

Appendix C. Sample of Items in Diagnostic Attitude Survey

1. In general I am satisfied with my job.

2. My co-workers encourage each other to give their best effort.

3. What happens to this organization is really important to me.

4. My pay is fair considering what other employers in this area pay.

5. During the next year I will probably look for a new job outside this organization.

6. Management is flexible enough to make changes when necessary.

7. Coordination among work groups is good in this organization.

8. My supervisor encourages subordinates to participate in important decisions.

9. I have to depend on work performed by co-workers in order to get

the materials or information I need to do my job.

10. Supervisors here feel their ability to manage is restricted by unnecessary personnel rules and regulations.

Note.—All items have the following response scale: (1) Strongly disagree (2) disagree (3) undecided (4) agree (5) strongly agree.

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The first of these is the fact that the majority of the cases of this disease are reported from the United States and Europe. It is not known whether this is due to a higher incidence of the disease in these countries or to a more complete reporting system. The second fact is that the disease is more common in the summer months. This may be due to the fact that the disease is more common in the tropics, where the climate is more favorable to the development of the parasite. The third fact is that the disease is more common in the lower social classes. This may be due to the fact that these classes are more likely to live in unsanitary conditions, which are more favorable to the development of the parasite.

The fourth fact is that the disease is more common in the lower social classes. This may be due to the fact that these classes are more likely to live in unsanitary conditions, which are more favorable to the development of the parasite. The fifth fact is that the disease is more common in the lower social classes. This may be due to the fact that these classes are more likely to live in unsanitary conditions, which are more favorable to the development of the parasite.

The sixth fact is that the disease is more common in the lower social classes. This may be due to the fact that these classes are more likely to live in unsanitary conditions, which are more favorable to the development of the parasite. The seventh fact is that the disease is more common in the lower social classes. This may be due to the fact that these classes are more likely to live in unsanitary conditions, which are more favorable to the development of the parasite.

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The tenth fact is that the disease is more common in the lower social classes. This may be due to the fact that these classes are more likely to live in unsanitary conditions, which are more favorable to the development of the parasite. The eleventh fact is that the disease is more common in the lower social classes. This may be due to the fact that these classes are more likely to live in unsanitary conditions, which are more favorable to the development of the parasite.

The twelfth fact is that the disease is more common in the lower social classes. This may be due to the fact that these classes are more likely to live in unsanitary conditions, which are more favorable to the development of the parasite. The thirteenth fact is that the disease is more common in the lower social classes. This may be due to the fact that these classes are more likely to live in unsanitary conditions, which are more favorable to the development of the parasite.

Federal Register

Friday
July 17, 1987

Part V

Environmental Protection Agency

**EBDC Pesticides; Initiation of Special
Review; Notice**

ENVIRONMENTAL PROTECTION AGENCY

[OPP-30000/53; FRL-3234-6]

EBDC Pesticides; Initiation of Special Review

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of initiation of special review.

SUMMARY: This notice announces that EPA is initiating a Special Review of the ethylene bisdithiocarbamate (EBDC) pesticides. There are five such active ingredients currently registered, mancozeb, maneb, metiram, nabam, and zineb. All registrations of amobam products are now cancelled. A common contaminant, metabolite, and degradation product of these pesticides is ethylenethiourea (ETU), which has been classified as a Group B2 carcinogen based on oncogenic effects in mice and rats. ETU has also caused effects on the thyroid in three species of animals, and has been shown to be teratogenic in animal studies. EPA has determined that exposure to ETU from the registered uses of the EBDC pesticides may pose risks of concern to the Agency, including an oncogenic risk to humans from dietary exposure, and a risk to applicators and mixer/loaders for thyroid and teratogenic effects. Accordingly, the Agency concludes that the EBDC pesticides meet or exceed the criteria for initiation of Special Review set forth in 40 CFR 154.7(a)(2) and 154.7(a)(6), and that a Special Review of these products is appropriate to determine whether additional regulatory actions are required. During the Special Review, EPA will carefully examine the risks and benefits of using the EBDC pesticides as compared to the risks from alternative pesticides, and will determine whether such uses should be cancelled or otherwise regulated. The documents cited as references in Unit VII of this Notice constitute the technical documents in support of this action.

