc.

Worker Protection Standard (Ag Use ONLY):

A thorough label review should take place so that compliance with label requirements can be determined and to determine the applicability of the other provisions of the Worker Protection Standard. Address the following items during the inspection if the Worker Protection Standard applies:

- < Information at the central location
- < Application records
- < Pesticide safety training
- < Decontamination supplies
- < Notice of application and posting of application
- < Early entry requirements
- < Emergency assistance procedures

The Use Investigation Report (EPA Form 3540-20) or equivalent, may be used to assist the inspector in documenting use information (Exhibit 12-2).

Sampling

The collection of official samples for evidence is an important part of this program. Samples may also be collected to substantiate that pesticides were properly mixed and applied. It is essential to collect documentary samples or physical samples of any/all pesticides suspected of having been misused.

Documentary Samples

A documentary sample must be collected when a physical sample is not necessary, including those circumstances where no problem with the chemistry of the pesticide is suspected. Documentary samples consist of anything other than a physical sample (e.g. bin labels, photographs, advertising or records such as, invoices, shipping records, bills of lading, etc.)

Physical Samples

- < **Formulation Samples.** If the user is obtaining unusual or adverse results from the use of a product and his/her use is in accordance with label directions, a sample of the commercially packaged pesticide must be taken to determine whether it was misformulated. A formulation sample must also be collected for each use dilution sample to verify that problems associated with the use dilution are not related to the pesticide itself. A reasonable effort must be made to collect a sample at the user, dealer/distributor level. If it is

necessary to obtain a sample from a previously opened container, the investigator must obtain a statement from the user stating that the product has not been altered (see Chapter 9 for Formulation Sampling).

- < **Diluted Material.** Pesticides diluted or mixed for use must be sampled at the user level whenever there is reason to believe that the pesticides may have been diluted or mixed in a manner inconsistent with the label. Conversely, these samples may be taken to show that the dilution was consistent with label directions. This type of sample may be difficult to collect and preserve. Thus, they must be collected when mixing differs from label directions or improper pesticide selection is suspected. A copy of the registered product's pesticide label must be obtained to accompany the sample of diluted material. If a photograph of the label and/or a identical label copy cannot be obtained to accompany the sample, the pertinent portions of the label (ingredient statement and applicable dilution/mixing directions) must be hand-written and attached to the sample. If not observed first hand, a statement and/or record copy must be obtained from the user telling how the material had been diluted and mixed. Because the dilution rate may vary with the specifications of the application equipment used, information must be obtained regarding the type of application equipment used and its calibration. If the pesticide is being applied in accordance with section 2(ee) recommendations, the source of those recommendations must be documented with a copy of the recommendations and/or a statement from the applicator.
- < **Residue Samples.** Residue samples include plant materials, animal tissues, soil, drinking water, surfaces, air, runoff water, etc. A residue sample must be collected when there is reason to believe that a pesticide may have been misapplied.

Specific Sampling Procedures

Refer to Appendix A.

Records

Determine what records are being maintained by the applicator/firm, review pertinent records, and document the pesticide application in question, even if no violations are apparent. Pesticide application records for adjoining properties and field history(s) must be documented to address pesticide drift and carry-over issues. Additionally, document application records of all apparent or suspected violations. Note: Applicators/firms are only required to keep records for RUP use. However, State requirements may specify that all pesticide applicator records be maintained by the applicator/firm.

Discussion with Owner/Operator, Applicator, or Agent in Charge

The inspector must discuss proper pesticide use with the owner/operator, applicator, or agent in charge. Topics that should be covered include (1) the existence and purpose of FIFRA, (2) the importance of following label directions, and (3) the need to use pesticides safely, so as to protect human health and the environment by observing all label precautions during all phases of use, including mixing, application, storage, and disposal.

The inspector must give the owner, operator, applicator, or agent in charge of the establishment a copy of the completed and signed Receipt for Use/Misuse Samples (EPA Form 3540-26) (Exhibit 12-3) for any official samples.

The results of the inspections must be discussed with management. Any problems or discrepancies noted during the inspection must be brought to the attention of the applicator/management so that immediate corrective action may be taken. The inspector must explain that violations may be found by the laboratory and/or Regional office.

The inspector must note in the Inspection Report any voluntary corrective actions.

FOLLOW-UP INVESTIGATION PROCEDURES

An investigation will be conducted in response to reported or suspected incidents to develop the necessary evidence to support any enforcement action that may be taken as a result of an apparent pesticide misuse. Because the ultimate purpose of a follow-up investigation is to substantiate and document alleged pesticide misuse, the inspector's function shifts from a more passive role, as in the context of a use inspection, to a more investigative role.

Follow-up investigations tend to be more complex than use inspections, because the inspector may be required to visit a number of sites, interview various persons, and/or collect a number of samples of various types in the course of a single investigation. See Appendix C for information on handling high visibility incidents.

The inspector investigating a case of alleged misuse is trying to find and document answers to a number of questions, while the routine pesticide use inspection typically only involves the observation and documentation of the physical elements involved at the time of the application. Parties involved in an investigation may include, but are not limited to the following:

- Complainants
- Physicians/Veterinarians
- Applicators
- Pest Control Operators, Dealers/Distributors

- Eye Witnesses
- Cooperative Extension
- Property Owners
- Other Federal, State, and/or local Agencies
- Other Experts and/or operators
- Agricultural Employers/Employees

Inspector Obligations and Procedures

Due to the potential for harm to humans and the environment and the need to be responsive to public concern, it is important that the inspector initiate follow-up investigations as soon as possible after the receipt of an alleged misuse. Also, the chances of finding pesticide residues in environmental samples decreases over time. Credentials must be presented and the appropriate written inspection notice issued at each facility or location where persons are interviewed or samples are collected. A Notice of Inspection must be used where pesticides are held for distribution or sale. A Notice of Use/Misuse Inspection must be used at other locations (refer to Chapter 7).

- < Interview complainant, witness, and other parties involved.
- < Complete statements, etc.
- < Complete a narrative report of the investigation to include details of the inspection.
- < Collect and document all evidence pertaining to the use of the pesticide to include photographs, all labeling, diagrams/maps, shipping/purchasing records, etc.
- < Collect documentary and/or physical samples of pesticide use.

Conducting the Investigation

The inspector must interview, at a minimum, the complainant and the applicator. When interviewing the applicator, the procedures outlined in this section must be followed. Additional interviews should be conducted as necessary.

When conducting a follow-up investigation, it will be necessary to gather sufficient documentary and physical evidence to support any alleged violations of FIFRA. This evidence may include the following:

- < Photographs, originals, or copies of labels and labeling for pesticides used.
- < Photographs or video tapes showing actual pesticide misuse and/or damage caused by an alleged misuse.
- < Application records and central location information (refer to the WPS Pocket Guide).
- < Copies of the applicator certification documents.

- < Statements from the property owner, applicator, owner/operator, or witnesses that can attest to the relevant circumstances.
- < Copies of any available investigation reports completed by other agencies or companies including State and local agencies, insurance companies, etc.
- < Sketches or maps of the area treated and surrounding properties.
- < Samples (Physical or Documentary).

Sampling

Refer to Chapter 13 (Residue and Environmental Samples) and Appendix A.

Records

The inspector must determine what records are routinely maintained by the applicator/responsible firm. Pertinent records must be reviewed and all apparent violations as well as records specific to the application must be documented. In some cases, records of applications that were made immediately prior to the incident application must be collected in case cross contamination of the pesticide solution is a possibility.

It may be necessary to collect copies of other records, including but not limited to, the following:

- < Written recommendations (advisor, consultants, USDA/Cooperative Extension Service bulletins, etc.).
- < State and/or locally required permits and/or notifications.
- < Weather records.
- < Certification/licensing records.
- < Additional labeling (Supplemental Labels).
- < Regulations/standards.
- < Work order or mix/load sheets.
- < Medical Records.
- < Application records from application(s) to adjoining property(ies).
- < Employee records (WPS).
- < Witness statements (i.e., WPS training).

Reports

A narrative report must be submitted as soon as possible following the completion of the investigation. At a minimum, the report must indicate whether a pesticide was involved. If a pesticide was involved, the report must indicate what pesticide was used; where it was applied (site/crop); how it was applied (method, dilution rate, application rate, application equipment, safety equipment, etc.); weather conditions(if appropriate); who the responsible party is;

and when the pesticide was applied. In addition, the report must include all other relevant information such as consequences of the application (drift, crop damage, illness, or injury); explanation of samples, photographs and other evidence collected; and a description of any follow-up investigations that may be warranted. All completed forms and documents gathered during the course of the investigation must be attached to the narrative report as exhibits. The report must be limited to factual information. The introduction of personal opinions into the written narrative allows an opportunity for the defendant to find fault and could result in the dismissal of a case. Keep the reports factual.

Other useful tools to assist inspectors in conducting use/misuse inspections include:

- < EPA Worker Protection Field Inspection Pocket Guide (EPA 300-B-02-001, March 2002).
- < EPA Worker Protection Standard Phrase Translation Cards and Tape (1999).
- < EPA Worker Protection Inspection Guidance (EPA 722-B-94-002, January 1994).

For more information see Chapter 20 - Preparing Inspection Reports.

