

36.3 g/t with bacitracin zinc 10 g/t and roxarsone 30 to 45.4 g/t is used as an aid in the prevention of coccidiosis where severe exposure to coccidiosis from *E. acervulina*, *E. maxima*, and *E. brunetti* is likely to occur, and for improved feed efficiency and improved pigmentation.

Alpharma Inc.'s ANADA 200-214 provides for combining approved AMPROL HI-E® (Merck Research Laboratories' amprolium and ethopabate NADA 13-461), ALBAC® (Alpharma Inc.'s bacitracin zinc ANADA 200-223), and 3-NITRO® (Alpharma Inc.'s roxarsone NADA 7-891) Type A medicated articles to make the combination drug Type C medicated feeds.

Alpharma Inc.'s ANADA 200-214 is approved as a generic copy of Hoffmann-LaRoche, Inc.'s NADA 105-758. The ANADA is approved as of November 12, 1997, and the regulations are amended in 21 CFR 558.58(d)(1)(iii) to reflect the approval. The basis for approval is discussed in the freedom of information summary.

In accordance with the freedom of information provisions of 21 CFR part 20 and 514.11(e)(2)(ii), a summary of safety and effectiveness data and information submitted to support approval of this application may be seen in the Dockets Management Branch (HFA-305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1-23, Rockville, MD 20857, between 9 a.m. and 4 p.m., Monday through Friday.

The agency has determined under 21 CFR 25.33 that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

List of Subjects in 21 CFR Part 558

Animal drugs, Animal feeds.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to the Center for Veterinary Medicine, 21 CFR part 558 is amended as follows:

PART 558—NEW ANIMAL DRUGS FOR USE IN ANIMAL FEEDS

1. The authority citation for 21 CFR part 558 continues to read as follows:

Authority: 21 U.S.C. 360b, 371.

§ 558.58 [Amended]

2. Section 558.58 *Amprolium and ethopabate* is amended in the table in paragraph (d)(1)(iii) in the entry for "Bacitracin 10 to 50 plus roxarsone 15.4

to 45.4 (0.0017% to 0.005%)" under "Limitations" by removing "No. 000004" both times it appears and adding in their place "Nos. 000004 and 046573", and under "Sponsor" by removing "000004" and adding in its place "000004, 046573".

Dated: October 22, 1997.

Stephen F. Sundlof,

Director, Center for Veterinary Medicine.

[FR Doc. 97-29653 Filed 11-10-97; 8:45 am]

BILLING CODE 4160-01-F

DEPARTMENT OF THE INTERIOR

Office of Surface Mining Reclamation and Enforcement

30 CFR Part 946

[VA-106-FOR]

Virginia Regulatory Program

AGENCY: Office of Surface Mining Reclamation and Enforcement (OSM), Interior.

ACTION: Final rule; correction.

SUMMARY: This document corrects and explains an OSM decision on a provision of a proposed amendment submitted by the State of Virginia as a modification to its permanent regulatory program (hereinafter referred to as the Virginia program) under the Surface Mining Control and Reclamation Act of 1977 (SMCRA). OSM published its decision on the provision in a September 17, 1997, final rule **Federal Register** document. The provision concerns an exemption from the requirement to conduct mitigation measures to prevent or lessen the impact of subsidence damage, when planned subsidence mining methods are used, when the structure owners deny the permittee access to implement the measures to minimize material damage.

DATES: Effective: November 12, 1997.

FOR FURTHER INFORMATION CONTACT: Mr. Robert A. Penn, Director, Big Stone Gap Field Office, Office of Surface Mining Reclamation and Enforcement, 1941 Neeley Road, Suite 201, Compartment 116, Big Stone Gap, Virginia 24219, Telephone: (540) 523-4303.

SUPPLEMENTARY INFORMATION: By letter dated May 21, 1996 (Administrative Record No. VA-882), Virginia submitted amendments to the Virginia program concerning subsidence damage. The amendments are intended to make the Virginia program consistent with the Federal regulations as amended on March 31, 1995 (60 FR 16722). Virginia stated that the proposed amendments implement the standards of the Federal

Energy Policy Act of 1992, and sections 45.1-243 and 45.1-258 of the Code of Virginia.