DATE: Comments, evidence to rebut the presumptions in this Notice, and other relevant information must be received on or before October 15, 1987.

ADDRESS: Submit three copies of written comments, bearing the document control number "OPP 30000/53," by mail to:

Information Services Section, Program Management and Support Division (TS-757C), Office of Pesticide Programs, Environmental Protection Agency, 401 M Street SW., Washington, DC 20460

In person, bring comments to: Rm. 236, Crystal Mall Building #2, 1921 Jefferson Davis Highway, Arlington, VA.

Information submitted in any comment concerning this Notice may be claimed confidential by marking any part or all of that information as "Confidential Business Information" (CBI). Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR Part 2. A copy of the comment that does not contain CBI must be submitted for inclusion in the public docket. Information not marked confidential may be disclosed publicly by EPA without prior notice to the submitter. All non-CBI written comments, will be available for public inspection in Room 236 at the Virginia address given above, from 8 a.m. to 4 p.m. Monday through Friday, excluding legal holidays.

FOR FURTHER INFORMATION CONTACT:

By mail: David Giamporcaro, Registration Division (TS-767C), Office of Pesticide Programs, Environmental Protection Agency, 401 M Street, SW., Washington, DC 20460
Office location and telephone number: Rm. 1008, Crystal Mall Building #2, 1921 Jefferson Davis Highway, Arlington, VA (703-557-0481)

For a copy of documents in the public docket, to request information concerning the Special Review, or to request indices to the Special Review public docket, contact Frances Mann (703-557-2805).

SUPPLEMENTARY INFORMATION: This Notice is organized in the following units. Unit I is a description of the Agency's Special Review Process. Unit II sets forth the regulatory history of the EBDC pesticides to date, and describes the basis of the Agency's decision to initiate this Special Review. Unit III provides a use profile and solicits benefits information for the EBDC pesticides. Unit IV sets forth the duty to submit information on adverse effects. Unit V describes the public comment opportunity and the procedures for submission of public comments to the Agency. Unit VI describes the contents of the public docket for this Notice. Unit VII lists the references in support of this action.

I. Background

A. Legal Requirements

A pesticide product may be sole or distributed in the United States only if it is registered or exempt from registration under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) as amended (7 U.S.C. 136 et seq.). Before a

product can be registered it must be shown that it can be used without "unreasonable adverse effects on the environment" [FIFRA section 3(c)(5)], that is, without causing "any unreasonable risk to man or the environment, taking into account the economic, social, and environmental costs and benefits of the use of the pesticide" [FIFRA section 2(bb)]. The burden of proving that a pesticide meets this standard for registration is, at all times, on the proponent of initial or continued registration. If at any time the Agency determines that a pesticide no longer meets the standard, the Administrator may cancel this registration under section 6 of FIFRA.

The Special Review process provides a mechanism to permit public participation in EPA's deliberations prior to issuance of any Notice of Final Determination describing the regulatory action which the Administrator has selected. The Special Review process is described in 40 CFR Part 154, published in the Federal Register of November 27, 1985 (50 FR 49015). During the Special Review process the Agency: (1) Announces and describes the basis for the Agency's finding that use of the pesticide meets one or more of the risk criteria set forth in § 154.7; (2) establishes a public docket; (3) solicits comments from the public regarding whether the use of a pesticide product as currently registered or as it is proposed to be registered satisfies any of the risk criteria for initiation of Special Review set forth at 40 CFR 154.7, whether any risks posed by the use or proposed use of the product that satisfy the risk criteria at 40 CFR 154.7 are unreasonable, taking into account the economic, social, and environmental costs and benefits of the use of the product, and what regulatory action, if any, the Agency should take with respect to the use of the product; and (4) solicits comment from the Secretary of Agriculture and the Scientific Advisory Panel if the Administrator proposes to cancel, deny, or change the classification of the registration of a pesticide product which is the subject of a Special Review, or to hold a hearing under FIFRA section 6(b)(2) on whether to take any of those actions. Issuance of this Notice means that potential adverse effects associated with the use of the EBDC pesticides have been identified and will be examined further to determine their extent and whether, when considered together with the benefits of these pesticides, such risks are unreasonable.