Exhibit 12-2: Use Investigation Report (EPA Form 3540-20)

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY USE INVESTIGATION REPORT			
1. PERSON INTERVIEWED			
a. NAME		b. ADDRESS	
c. TELEPHONE			
2. APPLICATOR			
a. NAME		b. ADDRESS	
c. TELEPHONE	d. CERTIFICATION NUMBER		
3. SITE OF APPLICATION			
a. NAME		b. ADDRESS	
c. TELEPHONE			
d. TYPE OF BUSINESS	e. CROP, AREA OR OBJECT TREATED		
f. TARGET PEST		g. DATE AND TIME OF APPLICATION	
h. WEATHER AT TIME OF APPLICATION (Wind, temperature, humidity, rain, etc., list source of information)			
4. PESTICIDE APPLIED			
a. BRAND NAME		b. EPA REG. NO.	c. BATCH NO.
d. CLASSIFICATION			
e. TYPE OF FORMULATION			
<input type="checkbox"/> DUST <input type="checkbox"/> SPRAY <input type="checkbox"/> GRANULAR <input type="checkbox"/> MIST <input type="checkbox"/> FOG <input type="checkbox"/> OTHER (Specify):			
5. RATE OF APPLICATION			
a. METHOD OF APPLICATION			
b. DILUTION RATE			
c. DILUTED MATERIAL APPLIED PER UNIT (Gallons/Acre)		e. ACTUAL ACTIVE PER UNIT (Lbs/Acre)	
6. SAMPLES COLLECTED (List sample numbers)			
a. FORMULATION	b. DILUTED MATERIAL		c. RESIDUE
7. WERE THE FOLLOWING LABELING INSTRUCTIONS FOLLOWED? <input type="checkbox"/> YES <input type="checkbox"/> NO (If "NO," check and explain)			
<input type="checkbox"/> TARGET PEST <input type="checkbox"/> METHOD OF APPLICATION <input type="checkbox"/> DILUTION USED <input type="checkbox"/> OTHER:		<input type="checkbox"/> RATE OF APPLICATION <input type="checkbox"/> CROP, AREA OR OBJECT TREATED <input type="checkbox"/> CAUTIONARY LABELING	
<input type="checkbox"/> REENTRY INTERVAL <input type="checkbox"/> APPLICATOR CERTIFIED <input type="checkbox"/> PREHARVEST INTERVAL			
8. CONSEQUENCES OF USE (List any unusual results or adverse effects from treatments)			
9. REMARKS			
10. DATE OF INVESTIGATION	11. TIME	12. INVESTIGATOR (Signature)	13. TITLE

EPA FORM 3540-20 (Rev. 01-01)

- 1. Original - REGION COPY
- 2. INTERVIEWEE COPY
- 3. HEADQUARTERS COPY
- 4. INSPECTOR'S COPY

Exhibit 12-3: Receipt for Use/Misuse Samples (EPA Form 3540-26)

 UNITED STATES ENVIRONMENTAL PROTECTION AGENCY RECEIPT FOR PESTICIDE USE/MISUSE SAMPLES		ADDRESS (EPA Regional Office)
		DATE
NAME OF INDIVIDUAL		TITLE
NAME (Firm, Farmer, Homeowner, etc.)		ADDRESS (Number, Street, City, State, and ZIP Code)
SAMPLE NUMBERS		
SAMPLES COLLECTED (Describe fully, List Registration, Lot, Batch, Model, Serial Numbers, and other positive identification) The following pesticide and/or environmental samples were collected by the U.S. Environmental Protection Agency in connection with the administration and enforcement of the Federal Insecticide, Fungicide, and Rodenticide Act and receipt is hereby acknowledged.		
SIGNATURE (Owner, Operator, or Agent)		TITLE (Owner, Operator, or Agent)
<input type="checkbox"/> DUPLICATE SAMPLES REQUESTED AND PROVIDED	<input type="checkbox"/> DUPLICATE SAMPLES NOT REQUESTED	SAMPLES WERE <input type="checkbox"/> PURCHASED <input type="checkbox"/> RECEIVED, NO CHARGE
AMOUNT PAID FOR SAMPLES <input type="checkbox"/> CASH <input type="checkbox"/> VOUCHER <input type="checkbox"/> TO BE BILLED		
NAME OF COLLECTOR (Print or Type)	TITLE OF COLLECTOR	SIGNATURE OF COLLECTOR

EPA FORM 3540-26 (Rev. 01-01)

1. Original - OWNER/AGENT COPY
2. SAMPLE RECORD COPY
3. REGION COPY
4. INSPECTOR'S COPY

Exhibit 12-4: Biosecurity Guidance

December 10, 2001

MEMORANDUM

SUBJECT: Routine Biosecurity Procedures for EPA Personnel Visiting Farms, Ranches, Slaughterhouses and other Facilities with Livestock and Poultry

FROM: Michael M. Stahl, Director /s/
Office of Compliance

TO: Acting and Current Regional Administrators and Deputy Regional Administrators

Attached is the final biosecurity guidance for EPA personnel visiting livestock or poultry facilities, including ranches, dairies, feed yards, sale yards, swine premises, slaughterhouses, and other facilities where there are animals or unprocessed animal tissues that may transmit diseases. The guidance was prompted by heightened national concern about the spread of animal diseases. Failing to take appropriate steps to prevent disease transmission could result in severe financial impacts on farmers and the destruction of potentially many of thousands of animals.

While EPA had already incorporated biosecurity discussions into basic CAFO Inspector Training, it was clear that EPA needed to formalize and to reinforce biosecurity measures. Also, while CAFO inspections could be one avenue for possible disease transmission by EPA personnel, guidelines were needed for all EPA field activities that could affect livestock.

The guidance was developed in coordination with USDA's Natural Resources Conservation Service and Animal and Plant Health Inspection Service (APHIS) and the Food and Drug Administration. We circulated drafts for comment to these organizations, EPA headquarters offices, regions, states, and academic and industry contacts. The final guidance relies heavily on and incorporates much of guidance developed by APHIS for USDA employees on June 21, 2001. My thanks to all who contributed to the development of this guidance.

If you have any questions about this guidance, please contact me or Carol Galloway, National Agriculture Compliance Assistance Center, at 913-551-5008.

Attachment:

Routine Biosecurity Procedures for EPA Personnel Visiting Farms, Ranches, Slaughterhouses, and Other Facilities with Livestock and Poultry

cc: Sylvia Lowrance, OECA, AAA (w/o attachments)
Rick Colbert, OC/AgD (w/o attachments)
Regional Enforcement Coordinators, Regions 1-10 (electronic only)
National Agriculture Sector Contacts (electronic only)
Eric Schaeffer, Director, ORE
James Makris, Director, CEPPPO
Marcia Mulkey, Director, OPP
Michael Cook, Director, OWM
John Seitz, Director, OAQPS
John Chamberlin, OARM, OA
Ty Vannieuwenhoven, USDA, APHIS
Tom Christensen, USDA, NRCS
Julius Jimeno, OARM, OA, SHEMD
Jeff Davidson, OARM, OA, SHEMD
Judy Nelson, OPPTS
Jean-Mari Peltier, OA
Ray Mars, FDA

ROUTINE BIOSECURITY PROCEDURES FOR EPA PERSONNEL VISITING FARMS, RANCHES, SLAUGHTERHOUSES AND OTHER FACILITIES WITH LIVESTOCK AND POULTRY

This guidance establishes routine procedures to minimize the risk of EPA personnel transmitting animal diseases from livestock or poultry facilities, including farms, ranches, dairies, feed yards, sale yards, swine premises, slaughterhouses, and other facilities where there are animals or unprocessed animal tissues, secretions or excretions (including saliva, manure or urine, soiled feed, bedding, water or dirt, milk) to livestock or poultry. Often, owners/producers have adopted more stringent biosecurity measures than these procedures. More stringent measures might include specific directions on site entry (e.g., showering, changing clothes to come onto or leave the premises, vehicle washing), or vehicle travel on the site, and other measures. EPA should discuss appropriate biosecurity measures with the operator prior to entering animal areas, and are encouraged to follow the more stringent measures.

Separate emergency procedures will be applicable in cases of actual outbreaks of contagious animal diseases. In such a case, EPA generally will avoid visiting affected areas and will coordinate with USDA's Animal and Plant Health Inspection Service (APHIS) and local emergency control authorities concerning activities in these areas. Periodically, EPA will contact the offices of the appropriate APHIS Area Veterinarians in Charge and the offices of the State veterinarians to identify any areas with existing emergency animal disease events. The addresses and telephone numbers of these offices are attached.

EPA personnel should be aware of personal health and safety issues when visiting livestock facilities and consult with EPA's Health and Safety staff with questions about proper procedures. Livestock facilities may include OSHA-defined "confined spaces," e.g., manure pits. If staff need to enter such areas, all appropriate safety precautions must be followed. In addition, some animal diseases can be spread to humans, such as brucellosis (bacteria) and echinococcus (parasite).¹ Fortunately, the U.S. largely has eliminated major risk of disease transmission from animals to humans by a combination of veterinary medicine and State regulation.

The following procedures are consistent with written procedures developed by APHIS for use by USDA personnel (June 12, 2001).

¹Brucellosis is transmitted through contaminated and untreated milk and milk products and by direct contact with infected animals (cattle, sheep, goats, pigs, camels, buffaloes, and wild ruminants) or animal carcasses. It is extremely variable in humans. The acute form (less than 8 weeks from illness onset) may result in nonspecific and "flu-like" symptoms including fever, sweats, malaise, anorexia, headache, myalgia, and back pain. Echinococcus granulosus lives on dogs and livestock, and infects humans through contact with these animals. Allergic reactions and damage to various organs from cyst formation are the most common forms of disease in humans.