On September 17, 1997, OSM approved, with certain exceptions, the amendment submitted by Virginia (62 FR 48758). This document revises and explains one of OSM's decisions.

Subsidence Control

In the September 17, 1997, final rule, **Federal Register** document, OSM stated that it was approving, for longwall mining permittees, Virginia's proposed language at 480-03-19.817.121(a)(2)(iii) concerning an exemption from the requirement to conduct mitigation measures to minimize material damage from subsidence. The exemption would apply when the structure owners deny the permittee access to implement the measures to minimize material damage. (See Finding No. 5 of the September 17, 1997, final rule, 62 FR 48760.)

In that finding, OSM excluded room and pillar retreat mining from qualifying for the proposed exemption. Upon further consideration of Virginia's proposed provision at 480-03-19.817.121(a)(2)(iii), OSM is changing its previous finding and decision. The rationale for the revised decision is discussed below. The following finding replaces the preamble discussion for that part of Finding 5 that concerns amendments to subsection (a) of 480-03-19.817.121, in the final rule (62 FR 48758, second and third columns on page 48760).

5. § 480-03-13.817.121 Subsidence Control

Subsection (a) concerning measures to prevent or minimize damage is amended by adding new language (at new subsection (a)(2)) to provide that planned subsidence must include measures to minimize material damage to protected structures, except if the permittee has written consent of the structure owners, the costs of such measures exceed the anticipated costs of repair (unless the anticipated damage would constitute a threat to health or safety), or the structure owners deny the permittee access to implement the measures to minimize material damage and the permittee provides written evidence of good faith efforts to obtain access.

The proposed language is substantively identical to and no less effective than the counterpart Federal language at 30 CFR 817.121(a)(2) with one exception. 30 CFR 817.121(a)(2) contains no counterpart to the proposed language that provides an exception to the requirement to include measures to minimize material damage to protected

structures if the structure owners deny the permittee access to implement the measures to minimize material damage.

"Planned subsidence in a predictable and controlled manner" includes longwall mining and pillar retreat mining. Mitigation efforts performed on the surface to minimize material damage from planned subsidence include trenching, bracing, or jacking of the structures to be protected. These mitigation measures remain in place while the ground underneath the structures subsides, keeping the structures level and, thereby, helping to minimize damage to the structures.

It is possible to prevent or minimize damage to the surface and surface structures by leaving coal in place (for example, by leaving support pillars or reducing the width of a longwall extraction panel). Such underground measures are not undertaken, however, if the approved mining method involves planned subsidence in a predictable and controlled manner as with longwall and pillar retreat mining, "because they are not normally consistent with longwall technology." (60 FR at 16731) As stated in the final rule preamble to 30 CFR 784.20(b), "OSM does not intend to require anything other than surface measures to minimize material damage from longwall mining where conventional underground measures may not be practicable." (60 FR at 16731) Note that in the preamble, OSM used the term "longwall mining" to refer to the "longwall mining and pillar recovery technologies." (60 FR at 16731)

Subsidence is a natural and common result of underground mining. However, there is a clear distinction between the mining methods that produce planned subsidence and those that produce unplanned subsidence. The following is a brief explanation of planned and unplanned subsidence and the mining methods that produce them.

Unplanned subsidence. The standard method of room and pillar mining produces unplanned subsidence. Standard room and pillar mining is accomplished as follows. First, a series of parallel paths are cut through the coal. These cuts are called entries. As the entries are increased in length, they are connected together by cutting a series of cross cuts through the coal from one entry to the next. These cross cuts produce a series of coal pillars surrounded by mined-out spaces (called rooms). Room and pillar mining produces a pattern much like a common checkerboard: on a checkerboard, each black square is surrounded by red squares. In a room and pillar underground mine, a pillar of coal is surrounded by mined-out coal. In

standard room and pillar mining, the pillars are left in place to support the rock (roof) above the coal layer.

The size of the pillar that is left to support the roof is determined by the strength of the coal, depth of the coal, the characteristics of the rock (above the coal) that is being supported, and the width of the entry system. The pillars in place support the roof of an underground coal mine for an undetermined length of time. It is possible that, sometime in the future, roof and/or pillar failure may occur and surface subsidence may take place. Normally, the extraction of coal from this type of mine development is less than 70 percent.