A Preliminary Notification

Registrants of the EBDC pesticides were notified by letter dated March 31, 1987, under 40 CFR 154.21(a), that the Agency was considering initiation of Special Review on these pesticides (Ref. 1).

II Determination to Initiate A Special Review

A. Regulatory Background of the EBDC Pesticides

In 1977, the Agency initiated a Rebuttable Presumption Against Registration, or RPAR process on the EBDC pesticides. (The Agency now uses the term "Special Review" for the process previously called the RPAR process). The RPAR was based on the presumption that the EBDCs and ETU posed three kinds of risk to human health or the environment: oncogenicity, teratogenicity, and acute toxicity to aquatic organisms. Three additional areas of concern were also identified: thyroid toxicity, mutagenicity, and skin sensitization.

In 1982, the Agency concluded the RPAR by issuing a Decision Document reporting the results of its evaluation, and adopting risk reduction measures to preclude unreasonable adverse effects pending development of additional data needed to arrive at a more realistic assessment of the risks. (Ref. 2). The Agency concluded that the potential risk of acute toxicity to aquatic organisms could be reduced through the addition of a label statement warning users of a hazard to fish. Potential risks to applicators from teratogenic and thyroid effects could be adequately reduced by requiring protective clothing. Potential dietary exposure resulting from consumption of EBDC-treated home grown produce was addressed by a label statement highlighting preharvest intervals on labels of home use products.

The Agency also concluded that there were insufficient exposure data to reach any regulatory conclusions regarding the potential risk of oncogenic effects to man. Additional data were required to be submitted to address mutagenic effects. The skin sensitization effect was determined not to meet the criteria for an RPAR.

B. Initiation of Special Review on the EBDC Pesticides

During the course of the Agency's reassessment of the EBDC pesticides, concerns have surfaced about the potential oncogenic risk to consumers from consumption of foods treated with this category of pesticides. The Agency is also concerned about the potential for

exposure to ETU to induce thyroid and teratogenic effects among applicators and mixer/loaders who mix and apply these pesticides. Based on consideration of oncogenicity and teratogenicity studies and other studies described below, crop residue and exposure data for applicators and mixer/loaders, EPA has determined that the uses of the EBDC pesticides have met the criteria for initiation of Special Review set forth in 40 CFR 154.7(a)(2); specifically, that these pesticides "[m]ay pose a risk of inducing in humans an oncogenic, heritable genetic, teratogenic, fetotoxic, reproductive effect, or a chronic or delayed toxic effect. . . ." Further, based on the subchronic thyroid and the exposure data described below, the uses of the EBDC pesticides also meet the criteria of 40 CFR 154.7(a)(6)—that the use of these pesticides "[m]ay otherwise pose a risk to humans . . . of sufficient magnitude to merit a determination whether the use of the pesticide product offers offsetting social, economic, and environmental benefits that justify initial or continued registration."

The Agency is initiating this Special Review based on an assessment of the risks from exposure to ETU present in, or formed as a result of metabolic conversion from, pesticide products containing the active ingredient mancozeb. ETU, a potential human carcinogen, teratogen, and thyroid toxicant, is present as a contaminant, degradation product, and metabolite of all the EBDC pesticides. The Agency therefore believes that the level of potential risk from mancozeb products, coupled with the presence of and conversion to ETU in all other EBDC pesticide products, warrants an assessment of the risks and benefits of all EBDC pesticides as a group.

The Agency believes that initiation of a Special Review is appropriate at this time because of the improved exposure data base available. The Agency's estimate of dietary exposure in 1982 was based on limited data pertaining to residues of the EBDC pesticides and ETU. Dietary exposure to the EBDC pesticides was calculated for the United States population based on estimated consumption of dietary residues of ETU in treated crops (Ref. 2). With limited ETU data, assumptions were made about the conversion of the EBDC pesticides to ETU in treated crops. Data on possible residues in drinking water, meat, milk, eggs, animal feed, and processed foods were not available. Uncertainty in the dietary exposure estimates was introduced because of limited data on: (1) ETU residue data on most raw agricultural commodities, (2)

conversion of EBDC pesticides to ETU during food processing and (3) animal metabolism data.