Biosecurity Procedures

- Individuals should not make on-site visits to livestock operations if they have visited a foreign country and were exposed to or had contact with farm animals (with or without a known contagious disease) within 5 days prior to the site visit. Also, clothing and shoes worn on foreign farm visits should be cleaned before use on U.S. facilities.
- Thoroughly wash hands with soap and water or antibacterial wipes or gel before entering and after leaving any animal facility. Disposable latex gloves also may be used but not as a substitute for proper hand washing.
- Park your vehicle on paved or concrete areas, away from farm production sites, to avoid contact with dirt, mud or manure. If not possible, be certain that tires are free of dirt and debris by hosing the tires and wheel wells before leaving the premises. If this does not clean the tires adequately, take the vehicle to a nearby pressure car wash. Including dates and types of vehicle washing in the vehicle log book is recommended.
- Consider using a vehicle supplied by the facility operator for on site travel if available.
- Prior to entering the site, put on disinfected rubber boots or other footwear that has been cleaned and disinfected, or wear new disposable boot covers. The operator may have its own coveralls and boots for you to wear. However, if visiting only low-risk areas, such as offices that are located away from animal areas, clean street shoes or boots are acceptable (hand washing is still needed). [Note: Boot covers may not provide sufficient traction to safely navigate slopes surrounding lagoons and pits. Personnel may want to use tape to secure the boot cover to prevent slippage].
- On entering a facility, acknowledge any and all other livestock facilities visited within the previous 48 hours including whether or not EPA entered any animal confinement or waste storage areas.
- Inform the operator of where the EPA staff wants to go on the site, determine what biosecurity procedures, if any, the owner/operator has for the on-site locations to be visited, and determine which biosecurity procedures will be followed for the areas to be visited.
- EPA should only enter animal production buildings if it is essential to complete the goals of the visit, and should avoid contact with livestock, poultry or other animals (wild or domestic) on any facility. If close contact with animals is expected, including walking through narrowly confined pens or lots where animals are within reach, wearing coveralls is recommended.
- Designate the interior of your vehicle as a “clean area” and keep clean supplies in this area.
- Designate a “dirty area” of your vehicle, such as the trunk of the car or a specified enclosed area of a truck bed for double bagged clothes or dirty equipment to be taken off site.
- Before leaving the site, clean and disinfect boots or tightly bag boots for later cleaning. Scrub boot bottom and sides to remove all dirt and debris, then wash with disinfectant solution. Disinfectants are not effective on dirt, manure or other organic matter.
- Clean and disinfect equipment if contaminated.
- Use disinfectants that have been registered (or exempted) by EPA for the intended use (see below). Keep a copy of the label and the Material Safety Data Sheet (MSDS) for any registered disinfectant used and make both available to the facility upon its request. Follow all label safety precautions and dispose of empty containers, unused disinfectant solution, and used disinfectant in accordance with label instructions.

- If non-disposable clothing is soiled with manure, blood, milk, or other animal secretions or there has been close contact with livestock (actual handling or walking where animals were within reach), before leaving the site, double bag clothing for later cleaning.
- Dispose of soiled boot covers, and disposable clothing on-site if acceptable to the owner/operator. Where on-site disposal is not possible, double bag and tightly seal all contaminated clothing and gear in disposable bags.
- Inform the owner/operator of the areas of the site that were visited, and the biosecurity procedures taken. This can be done at an inspection closing conference.

Supplies:

- ! clean boots or new disposable boot covers
- clean change of clothing or coveralls
- appropriate registered or exempted disinfectant (see below)
- water (at least minimum required for hand washing and disinfection)
- a bucket or tray to contain disinfectant
- long handled brush
- clean bags for trash disposal or storage of items to be cleaned
- liquid and/or gel antibacterial soap or wipes
- first aid kit including an eye wash
- phone numbers of the State veterinarian or other local officials available in case you suspect animal diseases are present. Share any such observations with the owner/operator as soon as possible

Disinfectants for Routine Biosecurity

The following products are currently registered by EPA as being effective against a broad range of disease-causing organisms, including Foot and Mouth Disease; they are not effective against all disease-causing organisms. Consult the label information and, if other diseases are a concern, consult the State veterinarian or State Department of Agriculture.

Virkon S (EPA Reg. No. 62432-1, label and MSDS)
Oxonia Active (EPA Reg. No. 1677-129, label and MSDS)

There are also two household chemicals subject to EPA Section 18 “quarantine exemptions” (i.e., they are exempted from FIFRA pesticide registration requirements) for use as Foot and Mouth Disease disinfectants. They are issued to APHIS but designed so that the general public can make treatments themselves using these chemicals. One permits vinegar (acetic acid) to be applied as a 4% solution, and the other permits bleach (sodium hypochlorite) to be used in a solution of 3 parts bleach to 2 parts water. Information on these Section 18 actions is attached.

Attachments:

1. APHIS Veterinary Series Area Offices and State Veterinarians
2. Copies of EPA-approved labels for Virkon S (April 26, 2001) and Oxonia Active (May 11, 2001) and associated Material Safety Data Sheets
3. Section 18s for Acetic Acid and Sodium Hypochlorite (Bleach)

Disclaimer □

The discussion in this document is intended solely as guidance. This document is not a regulation. It does not impose legally binding requirements on EPA, states, or the regulated community. This guidance does not confer legal rights or impose legal obligations upon any member of the public. The general description provided here may not apply to a particular situation based on the circumstances. Interested parties are free to raise questions and objections about the substance of this guidance and the appropriateness of the application of this guidance to a particular situation. EPA retains the discretion to adopt approaches on a case-by-case basis that differ from those described in this guidance where appropriate. This document may be revised periodically without public notice. EPA welcomes public input on this document at any time.

APHIS Veterinary Services Area Offices

Eastern Region - (919) 716-5570

Montgomery, Alabama -- (334) 223-7141
Gainesville, Florida -- (352) 333-3120
Conyers, Georgia -- (770) 922-7860
Springfield, Illinois -- (217) 241-6689
Indianapolis, Indiana -- (317) 290-3300
Frankfort, Kentucky -- (502) 227-9651
Annapolis, Maryland -- (410) 349-9708 (also serves DC & DE)
Sutton, Massachusetts -- (508) 865-1421 (also serves CT, ME, NH, RI & VT)
Lansing, Michigan -- (517) 324-5290
St. Paul, Minnesota -- (651)-290-3691
Jackson, Mississippi -- (601) 965-4307
Robbinsville, New Jersey -- (609) 259-8387
Albany, New York -- (518) 453-0187
Raleigh, North Carolina -- (919) 716-5570
Pickerington, Ohio -- (614) 469-5602 (also serves WV)
Harrisburg, Pennsylvania -- (717) 782-3442
San Juan, Puerto Rico -- (787) 766-6050, 6055
Columbia, South Carolina -- (803) 788-1919
Nashville, Tennessee -- (615) 781-5310
Richmond, Virginia -- (804) 771-2774
Madison, Wisconsin -- (608) 270-4000

Western Region - (817) 276-2201

Little Rock, Arkansas -- (501) 224-9515
Tempe, Arizona -- (480) 491-1002
Sacramento, California -- (916) 857-6170 (also serves NV)
Englewood, Colorado -- (303) 784-6229
Denver, Colorado -- (303) 231-5385
Honolulu, Hawaii -- (808) 861-8560
Boise, Idaho -- (208) 378-5631
Des Moines, Iowa -- (515) 284-4140
Topeka, Kansas -- (785) 235-2365
Baton Rouge, Louisiana -- (504) 389-0436
Jefferson City, Missouri -- (314) 636-3116
Helena, Montana -- (406) 449-5407

APHIS Veterinary Services Area Offices

Lincoln, Nebraska -- (402) 434-2300
Albuquerque, New Mexico -- (505) 761-3160
Bismarck, North Dakota -- (701) 250-4210
Oklahoma City, Oklahoma -- (405) 427-9413
Salem, Oregon -- (503) 399-5871
Pierre, South Dakota -- (605) 224-6186
Austin, Texas -- (512) 916-5551
Salt Lake City, Utah -- (801) 524-5010
Olympia, Washington -- (360) 753-9430 (also serves AK)
Cheyenne, Wyoming -- (307) 772-2186

State Veterinarians

ALABAMA

Phone: 334-240-7255
Fax: 334-223-7352
Dept. of Agriculture & Industries
Animal Industry Division
P. O. Box 3336
Montgomery, AL 36109-0336

ALASKA

Phone: 907-745-3236
Fax: 907-745-8125
500 S. Alaska Street, Suite A
Palmer, Alaska 99645

ARIZONA

Phone: 602-542-4293
Fax: 602-542-4290
Arizona Dept. of Agriculture
1688 West Adams
Phoenix, AZ 85007

ARKANSAS

Phone: 501-225-5138
Fax: 501-225-9727
Arkansas Livestock & Poultry Commission
One Natural Resources Drive
P. O. Box 5497
Little Rock, AR 72215

CALIFORNIA

Phone: 916-654-0881
Fax: 916-653-2215
CA Dept. of Food & Agriculture
1220 "N" Street, Room A-114
Sacramento, CA 95814

COLORADO

Phone: 303-239-4161
Fax: 303-239-4164
700 Kipling Street, Suite 4000
Lakewood, CO 80215-5894

CONNECTICUT

Phone: 860-566-4616
Fax: 860-566-8791
State Office Building, Room 291
165 Capitol Avenue
Hartford, CT 06106

DELAWARE

Phone: 302-739-4811
Fax: 302-697-6287
Delaware Dept. of Agriculture
2320 S. Dupont Highway
Dover, DE 19901

FLORIDA

Phone: 904-488-8280
Fax: 904-487-3641
Florida Dept. of Agriculture
Division of Animal Industry
Room 32B, Mayo Building
Tallahassee, FL 32399-0800

GEORGIA

Phone: 404-656-3671
Fax: 404-657-1357
Dept. of Agriculture
Capital Square
Atlanta, GA 30334-4201

HAWAII

Phone: 808-483-7111
Fax: 808-487-5789
Hawaii Dept. of Agriculture
99-941 Halawa Valley Street
Aiea, Hawaii 96701-5699

IDAHO

Phone: 208-334-3256
Fax: 208-334-2170
Bureau of Animal Health
128 Klotz Lane
P. O. Box 7249
Boise, Idaho 83707

ILLINOIS

Phone: 217-782-4944
Fax: 217-524-7702
Division of Animal Industries
State Fairgrounds
P. O. Box 19281
Springfield, IL 62794-9281

INDIANA

Phone: 317-232-1344
Fax: 317-232-1330
805 Beachway Drive, Suite 50
Indianapolis, IN 46224

IOWA

Phone: 515-281-5305
Fax: 515-281-4282
Bureau of Animal Industry,
IA Dept. of Ag. & Stewardship, Henry Wallace Bldg
Des Moines, Iowa 50319