Planned subsidence. Planned subsidence is achieved by both retreat mining of the pillars of a room and pillar system, and by longwall mining. In retreat mining, the pillars of a room and pillar system are reduced in size (robbed) as the miners retreat back out of the room and pillar system. In retreat mining, the pillars are reduced in size to the point of allowing a controlled failure of the roof (roof fall) to occur. Total extraction of coal within the area defined for retreat mining is usually greater than 75 percent. It is important to note that in pillar retreat mining, it is essential that the roof fall take place in order to reduce the forces on the remaining pillars. If the load forces on the remaining pillars aren't reduced by roof fall, the mining equipment can't properly and safely mine the remaining pillars.

A longwall mining operation is first developed by using room and pillar methods to develop entries, haulageways, paths for ventilation, and to define the blocks of coal to be removed by the longwall cutter. The blocks of coal to be removed are often quite large (for example, 500 to 1,000 feet wide by thousands of feet long). Since all the coal is removed in these large blocks, the unsupported roof falls shortly following passage of the longwall cutter. The amount of surface subsidence that is expected to take place is determined from the thickness of the coal, width of the block of coal removed, and the characteristics and thickness of the overburden.

The Federal regulations at 30 CFR 817.121(a)(1) provide that a permittee must either adopt measures to prevent subsidence from causing material damage, or adopt mining technology that provides for planned subsidence in a predictable and controlled manner. Room and pillar retreat mining and longwall mining are examples of mining technology that provides for planned subsidence in a predictable and

controlled manner. Thus, Virginia's proposal with regard to longwall mining operations and room and pillar retreat mining operations is consistent with the Federal rule at 30 CFR 817.121(a)(2) which requires measures to minimize subsidence damage only when such measures are "consistent with the mining method employed" and they are "technologically feasible."

Section 516(b)(1) of SMCRA provides a special exemption for planned subsidence methods of mining from the requirement to adopt measures consistent with known technology in order to prevent subsidence from causing material damage. Section 720(a)(2) of SMCRA, which concerns subsidence related to underground mining operations, provides that nothing in section 720(a)(2) "shall be construed to prohibit or interrupt underground coal mining operations." Additionally, the preamble to 30 CFR 817.121(a)(2) states that the damage minimization requirements for planned subsidence operations are based on both sections of SMCRA. (60 FR at 16734, 1st column; March 31, 1995)

OSM was also concerned about whether or not the structure owner would be notified by the longwall permittee of the consequences of failing to allow access for the placement of mitigation measures. Since Virginia's proposal had no direct Federal counterpart, there was no direct Federal notice counterpart. The Federal regulations at 30 CFR 784.20(a)(3) provide a relevant comparison. 30 CFR 784.20(a)(3) provides that, if an owner denies access for a pre-mining survey, the permittee must provide certain information to the landowner concerning the potential negative effect of their actions, but the lack of access does not prevent the permittee from mining. Virginia, by a letter dated January 3, 1997 (Administrative Record Number VA-902) clarified that under 480-03-19.817.121(a)(2)(iii), the permittee must provide a written document to the structure owner informing the owner of the consequences of denying access. Further, the permittee must provide Virginia with evidence documenting such notice.

The Director finds, therefore, that Virginia's proposal is reasonable and not inconsistent with SMCRA, since it would facilitate both the use of planned subsidence mining methods and the continuation of underground mining in situations in which surface owners refuse to allow implementation of surface measures approved by the regulatory authority.

In addition, the preamble to the Federal regulation at 30 CFR 817.121(a)(2) does not address the question of what happens when a landowner denies access. Therefore, it is reasonable to presume that OSM never envisioned this situation, thus creating the regulatory gap that Virginia is endeavoring to fill.

Subsection (c) has been revised by deleting the existing language and replacing new language.

* * * * *

The Federal regulations at 30 CFR part 946 codifying decisions concerning the Virginia program are being amended to implement this revised finding.

Section 946.15 Approval of Virginia regulatory program amendments is being amended in the table (third column on page 48765, 62 FR 48758) to show both the September 17, 1997, final publication of this amendment, and the date of the revision discussed in this notice.

Dated: November 3, 1997.

Tim L. Dieringer,
Acting Regional Director, Appalachian
Regional Coordinating Center.