Applicator exposures to ETU were estimated for inhalation or dermal absorption, as well as from metabolic conversion of the EBDC pesticides, during mixing/loading and during ground spray or aerial applications. Field data from two studies were used along with reasonable assumptions to estimate daily, seasonal and annual exposures (Ref. 2). The fact that the available studies were not comprehensive and that the Agency did not have adequate dermal penetration data for the EBDC pesticides and ETU added uncertainty to the exposure estimates.

Since 1982, the Agency has received data on the dermal absorption of mancozeb (Ref. 3), on subchronic feeding and inhalation effects of mancozeb, on animal and plant metabolism, on the level of residues of mancozeb and ETU on 21 different raw agricultural commodities, and on ETU levels in processed foods as a result of conversion of the EBDC pesticides (Refs. 4, 5 and 6). The Agency has also obtained better information, through consultation with U.S.D.A. extension service personnel, university plant pathologists, State agricultural advisors and publicly-available agricultural journals such as *Fungicides and Nematicide Trials*, on typical rates and numbers of applications, acres treated, estimates of numbers of hours exposed, and numbers of applicators and mixer/loaders (Refs. 7 and 8). Based on these new data, the Agency believes its present calculations provide more realistic estimates of the dietary and mixer/loader and applicator exposure and risks of ETU from the use of the EBDC pesticides.

The Agency therefore believes that it has ample basis to initiate a Special Review of the EBDC pesticides based on a concern that these pesticides may pose a risk of inducing an oncogenic, teratogenic, or thyroid effect in humans. A discussion of the Agency's concerns about dietary and applicator and mixer/loader exposure appears below.

This Special Review applies to all registrations of the EBDC pesticides, including suspended registrations. Suspended registrations are included because uses which are suspended may be reactivated upon satisfaction by the registrant of the condition(s) which led to the suspension. Nabam products are consequently within the scope of this Special Review as are suspended registrations of any other EBDC pesticides. All field or food crop uses of

nabam pesticide products are currently suspended, with the exception of use in sugar beet flume water (Ref. 9).

As is described more fully below, the exposure and dietary risk assessments are based principally on data obtained on mancozeb. The Agency has required the submission of additional crop residue, processing, animal feeding, and storage stability studies on maneb and metiram. These data are due to be submitted on March 1, 1988, and can be used to refine the overall assessment of dietary risk. Residue and storage stability data are due for zineb on December 31, 1988.

1. *Toxicology Studies.* ETU is a common contaminant, degradation product, and metabolite of the EBDC pesticides. ETU has been classified by the Agency as a Group B2 oncogen (probable human carcinogen). The Agency's classification of ETU was made in accordance with its guidelines for carcinogen risk assessment. 51 FR 33992 (September 26, 1986). These guidelines categorize the evidence on carcinogenicity of chemicals in terms of how likely it is that the chemical is a human carcinogen. Under this scheme, Group B2 categorization is appropriate if there is "sufficient evidence" of the chemical's carcinogenicity from animal studies. "Sufficient evidence" of carcinogenicity is established according to the guidelines, when there is "an increased incidence of malignant tumors or combined malignant and benign tumors: (a) In multiple species or strains; or (b) in multiple experiments (e.g., with different routes of administration or using different dose levels); or (c) to an unusual degree in a single experiment with regard to high incidence, unusual site or type of tumor, or early age at onset. Additional evidence may be provided by data on dose-response effects, as well as information from short-term tests or on chemical structure".

ETU induced an increased incidence of thyroid follicular cell adenomas and adenocarcinomas in Charles River CD rats (Refs. 10, 11, and 12), and hepatomas in two strains of mice (Ref. 13). ETU induced the thyroid tumors in rats after one year or less of treatment and the magnitude of response in both the rat and mouse studies was unusually high. The classification as a Group B2 oncogen is also supported by structure-activity reasoning since several other thyroid inhibitors which are structurally related to ETU (e.g., thiouracil and thiourea) have been found to induce hepatomas and/or thyroid tumors in rodents.

The Agency received several comments in response to its preliminary

notification letter which questioned the Agency's reliance on the rat and mouse oncogenicity studies (Ref. 14).