KANSAS
 Phone: 913-296-2326
 Fax: 913-296-1765
 Livestock Commission
 Anchor Savings Building, Ste.4B
 712 Kansas Avenue
 Topeka, Kansas 66603-3808

KENTUCKY
 Phone: 502-564-3956
 Fax: 502-564-7852
 Division of Animal Health
 100 Fair Oaks Lane, Suite 252
 Frankfort, Kentucky 40601

LOUISIANA
 Phone: 504-925-3980
 Fax: 504-925-4103
 P. O. Box 1951
 Baton Rouge, LA 70821

MAINE
 Phone: 207-287-3701
 Fax: 207-287-7548
 Div. of Animal Health & Industry
 Dept. of Ag., Food & Rural Res.
 State House Station 28
 Augusta, ME 04333-0028

MARYLAND
 Phone: 410-841-5810
 Fax: 410-841-5999
 Div. of Animal Industries
 MD Dept. of Agriculture
 50 Harry S. Truman Parkway
 Annapolis, MD 21401

MASSACHUSETTS
 Phone: 617-626-1700
 Fax: 617-626-1850
 Department of Food and Agriculture
 Bureau of Animal Health
 251 Causeway Street, Suite 500
 Boston, MA 02114-2151

MICHIGAN
 Phone: 517-373-1077
 Fax: 517-373-6015
 MI Dept. of Agriculture
 Animal Industry Division
 P. O. Box 30017
 Lansing, Michigan 48909

MINNESOTA
 Phone: 612-296-2942
 Fax: 612-296-7417
 Executive Secretary,
 Board of Animal Health
 90 West Plato
 St. Paul, MN 55107

MISSISSIPPI
 Phone: 601-354-6089
 Fax: 601-354-6097
 State Veterinarian
 Box 4389
 Jackson, MS 39216

MISSOURI
 Phone: 573-751-3377
 Fax: 573-751-6919
 Div. of Animal Health
 MO Dept. of Agriculture
 P. O. Box 630
 Jefferson City, MO 65102

MONTANA
 Phone: 406-444-2976
 Fax: 406-444-1929
 MT Dept. of Livestock
 Animal Health Division
 Import/Export Section
 P. O. Box 202001
 6th & Roberts
 Helena, MT 59620-2001

NEBRASKA
 Phone: 402-471-2351
 Fax: 402-471-3252
 Dept. of Agriculture
 Bureau of Animal Industry
 P. O. Box 94787
 Lincoln, Nebraska 68509

NEVADA
 Phone: 702-688-1180
 Fax: 702-688-1178
 Dir. Div. of Animal Industry
 State Dept. of Agriculture
 P. O. Box 11100
 Reno, NV 89510

NEW HAMPSHIRE
 Phone: 603-271-2404
 Fax: 603-271-1109
 NH Dept. of Agriculture
 Div. of Animal Industry
 P. O. Box 2042
 Concord, NH 03302-2042

NEW JERSEY

Phone: 609-292-3965
Fax: 609-633-2550
Dir., Div. of Animal Health
NJ Dept. of Agriculture
CN 330
Trenton, NJ 08625

NEW MEXICO

Phone: 505-841-4000
Fax: 505-841-4012
New Mexico Livestock Board
7013 Central Ave., N. E.
Albuquerque, NM 87108-2049

NEW YORK

Phone: 518-457-3502
Fax: 518-457-8892
Div. of Animal Industry
NY St. Dept. of Ag. & Markets
1 Winners Circle
Albany, NY 12235

NORTH CAROLINA

Phone: 919-733-7601
Fax: 919-733-2277
North Carolina Dept. of Agriculture & Consumer
Services
Veterinary Division
P.O. Box 26026
Raleigh, NC 27611

NORTH DAKOTA

Phone: 701-328-2655
Fax: 701-328-4567
ND Board of Animal Health
600 E. Boulevard, 6th Floor
Bismarck, ND 58505-0020

OHIO

Phone: 614-728-6220
Fax: 614-728-6310
Chief, Div. of Animal Industry
Ohio Dept. of Ag.
8995 East Main Street
Reynoldsburg, Ohio 43068

OKLAHOMA

Phone: 405-521-3891
Fax: 405-522-4583
Animal Industry Div.
OK Dept. of Ag
2800 N. Lincoln Blvd.
Oklahoma City, OK 73105-4298

OREGON

Phone: 503-986-4680
Fax: 503-986-4734
OR Dept. of Agriculture
635 Capitol Street NE
Salem, OR 97310-0110

PENNSYLVANIA

Phone: 717-783-5301
Fax: 717-787-1868
Dir., Bureau of Animal Industry
PA Dept. of Agriculture
2301 North Cameron Street
Harrisburg, PA 17110

RHODE ISLAND

Phone: 401-277-2781
Fax: 401-277-6047
RI Dept. of Environmental Mgmt.
Div. of Agriculture
Roger Williams Building
22 Hayes Street
Providence, RI 02908

SOUTH CAROLINA

Phone: 803-788-2260
Fax: 803-788-8058
Clemson University
Livestock-Poultry Health Division
P. O. Box 102406
Columbia, SC 29224-2406

SOUTH DAKOTA

Phone: 605-773-3321
Fax: 605-773-5459
Animal Industry Board
411 South Fort Street
Pierre, SD 57501

TENNESSEE

Phone: 615-360-0120
Fax: 615-781-5309
Ellington Ag. Center
P. O. Box 40627, Melrose Station
Nashville, TN 37220

TEXAS

Phone: 512-719-0777
Fax: 512-719-0719
TX Animal Health Commission
2105 Kramer Lane
P. O. Box 12966
Austin, TX 78711-2966

UTAH

Phone: 801-538-7160
Fax: 801-538-7169
Utah St. Dept. of Agriculture
350 N. Redwood Rd.
P. O. Box 146500
Salt Lake City, UT 84114-6500

VERMONT

Phone: 802-828-2421
Fax: 802-828-2361
Dept. of Ag., Food & Markets
Animal Health Section
116 State St., Drawer 20
Montpelier, Vermont 05620-2901

VIRGINIA

Phone: 804-786-2481
Fax: 804-371-2380
Dept. of Ag. & Consumer Services
Division of Animal Health
Washington Building, Suite 600
1100 Bank Street
Richmond, VA 23219

WASHINGTON

Phone: 360-902-1878
Fax: 360-902-2087
Dept. of Agriculture
Food Safety/Animal Health Division
P. O. Box 42577
1111 Washington St.
Olympia, WA 98504-2577

WEST VIRGINIA

Phone: 304-558-2214
Fax: 304-558-2231
Dir. of Animal Health Programs
WV Dept. of Ag.
1900 Kanawha Blvd., East
Charleston, WV 25305-0170

WISCONSIN

Phone: 608-224-4873
Fax: 608-224-4871
WI Dept. of Ag., Trade & Consumer Protection
Animal Health Division
P. O. Box 8911
Madison, WI 53708-8911

WYOMING

Phone: 307-777-7515
Fax: 307-777-6561
2020 Carey Ave., 4th Floor
Cheyenne, WY 82002

PUERTO RICO

Phone: 809-725-1685
Fax: 809-723-6199
Dir., Vet. Services
Dept. of Agriculture
Commonwealth of Puerto Rico
Box 10163
Santurce, PR 00908

VIRGIN ISLANDS

Office of the Commissioner of Agriculture
P. O. Box "U"
Kingshill, St. Croix, USVI 00850

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EFFECTIVE AGAINST:

EQUINE BACTERIA

Clostridium perfringens
 Fistulous withera (Poll Evil)
 Taylorella equigenitalis
 Streptococcus equi (Strangles)
 Pseudomonas mallei
 (Glanders)
 Bordetella bronchiseptica

EQUINE VIRUSES

African Horse Sickness
 African Viral Arteritis
 (Pink Eye)
 Coital Exanthema
 Myeloencephalopathy
 Rhinopneumonitis
 Equine Infectious Anemia
 (Swamp Fever)
 Equine papillomatosis
 Equine Contagious Abortion
 Adenovirus Pneumonia
 Equine Influenza (The Cough)

EQUINE FUNGI

Trichophyton spp. (Ringworm)
 Trichophyton spp.
 (Mud Fever)
 Fusarium moniliforme

BOVINE BACTERIA

Moraxella bovis
 Mycobacterium bovis
 Haemophilus somnus

BOVINE VIRUSES

Calf rotavirus
 Infective Bovine
 Rhinotracheitis
 Bovine Adenovirus Type 4
 Pseudorabies
 Foot & Mouth Disease

BOVINE FUNGI

Fusarium moniliforme

POULTRY BACTERIA

Streptococcus pyogenes
 Campylobacter pyloridis
 Klebsiella pneumoniae
 Escherichia coli
 Salmonella typhimurium
 Salmonella choleraesuis
 Pseudomonas aeruginosa
 Staphylococcus aureus
 Staphylococcus epidermidis
 Mycoplasma gallisepticum
 Clostridium perfringens
 Bordetella avium

POULTRY VIRUSES

Newcastle Disease
 Infectious Bronchitis
 Infectious Bursal Disease
 Avian Laryngotracheitis
 Avian Influenza
 Marek's Disease
 Egg Drop Syndrome
 Adenovirus
 Turkey Herpes Virus
 Duck Herpes Virus
 Duck Viral Enteritis

POULTRY FUNGI

Aspergillus flavus
 Aspergillus fumigatus
 Candida albicans

SWINE BACTERIA

Bordetella bronchiseptica
 Pasteurella multocida
 Actinobacillus
 pleuropneumonia
 Treponema hyodysenteria
 Clostridium perfringens

SWINE VIRUSES

Hog Cholera
 Swine Influenza
 Porcine parvovirus
 Rotaviral diarrhea
 Vesicular stomatitis
 Pseudorabies
 Porcine Reproductive and
 Respiratory Syndrome
 (PRRS)
 African Swine Fever
 Foot and Mouth Disease