PART 946—VIRGINIA

1. The authority citation for part 946 continues to read as follows:

Authority: 30 U.S.C. 1201 *et seq.*

2. Section 946.15 is amended in the table by revising the entry having the original amendment submission date of May 21, 1996, to read as follows:

§ 946.15 Approval of Virginia regulatory program amendments.

* * * * *

Original amendment submission date	Date of final publication	Citation/description
May 21, 1996	September 17, 1997, and November 12, 1997	VA Code §§ 480-03-19.700.5; 784.14, 20; 817.41, 121.

[FR Doc. 97-29724 Filed 11-10-97; 8:45 am]
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ENVIRONMENTAL PROTECTION AGENCY

[OPP-300505A; FRL-5750-3]

40 CFR Part 180

RIN 2070-AB78

Corn Gluten; Exemption from the Requirement of a Tolerance

AGENCY: Environmental Protection Agency (EPA).
ACTION: Final rule.

SUMMARY: This document establishes an exemption from the requirement of a tolerance for residues of corn gluten also known as corn gluten meal, when used as an herbicide in or on all food commodities, when applied in accordance with good agricultural practice. This exemption from requirement of a tolerance is being established by the Agency on its own initiative, under the Federal Food, Drug, and Cosmetic Act (FFDCA) as amended by the Food Quality Protection Act (FQPA) of 1996.

DATES: This regulation becomes effective November 12, 1997. Written objections and requests for hearings must be received by January 12, 1998.
ADDRESSES: Written objections and hearing requests, identified by the docket control number [OPP-300505A], must be submitted to: Hearing Clerk (1900), Environmental Protection Agency, Rm. M3708, 401 M St., SW.,

Washington, DC 20460. Fees accompanying objections and hearing requests shall be labeled "Tolerance Petition Fees" and forwarded to: EPA Headquarters Accounting Operations Branch, OPP (Tolerance Fees), P.O. Box 360277M, Pittsburgh, PA 15251. A copy of any objections and hearing requests filed with the Hearing Clerk identified by the docket control number, [OPP-300505A], must also be submitted to: Public Information and Records Integrity Branch, Information Resources and Services Division (7506C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. In person, bring a copy of objections and hearing requests to Rm. 1132, CM #2, 1921 Jefferson Davis Hwy., Arlington, VA.

A copy of objections and hearing requests filed with the Hearing Clerk may be submitted electronically by sending electronic mail (e-mail) to: opp-docket@epamail.epa.gov. Copies of electronic objections and hearing requests must be submitted as an ASCII file avoiding the use of special characters and any form of encryption. Copies of electronic objections and hearing requests will also be accepted on disks in WordPerfect 5.1/6.1 or ASCII file format. All copies of electronic objections and hearing requests must be identified by the docket control number [OPP-300505A]. No Confidential Business Information (CBI) should be submitted through e-mail. Copies of electronic objections and hearing requests on this rule may be filed online at many Federal Depository Libraries.

FOR FURTHER INFORMATION CONTACT: By mail: Freshteh Toghrol, Biopesticides and Pollution Prevention Division (7511W), Office of Pesticide Programs, Environmental Protection Agency, 401 M St. SW., Washington, DC 20460. Office location, telephone number, and e-mail address: 5th Floor, Crystal Station 1, 2805 Crystal Drive, Arlington, VA; (703) 308-7014, e-mail: toghrol.freshteh@epamail.epa.gov..

SUPPLEMENTARY INFORMATION: In the **Federal Register** of July 18, 1997 (62 FR 38513) [OPP-300505; FRL-5717-8], EPA proposed, pursuant to section 408(e) of the FFDCA, 21 U.S.C. 346a(d) to amend 40 CFR 180.1164 by establishing an exemption from the requirement of a tolerance for corn gluten in or on all food commodities, when applied in accordance with good agricultural practice.

There were no comments received in response to the proposed rule.

Based on the reasons set forth in the preamble to the proposed rule, EPA establishes an exemption from tolerance for corn gluten as provided below.

I. Objections and Hearing Requests

The new FFDCA section 408(g) provides essentially the same process for persons to "object" to a regulation for an exemption from the requirement of a tolerance issued by EPA under new section 408(e) as was provided in the old section 408 and in section 409. However, the period for filing objections is 60 days, rather than 30 days. EPA currently has procedural regulations which governs the submission of objections and hearing requests. These