Commenters asserted that the Agency had declared the studies invalid for risk assessment purposes in the 1982 Decision Document (Ref. 2), and that the Agency should therefore not now initiate a Special Review of the EBDC pesticides based on these same studies. (Commenters raised several other toxicological issues which are addressed in separate memoranda included in the public docket for this action (Ref. 15)).

While acknowledging in the 1982 Decision Document the existence of some deficiencies in the exposure data and in the chronic data base for the parent EBDC pesticides, the Agency believed then, and continues to believe, that the animal studies constituted sufficient evidence to show that ETU is oncogenic. In fact, the Agency relied on the Innes chronic mouse study on ETU (Ref. 13) to conduct a quantitative risk assessment, and stated its position throughout the 1982 Decision Document that ETU is a strong animal carcinogen and consequently has the potential to induce cancer in humans. The toxicological deficiencies to which the Agency referred in 1982 concerned the usefulness of the studies on the parent EBDC compounds for purposes of conducting a quantitative risk assessment, and to such issues as selection of an appropriate risk assessment model and determination of the mechanism of action of the EBDC pesticides and ETU. The uncertainties did not pertain to whether ETU induced tumors in animals.

The Toxicology Branch Peer Review Committee in the Office of Pesticide Programs reexamined the toxicological data base on the EBDC pesticides and ETU in 1986. The Committee expressly addressed the question of the adequacy of the chronic animal studies, and concluded that "each of the studies considered do not meet today's standards for oncogenicity studies but that they were adequate to conclude that ETU is oncogenic to rats and mice due to the magnitude of the response seen." (Ref. 12).

The National Toxicology Program (NTP) has been conducting its own oncogenicity study of ETU. The results are expected in the next year. The Agency will review the NTP study as part of this Special Review if it is available in time to be incorporated.

ETU has been shown to be a teratogen in studies with rats and hamsters (Refs. 16 and 17). In rats, ETU produces a wide variety of anomalies in the central nervous, urogenital, and skeletal

systems, as well as in other organs at dosages that do not produce maternal or fetotoxicity (Ref. 18).

ETU has also demonstrated thyroid hyperplasia, decreased uptake of iodine, and decreased serum T_3 and T_4 in subchronic feeding studies in rats (Refs. 18 and 19).

2. *Dietary Exposure and Risk Assessment.* The Agency's concern about the potential dietary risk to consumers of food treated with EBDC pesticides was prompted by the recently completed assessment of dietary exposure and risk for mancozeb. That assessment is set forth in the Guidance for the Reregistration of Pesticide Products Containing Mancozeb as the Active Ingredient (Mancozeb Registration Standard) (Ref. 20).

The Agency's concern is founded on the fact that consumers are exposed to ETU due to residues in or on treated crops or manufactured products or commodities, as well as through *in vivo* conversion of the EBDC pesticides into ETU. The Agency calculated the cumulative risk from exposure to ETU for commodities treated with mancozeb. The calculations are described below.

The mancozeb dietary exposure analysis indicates that the average consumer in the U.S. population receives a dietary exposure of 3.6×10^{-5} mg/kg/day of ETU from conversion of mancozeb residues on crops. This analysis was based on average field trial residues of ETU obtained from studies submitted in response to the October 19, 1984, DCI Notice. The ETU residues for processed products were calculated by taking into account the rate of conversion of mancozeb into ETU during processing of each raw agricultural commodity (Ref. 4). These residues were then reduced by the percent of crop treated with mancozeb, obtained from actual usage data.

The potential dietary risk from exposure to ETU residues was then calculated by multiplying the daily estimated exposure to ETU by the cancer potency factor for ETU, designated as Q_1^* ($0.14 \text{ (mg/kg/day)}^{-1}$):

Dietary Risk

$$\begin{aligned} &= \text{Exposure} \times Q_1^* \\ &= 3.6 \times 10^{-5} \text{ mg/kg/day} \times 0.14 \text{ (mg/kg/day)}^{-1} \\ &= 5 \times 10^{-6} \end{aligned}$$

In addition, there is dietary risk from exposure to ETU from conversion of mancozeb *in vivo* after eating food containing mancozeb residues. Metabolism studies in rats show that 50 percent of the mancozeb residues are absorbed through the gastrointestinal tract and that 24 percent are then

metabolically converted to ETU (Ref. 21). Dietary exposure to mancozeb for the U.S. population was estimated to be 9.7×10^{-4} mg/kg/day. In order to determine the dietary exposure to ETU from conversion of mancozeb residues *in vivo*, the mancozeb dietary exposure of 9.7×10^{-4} mg/kg/day is multiplied by 12 percent (50 percent $\times$ 24 percent) to yield an exposure of 1.2×10^{-4} mg/kg/day ETU. Multiplying this by the Q_1^* yields a risk of 1.7×10^{-5} .