SWINE FUNGI

Fusarium moniliforme

COMPANION ANIMALS

BACTERIA
 Streptococcus aureus
 Streptococcus pyogenes
 Klebsiella pneumoniae
 Pseudomonas aeruginosa

VIRUSES

Canine Parvovirus
 Distemper
 Leptospira canicola
 Feline parvovirus
 Feline herpes
 Feline calicivirus

FUNGI

Microsporium canis

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4/26/2001

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VIRKON-S*
BROAD SPECTRUM DISINFECTANT

For Use in Cleaning and Disinfecting Industrial, Animal and Agricultural Facilities

ACTIVE INGREDIENTS:

Potassium peroxymonosulfate.....	20.4%
Sodium Chloride.....	1.5%
INERT INGREDIENTS.....	77.1%
TOTAL.....	100.00%

Equivalent to 9.75% Available Chlorine

KEEP OUT OF REACH OF CHILDREN
DANGER
See Back [Side] Panel[s] for Additional Precautions

___ lbs. (___) Net Weight

EPA Reg. No. 62432-1

EPA Est. No. 62432-EN-001

ANTEC INTERNATIONAL LTD.
 Windham Road, Chilton Industrial Estates
 Sudbury Suffolk C010 6XD, England
 Tel: (1787) 77305 Telex: 987495 Fax: (1787) 310846

VIRKON S is a registered trademark of and manufactured by Antec International Limited
US Patent No. 4822512

ACCEPTED
APR 26 2001
<small>Under the Federal Insecticide, Fungicide, and Rodenticide Act as amended, for the pesticide, registered under EPA Reg. No. 62432-1</small>

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**PRECAUTIONARY STATEMENTS
HAZARDS TO HUMANS AND DOMESTIC ANIMALS
DANGER**

Powder is corrosive. Causes skin burns and irreversible eye damage. Harmful if swallowed, absorbed through skin, or inhaled. Do not get in eyes, on skin, or on clothing. Wear protective clothing and rubber gloves. Avoid breathing dust. Wear goggles, face shield, or safety glasses. Wash thoroughly with soap and water after handling. Remove contaminated clothing and wash before reuse. Corrosive statement refers to powder only not in use solution.

FIRST AID

IF IN EYES: Hold eyelids open and flush with a steady, gentle stream of water for 15 minutes. Get prompt medical attention.

IF ON SKIN: Wash with plenty of soap and water. Get medical attention if irritation persists.

IF INHALED: If symptoms of coughing, choking, or wheezing are troublesome, remove to fresh air and seek medical attention.

IF SWALLOWED: Drink promptly a large quantity of water. Avoid alcohol. Get immediate medical attention.

NOTICE TO PHYSICIAN: Probable mucosal damage may contraindicate the use of gastric lavage.

BROAD SPECTRUM DISINFECTANT

VIRKON-S is effective against numerous microorganisms affecting animals: viruses, gram positive and gram negative bacteria, fungi (molds and yeasts), and mycoplasma. Efficacy was determined in the presence of hard water and organic material. *VIRKON-S passes the AOAC germicidal and detergent sanitizer test at a concentration of 0.5% (1:200) in the presence of 200 ppm hard water.*

DIRECTIONS FOR USE

Federal law prohibits use of this product in a manner inconsistent with its labeling.

This powder formula is easily diluted for use in manual or machine operations.

VIRKON-S DILUTION CHART
Fill container with desired amount of water and add VIRKON-S powder to achieve recommended solution concentration.

<i>Quantity of Water</i>	<i>Amount of Powder for 1% Solution</i>	<i>Amount of Powder for 2% Solution</i>
<i>1 Quart</i>	<i>0.3 ounces</i>	<i>0.7 ounces</i>
<i>1 Gallon</i>	<i>1.3 ounces</i>	<i>2.7 ounces</i>
<i>10 Gallons</i>	<i>13.4 ounces</i>	<i>26.7 ounces</i>
<i>50 Gallons</i>	<i>66.8 ounces</i>	<i>133.5 ounces</i>

1.3 oz. measuring scoop is provided.

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Add [1.3 oz. (1 scoop) of VIRKON-S] [the contents of one VIRKON-S packet] to one gallon of warm water. Solutions are stable for 7 days. Do not soak metal objects for long periods - 10 minutes is maximum necessary contact time. One gallon of solution is sufficient to treat 135 sq. ft.

POULTRY [AND RATITE PRODUCTION]

CONTROLS: Viruses of Newcastle Disease, Infectious Bronchitis, Infectious Bursal Disease, Avian Laryngotracheitis, Marek's Disease, Egg Drop Syndrome, Avian Influenza, Turkey Herpes Virus and Duck Viral Enteritis. Fungi (molds and yeasts - *Aspergillus flavus*, *Aspergillus fumigatus* and *Candida albicans*). Bacteria - *Streptococcus pyogenes*, *Campylobacter pyloridis*, *Klebsiella pneumoniae*, *Escherichia coli*, *Salmonella typhimurium*, *Salmonella choleraesuis*, *Pseudomonas aeruginosa*, *Staphylococcus aureus*, *Staphylococcus epidermidis*, *Bordetella avium* and *Mycoplasma gallisepticum*.

HATCHERIES: VIRKON-S at 1% solution *can be used* for cleaning and disinfecting hatchers, setters, evaporative coolers, humidifying systems, ceiling fans, chicken houses, transfer trucks, trays, and plastic chick boxes (use 2% solution for *Mycoplasma*, *Aspergillus flavus* and *Aspergillus fumigatus*). VIRKON-S at 1-2% solution is recommended for use in fogging (wet misting) operations as a *supplemental measure*, either *before or after* regular cleaning and *disinfecting* procedures. Fog (wet mist) until the area is moist using automatic foggers according to manufacturer's use directions.

BROILER/BREEDER HOUSES: *Remove chickens [birds], feed, and water troughs, then remove manure and litter. Spray floors and walls with VIRKON-S at 1% solution.* Thoroughly wash waterers and feeders with a 1% solution of VIRKON-S (use 2% solution for *Mycoplasma*, *Aspergillus flavus* and *Aspergillus fumigatus*). *After contact for 10 minutes, rinse with water. Do not house poultry or use equipment until treatment has dried.*

FOR AIR SANITIZING: Use VIRKON-S at 1-2% solution, *and fog until* surfaces are moist. Allow at least 2 hours before entering *treated area. Rinse foggers and sprayers with water following use.*

PROCESSING PLANTS: *Spray VIRKON-S at 1% solution to disinfect and clean walls, ceilings and floors.*

SWINE [PRODUCTION]

CONTROLS: Viruses of Hog Cholera, Swine influenza, Porcine Parvovirus, Pseudorabies, Porcine Reproductive and Respiratory Syndrome (PRRS), Rotoviral Diarrhea, African Swine Fever and Foot and Mouth Disease. Bacteria of *Pleuropneumonia*, *Treponema hyodysenteriae*, and *Clostridium perfringens*. Fungi: *Fusarium moniliforme*.

VIRKON-S at 1% solution is recommended for *cleaning and disinfecting* farrowing units, nurseries, finisher houses, processing plants (use a 2% solution for *Mycoplasma*, *Aspergillus flavus*

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and *Aspergillus fumigatus*), and agricultural production equipment such as trucks, water-proof footwear (such as rubber boots), and associated livestock equipment and instruments.

VIRKON-S at 1-2% solution is recommended for use in fogging (wet misting) operations or as a **supplemental measure** either **before** or **after** regular cleaning and **disinfecting** procedures. Fog (wet mist) until the area is moist using automatic foggers according to manufacture's use directions. **Rinse foggers and sprayers with water following use.**

EQUINE [PRODUCTION]

BROAD SPECTRUM EQUINE DISINFECTANT/DETERGANT/WASH FOR CLEANING AND DISINFECTING STABLES, EQUIPMENT, AND AERIAL DISINFECTION

CONTROLS

Viruses of African Horse Sickness, Equine Viral Arteritis (Pink Eye), Coital Exanthema, Myeloencephalopathy, Rhinopneumonitis, Equine Contagious Abortion, Equine Papillomatosis, Equine Infectious anemia (Swamp Fever), Adenovirus Pneumonia, Equine Influenza (The Cough) and Rhinitis. Bacterial: Clostridial Diarrhea, Fistulous Withers (Poll Evil), Taylorella equigenitalis, Bordetella bronchiseptica, Streptococcus equi (Strangles) and Pseudomonas mallei (Glanders). Fungi: Dermatophytosis (Ringworm), Dermatophylosis (Mud Fever), and Fusarium moniliforme.

APPLICATIONS: For cleaning and **disinfecting** all surfaces, equipment, utensils and instruments in Veterinary practices [, kennels, stables, catteries, etc].

USES:

Stables, [Horse Boxes,][Box]Stalls, Tack ,[Equipment,] and Feed Rooms: Thoroughly **clean and dry** [dry clean] **surfaces**, then wash the area manually or with pressure washer with a 1% VIRKON-S solution. Rinse with clean water.

Blankets, [Saddle Pads] [and] Rugs: Shampoo by hand or spray lightly with a hand-sprayer and leave to dry. Shake or vacuum to remove residue.

Aerial Spraying to control airborne diseases: **Use a hand [or knapsack] sprayer with fine setting**, or an **automatic** spraying system. Spray a **1% VIRKON-S solution** for 2-3 minutes twice daily [, first thing in the morning and last thing at night]. **Rinse sprayers with water after use.**

BOVINE [PRODUCTION]

CONTROLS: Viruses of Calf rotavirus, **Infectious Bovine Rhinotracheitis**, Bovine Adenovirus Type 4 and Pseudorabies and **Foot and Mouth Disease**; Bacteria of Maraxella bovis, Haemophilus somnus and Mycobacterium bovis; Fungi of Fusarium moniliforme.

A 1% solution of VIRKON-S is recommended to **clean and disinfect** areas associated with bovine **housing** [stabling], hospital [quarantine] pens, feedlot facilities, and **agricultural production**

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[] indicates optional language

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equipment such as trucks, water-proof footwear (such as rubber boots), and associated livestock equipment and instruments.

COMPANION ANIMALS

CONTROLS: Viruses Canine Parvovirus, Distemper, *Leptospira canicola*, Feline parvovirus, Feline herpes and Feline calicivirus. Bacteria of *Staphylococcus aureus*, *Streptococcus pyogenes*, *Klebsiella pneumoniae*, and *Pseudomonas aeruginosa*; Fungi of *Microsporium canis*.

[APPLICATIONS:] A 1% solution of VIRKON-S is recommended as a "one step" cleaning and *disinfecting* procedure for all surfaces, equipment, instruments, utensils and *cages* [caging systems] within [associated with][Veterinary Medical Hospitals,] [infections disease wards,] [quarantine areas,] [Humane Society facilities,] [laboratory animal quarters,] grooming and boarding facilities, kennels, catteries and animal transportation vehicles.

Do not immerse metal objects in VIRKON-S for long periods - 10 minutes is maximum contact time.

STORAGE AND DISPOSAL

STORAGE: Store in a cool, dry place in tightly closed container away from children. Always replace lid after use.

DISPOSAL: Wash empty container thoroughly and dispose in trash. Do not mix this product with other chemicals

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1677-129

5-11-2001

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

MAY 11 2001

Ecolab
Ecolab Inc.
370 N. Wabasha Street
St. Paul, MN 55102-1390

Attention: John G. Wood, Director
Product Registration and Compliance

Subject: Oxonia Active
EPA Registration Number 1677-129
Amendment Dated April 6, 2001

The Agency is conditionally approving your amendment to the registration of the product referenced above under authority of FIFRA Section 3(c)(7)(B). This amendment allows use of the subject product as a virucide against the animal pathogen "Foot and Mouth Disease (FMD)Virus."

This amendment will expire automatically on June 1, 2002. In addition, during the 1 year period that this amendment is effective, it will be subject to the conditions listed below

The following information must be submitted, and found acceptable by December 31, 2001 and the Agency must determine that the data is acceptable by June 1, 2002.

Failure to satisfy the data requirements listed below may result in EPA issuing a notice to cancel this amendment under FIFRA section 6(e). This conditional registration will expire automatically on June 1, 2002. Sale or distribution of the subject product bearing labeling claims for the Foot and Mouth Disease Virucidal use will be illegal if the requirements of this acceptance letter are not satisfied..

- A. The product must be tested, and found to be effective, against the FMD virus in an approved facility (Institute for Animal Health).
- B. Testing must be conducted on two batches of the product.

		CONCURRENCES						
SYMBOL								
SURNAME								
DATE								

EPA Form 1320-1A (1/90) Printed on Recycled Paper OFFICIAL FILE COPY

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C. The performance standard is total inactivation of the virus or a 3-log reduction if Cytotoxicity is present.

A stamped accepted copy of the label is enclosed for your records.

If you have any questions concerning this letter, please contact Martha Terry at (703) 308-6217.

Sincerely,


Marshall Swindell
Product Manager 33
Regulatory Management Branch I
Antimicrobial Division(7510C)

Enclosure

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OXONIA ACTIVE

ACID LIQUID SANITIZER FOR FOOD PROCESSING EQUIPMENT
in Dairies, Dairy Farms, Breweries, Wineries, Beverage and Food Processing Plants

ACID LIQUID SANITIZER FOR SANITIZING TABLEWARE

DISINFECTANT

Hospitals, Health Care Facilities, Animal Care Facilities, Veterinary Facilities, Farms,
Livestock Quarters, Poultry Premises, and Poultry Hatcheries

DISINFECTANT FOR THE PHARMACEUTICAL AND COSMETIC INDUSTRY

ACCEPTED
with COMMENTS
in EPA Letter Dated:

MAY 11 2001

Under the Federal Insecticide,
Fungicide, and Rodenticide Act as
amended, for the pesticide,
registered under EPA Reg. No.

1677-129

Active Ingredients:	
Hydrogen Peroxide.....	27.5%
Peroxyacetic Acid.....	5.8%
Inert Ingredients	66.7%

KEEP OUT OF REACH OF CHILDREN DANGER

PRECAUTIONARY STATEMENTS - HAZARDS TO HUMANS AND DOMESTIC ANIMALS

DANGER: CORROSIVE: Causes irreversible eye damage and skin burns. May be fatal if inhaled or absorbed through the skin. Harmful if swallowed. Do not get in eyes, on skin or on clothing. Do not breathe vapor or spray mist. Wear protective eyewear (goggles, face shield, or safety glasses), protective clothing and rubber gloves. Wash thoroughly after handling with soap and water, and before eating, drinking or using tobacco. Remove contaminated clothing and wash clothing before reuse. Wear a mask or pesticide respirator jointly approved by Mine Safety and Health Administration and the National Institute for Occupational Safety and Health.

STATEMENT OF PRACTICAL TREATMENT

IF IN EYES: Hold eyelids open and flush with a steady, gentle stream of water for 15 minutes. Get medical attention.

IF ON SKIN: Wash with plenty of soap and water. Get medical attention.

IF INHALED: Remove victim to fresh air. If not breathing, give artificial respiration, preferably mouth-to-mouth. Get medical attention.

IF SWALLOWED: Call a doctor or get medical attention. Do not induce vomiting or give anything by mouth to an unconscious person. Drink promptly a large quantity of milk, eggwhites, gelatin solution, or if these are not available, drink large quantities of water. Avoid alcohol. CALL A POISON CONTROL CENTER OR PHYSICIAN IMMEDIATELY.

FOR EMERGENCY MEDICAL INFORMATION CALL TOLL FREE: 1-800-328-0026

NOTE TO PHYSICIAN: Probable mucosal damage may contraindicate the use of gastric lavage.

PHYSICAL AND CHEMICAL HAZARDS: Strong oxidizing agent. Corrosive. Do not use in concentrated form. Mix only with water according to label instructions. Never bring concentrate in contact with other sanitizers, cleaners or organic substances.

ENVIRONMENTAL HAZARDS: Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans, or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance contact your State Water Board or Regional Office of the EPA.

FOR COMMERCIAL USE ONLY STRONG OXIDIZING AGENT

EPA Reg. No. 1677-129
EPA Est. 1677-MN-1 (P), 60158-IL-1 (S), 1677-CA-2(R),
1677-TX-1(D), 1677-OH-1(H), 1677-IL-1(J), 1677-GA-1(M),
1677-PR-1(B), 1677-CA-1(S), 1677-NJ-1(W), 1677-WV-1(V)
Superscript refers to first letter of date code

Net Contents:	1 U.S. Gal. (3.78 L)
	4 U.S. Gals. (15.1 L)
	2.5 U.S. Gals.
	15 U.S. Gals. (56.8 L)
	30 U.S. Gals. (113.5 L)
	50 U.S. Gals. (189 L)
	300 U.S. Gals. (toke)

Ecolab Food and Beverage Division
Ecolab Inc., 370 N. Wabasha Street
St. Paul, MN 55102

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Oxonia Active label

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April 6, 2001

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

SANITIZATION

Oxonia Active acid sanitizer is recommended for use on pre-cleaned surfaces such as equipment, pipelines, tanks, vats, fillers, evaporators, pasteurizers and aseptic equipment in dairies, breweries, wineries, beverage and food processing plants. This product is effective as a sanitizer when solution is prepared in water of up to 500 ppm hardness as CaCO₃.

SANITIZING FOOD CONTACT SURFACES

Prior to sanitizing, remove gross food particles, then wash with a detergent solution, followed by a potable water rinse. Sanitize with a concentration of 1.3 to 2.0 ounces **Oxonia Active** concentrate per 4 gallons of water (0.25 - 0.4% v/v concentration). At this dilution **Oxonia Active** is effective against *Staphylococcus aureus*, *Escherichia coli*, *Escherichia coli* O157:H7, *Listeria monocytogenes*, *Salmonella typhimurium*, *Pseudomonas aeruginosa* and *Vibrio cholerae*. Also effective against organisms found in the brewing industry, *Saccharomyces cerevisiae*, *Pedococcus damnosus* and *Lactobacillus malefermentans*. Use immersion, coarse spray or circulation techniques as appropriate to the equipment. All surfaces should be exposed to the sanitizing solution for a period of not less than two minutes unless otherwise specified by governing sanitary code. Drain thoroughly and allow to air dry. Do not rinse.

SANITIZING EATING, DRINKING, AND FOOD PREP UTENSILS

1. Remove gross food particles by a prescrape, preflush and, when necessary, a presoak treatment.
2. Wash with a recommended detergent.
3. Rinse with clean water.
4. Sanitize in a solution of 1.3 to 2.0 oz **Oxonia Active** to 4 gallon of water. Immerse all utensils for at least 1 minute or contact time specified by governing sanitary code.
5. Drain and air dry.

ELEVATED TEMPERATURE SANITIZING

For sanitization of equipment in food processing plants, restaurants, etc., clean and rinse equipment thoroughly. At a temperature of 120 deg F, **Oxonia Active** is an effective sanitizer for food contact surfaces at a concentration of 0.1% to 0.28% v/v (1 to 2.8 oz. **Oxonia Active** to 8 gallons water) against *Staphylococcus aureus* and *Escherichia coli*. All surfaces should be exposed to the sanitizing solution for a period of not less than 1 minute. Allow equipment to drain thoroughly.

SANITIZING TABLEWARE

For sanitizing tableware in low-temperature warewashing machines, inject **Oxonia Active** into the final rinse water at a concentration of 0.1 - 0.28% v/v (1 to 2.8 oz. per 8 gallons of water). Do not exceed 0.28% v/v. Air dry.

To insure that the **Oxonia Active** sanitizer concentration does not fall below 0.1%, periodically test the rinse solution with a suitable test kit and adjust the dispensing rate accordingly. Consult your local Ecobiab Specialist for technical assistance and further information on sanitizing tableware in warewashing machines.

FINAL SANITIZING BOTTLE RINSE

Oxonia Active may be used as a final sanitizing rinse for returnable and non-returnable bottles at a 0.25% dilution (1.3 oz to 4 gallons).

NOTE: FOR MECHANICAL OPERATIONS prepared use solution may not be reused for sanitizing but may be reused for other purposes such as cleaning.
FOR MANUAL OPERATIONS fresh sanitizing solutions should be prepared at least daily or more often if the solution becomes diluted or soiled.

ACCEPTED
with COMMENTS
in EPA Letter Dated:
MAY 11 2001

Under the Federal Insecticide,
Fungicide, and Rodenticide Act as
amended, for the pesticide,
registered under EPA Reg. No.
1677-129

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SANITIZING NON-FOOD CONTACT SURFACES

Preclean surfaces as directed above. Sanitize non-food contact surfaces such as floors, walls, tables, chairs, benches, drains, troughs, and drip pans with 1 oz Oxonia Active per 8 gal water. At this concentration the product is effective against *Staphylococcus aureus*, *Enterobacter aerogenes*, *Escherichia coli*, *Listeria monocytogenes*, *Salmonella typhimurium*, *Pseudomonas aeruginosa*, and *Saccharomyces cerevisiae*. Also effective against organisms found in the brewing industry, *Pediococcus damnosus* and *Lactobacillus malefermentans*. All surfaces should be exposed to the sanitizing solution for a period of not less than 5 minutes. Drain thoroughly and allow to air dry. No rinse necessary.

FOAM SANITIZING NON-FOOD CONTACT SURFACES

Oxonia Active is an effective foam sanitizer of precleaned non-food contact surfaces, such as boots, floors, walls, drains, and associated equipment. For this application, prepare a solution of 0.2% v/v (1 oz per 4 gallons water) Oxonia Active and 0.13% v/v (0.8 oz per 4 gallons water) Liquid K. For example, in four gallons of water, add 1 ounce of Oxonia Active and 0.8 ounces of Liquid K). Liquid K is the only approved foam generator. Apply solution as a foam using recommended equipment such as a Super Foamer. Wet surfaces thoroughly. At this concentration, the product is effective against *Staphylococcus aureus*, *Enterobacter aerogenes*, and *Listeria monocytogenes*. Surfaces should be exposed to the sanitizing foam for a period of not less than 5 minutes. No rinse is necessary. Contact your Ecolab representative for information on Liquid K and a recommended foamer.

DIRECTIONS FOR FOGGING: To sanitize hard surfaces as an adjunct to acceptable manual cleaning and disinfecting of room surfaces: Prior to fogging, food products and packaging materials must be removed from the room or carefully protected. Fog desired areas using one quart per 1000 cu. ft. of room area with a 0.3% to 3.0% (3 oz. to 30 oz. per 8 gallons of water) Oxonia Active solution. Vacate the area of all personnel during fogging and until the hydrogen peroxide air concentration is below 0.5 ppm. Allow surfaces to drain thoroughly before operations are resumed. Solutions above 0.5% may be corrosive and are not to be used on all surfaces. Test solutions on surfaces prior to use.

SANITIZING NON-FOOD CONTACT PACKAGING EQUIPMENT

Prior to use of this product, remove gross soil particles from surfaces. Wash with a recommended detergent solution, rinse thoroughly with potable water. For sanitization against beverage spoilage organisms that include *Pediococcus damnosus*, *Lactobacillus malefermentans*, and *Saccharomyces cerevisiae* apply 0.5 - 4.0% (5 oz. to 40 oz. per 8 gallons of water) of Oxonia Active to surfaces at a temperature of 25 to 45 deg C and allow to remain wet for at least 5 minutes. Allow surfaces to drain thoroughly before operations are resumed. Drainage may be followed by a potable or sterile water rinse.

SANITIZE PRECLEANED OR NEW RETURNABLE OR NON-RETURNABLE CONTAINERS

To sanitize precleaned or new returnable or non-returnable containers, apply Oxonia Active at a concentration of 1.0% to 4.0% (10 oz. to 40 oz. per 8 gallons of water) at a temperature of 40 to 60 deg. C for at least 7 seconds. At these conditions, Oxonia Active is effective against *Staphylococcus aureus*, *Escherichia coli*, *Salmonella typhi*, *Pediococcus damnosus*, *Lactobacillus malefermentans*, and *Saccharomyces cerevisiae*. After thorough draining, rinse interior container surfaces with sterile or potable water.

ANTIMICROBIAL TREATMENT OF WATER FILTERS

To reduce the number of beverage spoilage organisms that include *Pediococcus damnosus*, *Lactobacillus malefermentans*, and *Saccharomyces cerevisiae* apply Oxonia Active as a 0.5 to 2.0% (5 oz. to 20 oz. per 8 gallons of water) solution at 25 to 45 deg C for a minimum contact time of 5 minutes. After thorough draining, rinse filters with potable or sterile water.

ANTIMICROBIAL RINSE OF PRECLEANED OR NEW RETURNABLE OR NON-RETURNABLE CONTAINERS WITH THE ADDITION OF A SURFACTANT

To reduce the number of beverage spoilage organisms that include *Pediococcus damnosus*, *Lactobacillus malefermentans*, and *Saccharomyces cerevisiae*, add a 1.0 to 4.0% (10 oz. to 40 oz. per 8 gallons of water) solution of Oxonia Active to a 0.05 - 0.5% concentration (1 oz per 16 gallons to 2 oz per 3 gallons) of [insert name of surfactant blend] solution. Apply at a temperature of 40 to 60 deg C with a contact time of at least 7 seconds. After thorough draining, rinse interior container surfaces with sterile or potable water. Contact Ecolab for a list of acceptable surfactants.

ACCEPTED
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Under the Federal Insecticide,
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Oxonia Active label

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DISINFECTION

Oxonia Active disinfects as it cleans in one operation. **Oxonia Active** can be used to disinfect floors, walls and other hard nonporous surfaces such as tables, chairs, countertops, bathroom fixtures, sinks, shelves, racks, carts, refrigerators, coolers, tile, linoleum, vinyl, asphalt, porcelain, plastic (such as polypropylene and polyethylene), stainless steel, or glass.

Areas of Use: In Hospitals, use **Oxonia Active** for Surgical and Obstetrical Suites; Housekeeping Services; Physical Therapy Departments; Nursing Services; Autopsy Facilities. Also, use **Oxonia Active** in nursing homes, other health-care facilities, schools, colleges, veterinary clinics, animal life science laboratories, industrial facilities, dietary areas, office buildings, recreational facilities, retail and wholesale establishments. Not for use on food preparation surfaces, medical devices or medical equipment surfaces.

COMBINATION DISINFECTION AND CLEANING

Oxonia Active is effective against *Staphylococcus aureus*, *Salmonella choleraesuis*, *Pseudomonas aeruginosa*, *Salmonella enteritidis*, *Salmonella typhimurium*, *Proteus vulgaris*, *Streptococcus pyogenes* and *Histoplasma capsulatum** at 0.4% (4 oz per 8 gallons of water) in hard water (500 ppm as CaCO₃), 5% blood serum and dried soap film residue on hard nonporous surfaces. For heavily soiled areas a precleaning step is required. Prepare a disinfecting and cleaning solution by diluting 4 ounces **Oxonia Active** in 8 gallons of water (0.4% v/v). Apply solution with mop, cloth, sponge, brush, scrubber, or coarse spray device or by soaking so as to wet all surfaces thoroughly. Allow to remain wet for 10 minutes, then remove solution and entrapped soil with a clean wet mop, cloth, or wet vacuum pickup. Prepare a fresh solution daily or when it becomes soiled or diluted.

*Not tested in the presence of soap film residue.

TUBERCULOCIDAL

Oxonia Active passes the rigid requirements as a tuberculocide at 0.4% (4 oz. per 8 gallons of water) in the presence of 5% blood serum, 500 ppm hard water and residual soap scum on nonporous surfaces at 20 deg C. Remove heavy soil or gross filth prior to disinfection. Allow surfaces to remain wet for 10 minutes, then remove solution with a clean wet mop, cloth, or wet vacuum pickup.

VIRUCIDAL

At 0.4% (4 oz. per 8 gallons of water) **Oxonia Active** is effective against Influenza B/Taiwan/2/62, Influenza A(H3N2) and Influenza A (H1N1) when used at 20 deg C with a 10 minute contact time in the presence of 500 ppm hard water and organic soil. Apply as directed under disinfection.

DISINFECTING PHARMACEUTICAL AND COSMETIC SURFACES

Oxonia Active is recommended for use on hard, non-porous, environmental surfaces such as floors, walls and processing equipment in pharmaceutical and cosmetic processing facilities. This product is effective against *Staphylococcus aureus*, *Salmonella choleraesuis*, and *Pseudomonas aeruginosa* at 0.4% (4 oz in 8 gallons water) in hard water (500 ppm as CaCO₃), 5% blood serum and dried soap film residue. For heavily soiled areas a precleaning step is required. Rinse all surfaces thoroughly with the disinfecting solution and maintain a contact time of at least 10 minutes. Product contact surfaces must be rinsed with sterile water.

ACCEPTED
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OXONIA ACTIVE is designed for use in animal hospitals, animal laboratories, kennels, pet shops, zoos, pet animal quarters, poultry premises, poultry hatcheries, and livestock quarters. When used as directed, **Oxonia Active** is specifically designed to disinfect, deodorize and clean inanimate, hard, surfaces such as walls, floors, sink tops, furniture, operating tables, kennel runs, cages and feeding and watering equipment. In addition **Oxonia Active** will deodorize those areas which are generally hard to keep fresh smelling such as garbage storage areas, empty garbage bins and cans, and any other areas which are prone to odors caused by microorganisms.

All treated equipment that will contact feed or drinking water must be rinsed with potable water before reuse.

ACCEPTED
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Under the Federal Insecticide,
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For heavily soiled areas, a pre-cleaning step is required. Prepare a fresh solution for each use.

DISINFECTION OF POULTRY PREMISES, TRUCKS, COOPS AND CRATES

1. Remove all poultry and feeds from premises, trucks, coops and crates.
2. Remove all litter and droppings from floors, walls and surfaces of facilities occupied or traversed by poultry.
3. Empty all troughs, racks and other feeding and watering appliances.
4. Thoroughly clean all surfaces with a detergent and rinse with water.
5. Saturate surfaces with a 0.4% (4 oz. per 8 gallons of water) solution of **Oxonia Active** for a period of 10 minutes.
6. Ventilate buildings, coops and other closed spaces. Do not house poultry or employ equipment until treatment has been absorbed, set or dried.
7. Thoroughly scrub treated feed racks, troughs, automatic feeders, fountains and waterers with a detergent and rinse with potable water before reuse.

See your Ecolab or Airkem Representative for specific recommendations for all cleaning and rinsing requirements.

POULTRY HATCHERY DISINFECTION

Clean out any remaining eggs and chicks. Remove gross soils, such as litter, down, shell fragments or other hatching related debris. Empty all racks and other equipment. Thoroughly wash all surfaces, including floors, walls, conveyors, trays and water systems with a recommended detergent. Rinse thoroughly with water. Apply a 0.4% (4 oz. per 8 gallons of water) solution of **Oxonia Active** with a mop, cloth, brush or coarse spray. Wet all surfaces and allow to remain wet for 10 minutes. Ventilate buildings and other closed spaces. Allow to dry before reintroducing eggs.

DISINFECTION AND DEODORIZING OF ANIMAL HOUSING FACILITIES (BARN, KENNELS, HUTCHES)

Remove animals and feed from facilities. Remove litter, waste matter and gross soils. Empty all troughs, rack and other feeding and watering equipment. Wash surfaces with a recommended alkaline detergent, by manual, foam, or spray application. Rinse with water. Apply a 0.4% (4 oz. per 8 gallons of water) solution of **Oxonia Active** with a mop, cloth, brush or coarse spray. Wet all surfaces and allow to remain wet for 10 minutes. Ventilate buildings and other closed spaces. Allow to air dry before reintroducing animals. Effective against *Aspergillus fumigatus*.

VIRUCIDAL ACTIVITY - Poultry and Livestock Pathogens

Oxonia Active is useful as a disinfectant against viruses pathogenic to poultry that include Influenza A (H10N7), Newcastle Disease virus, Infectious bronchitis virus, Reovirus (C0₁), as well as bovine and other livestock pathogens, that include Infectious bovine rhinotracheitis (IBR), Parainfluenza 3 Virus, and the foot & mouth disease virus (Aphthovirus).

BACTERIOSTATIC

At 0.04% (1 oz. per 20 gallons of water) **Oxonia Active** is effective at inhibiting the growth of bacteria when used in the presence of 500 ppm hard water and organic soil.

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Oxonia Active label

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April 6, 2001

FOR SANITIZING OF HATCHING EGGS

Prepare a solution of Oxonia Active by diluting 2 oz product with 5 gallons of water. As eggs are gathered or prior to setting, apply solution as a coarse spray so as to lightly wet all shell surfaces.

ACCEPTED
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in EPA Letter Dated:

MAY 11 2001

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STERILIZATION OF MANUFACTURING, FILLING, AND PACKAGING EQUIPMENT IN ASEPTIC PROCESSES

Prior to use of this product, remove gross soil particles from processing surfaces, then wash with a recommended detergent solution, followed by a thorough potable water rinse. Prepare a sterilizing solution by diluting 6.4 ounces Oxonia Active concentrate per each gallon of water (50 mL/liter) (5.0% v/v). Circulate, coarse spray, or flood the sterilizing solution through the system. All surfaces should be exposed to the sterilizing solution for a minimum exposure time based on the product solution temperature. The following time and temperature relationships are required:

Oxonia Active Concentration	Temperature	Time
5%	68°F (20°C)	6 hours
5%	122°F (50°C)	20 minutes
5%	176°F (80°C)	5 minutes

Rinse surfaces completely with a sterile water rinse. For food-contact surfaces, follow with a sanitizing solution of Oxonia Active. Allow surfaces to drain thoroughly prior to any food product contact.

NOTE: This product in its use solutions is compatible with stainless steel and aluminum surfaces. If product is intended to be used on any other surface, it is recommended that you apply product to a smaller test area to determine compatibility before proceeding with its use.

STORAGE & DISPOSAL

DO NOT CONTAMINATE WATER, FOOD OR FEED BY STORAGE OR DISPOSAL

STORAGE: Product should be kept cool and in a vented container to avoid any explosion hazard.

PESTICIDE DISPOSAL: Pesticide wastes are acutely hazardous. Improper disposal of excess pesticide, spray mixture, or rinsate is a violation of Federal Law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste representative at the nearest EPA Regional Office for guidance.

CONTAINER DISPOSAL:

(1 gal) Do not reuse empty containers. Wrap container and put in trash.

(4, 15, 30, 50 gal plastic) Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or incineration, or, if allowed by state and local authorities, by burning. If burned, stay out of smoke.

(2.5 gal bladder in box) Remove empty bladder from outer corrugated box. Triple rinse bladder (or equivalent). Offer box and bladder for recycling or dispose of in a sanitary landfill or incineration, or if allowed by state and local authorities, by burning. If burned, stay out of smoke.

(Totes) Verify that the tote is empty. Do not rinse or clean. Seal tote and contact Ecolab for return.

ACCEPTED
with COMMENTS
in EPA Letter Dated:
MAY 11 2001

Under the Federal Insecticide,
Fungicide, and Rodenticide Act as
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registered under EPA Reg. No.
1677-129

***** SECTION 18 AMENDMENT *****

Carl Bausch, Deputy Director
Environmental Services
Policy and Program Development
Animal and Plant Health Inspection Service
(APHIS)
United States Department of Agriculture
4700 River Road, Unit 152
Riverdale, MD 20737-1237

Attn: Kelly White
Fax: 301-734-5992
Email: kelly.e.white@aphis.usda.gov

File Symbol: 99-DA-07
Chemical: sodium hypochlorite (bleach)

The Environmental Protection Agency hereby amends the quarantine exemption referred to above, originally issued to the United States Department of Agriculture (USDA), Animal and Plant Health Inspection Service (APHIS), pursuant to section 18 of the Federal Insecticide, Fungicide and Rodenticide Act, as amended, on April 9, 1999. The following provision of the April 9, 1999 authorization is hereby amended as follows:

- Treatments may be made by USDA/APHIS personnel, any State Department of Agriculture personnel, farmers, or any other individuals who need to use this disinfectant on surfaces potentially exposed to certain animal diseases, including Foot and Mouth Disease.

The effect of this amendment is to remove the language that restricts the use of sodium hypochlorite (bleach) to USDA/APHIS personnel. All other provisions of the original April 9, 1999 document and March 15, 2001 amendment remain in effect.

Robert A. Forrest, Chief
Minor Use, Inerts, & Emergency Response Branch
Registration Division/OPP

Date: _____

cc:

REGION 1

CONTACT: Robert Koethe
FAX: 617-918-1505

REGION 2

CONTACT: Adrian Enache
FAX: 732-321-6788

REGION 3

CONTACT: Harry Daw
Fatima ElAbdaoui
FAX: 215-814-3113

REGION 4

CONTACT: Lora Lee Schroeder
FAX: 404-562-8973

REGION 5

CONTACT: Lavarre Uhlken
FAX: 312-353-4788

REGION 6

CONTACT: Johnie Dowell
FAX: 214-665-7263

REGION 7

CONTACT: Luetta Flournoy
FAX: 913-551-7165 (-7065, alt)

REGION 8

CONTACT: Debbie Kovacs
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REGION 9

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REGION 10

CONTACT: Chad Schulze
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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES, AND
TOXIC SUBSTANCES

***** signed 8/31/2001 *****

Carl Bausch
Deputy Director, Environmental Services
Policy and Program Development
Animal and Plant Health Inspection Service (APHIS)
United States Department of Agriculture
4700 River Road
Riverdale, MD 20737-1237

Attn: Kelly White
Kelly.E.White@aphis.usda.gov
Fax: (301) 734-5992

File Symbol: 01-DA-05
Expires: Three years from the date of issuance

The Environmental Protection Agency (EPA) hereby grants a quarantine exemption under the provisions of section 18 of the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, to the United States Department of Agriculture (USDA), Animal and Plant Health Inspection Service (APHIS), for the use of acetic acid to control foot and mouth disease around the country. This quarantine exemption is subject to the conditions in your application as well as the following:

1. The USDA/APHIS is responsible for ensuring that all provisions of this quarantine exemption are met. It is also responsible for providing information in accordance with 40 CFR 166.32(b). This information must be submitted to EPA headquarters within 6 months of the above expiration date.
2. Treatments consisting of a 4-5% solution of acetic acid (vinegar) and water may be made to farm equipment and slaughter machinery, military equipment, footwear and clothing, agricultural facilities, quarantine facilities, shipping conveyance, aircraft, and any other non-food items or surfaces potentially contaminated with foot and mouth disease virus.
3. Treatments may be carried out nationally on an as-needed basis as part of a prevention or eradication program for the foot and mouth disease virus.

4. USDA/APHIS shall ensure that mixers will be advised to wear protective eye wear when diluting acetic acid with water.
5. No treatments are permitted under this authorization to food or feed items.
6. EPA headquarters and the appropriate regional offices shall be informed of any adverse effects resulting from use under this quarantine exemption. An interim report summarizing, to the extent available, the results of this program must be submitted annually and a final report summarizing the results of this program must be submitted six months after the expiration date of this exemption.

_____/s/_____
Anne E. Lindsay,
Acting Deputy Director for Pesticide Programs,
Office of Pesticide Programs

Date: 8/31/2001

cc:

REGION 1

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