The total potential dietary risk from exposure to ETU from use of mancozeb on food crops is obtained by adding 5×10^{-6} (which is equal to $.5 \times 10^{-5}$) and 1.7×10^{-5} :

Total Dietary Oncogenic Risk = 2.2×10^{-5}

As noted above, EPA has acceptable residue data on only one of the EBDC pesticides—mancozeb. Residue data on the remaining pesticides have been required through DCI Notices. Nevertheless, given the potential elevated oncogenic risk from consumption of food treated with a single EBDC pesticide, the Agency believes that the criteria for initiation of Special Review under 40 CFR 154.7(a)(2) have been met, and that initiation of a Special Review to examine the dietary risk posed by the presence of ETU as a contaminant, degradation product, and metabolite of all these substances is warranted. Mancozeb accounts for approximately 50 percent of the total poundage of active ingredients of EBDC pesticides used in agriculture (Ref. 22). In addition to agriculture, certain EBDC pesticide products are also registered for industrial food uses, which result in additional dietary exposure—paper and sugar manufacturing processes. Consequently, the total dietary oncogenic risk of ETU estimated above represents only a portion of the overall ETU risk to consumers from all the EBDC pesticides.

3. *Applicator and Mixer/Loader Exposure and Risk.* EPA has also assessed the potential risk to applicators and mixer/loaders from exposure to ETU. Exposure is by both the dermal and inhalational route (Ref. 23).

The Agency examined teratogenic, thyroid, and oncogenic effects. EPA calculated margins of safety (MOS) for the teratogenic and thyroid effects from exposure to mancozeb and ETU (Refs. 20 and 23). In addition to the mancozeb exposure data previously available to the Agency, dermal and inhalation exposure was calculated by using a large current surrogate data base with multiple replicates (Ref. 7).

The Agency's MOS calculations for systemic and teratogenic effects are

based on the use of the personal protective equipment specified in the Mancozeb Registration Standard, issued in April 1987 (Ref. 20). During application, a long-sleeve shirt and long pants, or coveralls that cover all parts of the body except head, hands and feet, chemical resistant gloves, shoes, socks, and goggles or a face shield must be worn. A chemical resistant apron is required during mixing and loading. During application from an enclosed cab or an enclosed cockpit, a long-sleeve shirt and long pants may be worn in place of the above protective clothing.

In assessing margins of safety, the Agency assumed 100 percent dermal absorption of ETU for applicators and mixer/loaders, in the absence of data on the rate of dermal absorption. Since the Agency used this assumption, the actual margin of safety may be higher than estimated. In the absence of data on the actual rate of dermal absorption of ETU, however, the Agency is justified in using this assumption. Based on submitted data, the Agency where appropriate applied a one percent rate for dermal absorption of mancozeb, and a 24 percent conversion factor was used to account for metabolic conversion of mancozeb into ETU (Refs. 3 and 23).

Several margins of safety were below the threshold of concern (100). Airblast applicators on apples had margins of safety of 87 for teratogenic effects and 11 for thyroid effects from exposure to ETU. Sprinkler applicators on potatoes have margins of safety for thyroid effects of only 9 from exposure to ETU. Other margins of safety below 100 for thyroid effects from exposure to ETU included ground boom applicators on onions, potatoes, and tomatoes, and potato seed piece applicators (Ref. 23). Hence an applicator risk of concern is presented by the teratogenic and thyroid effects from exposure to ETU.

The Agency has also calculated the oncogenic risk to applicators and mixer/loaders from exposure to ETU from both mancozeb absorbed and metabolized to ETU, and from direct exposure to ETU as a contaminant in the tank mix. The Agency's estimates were based on use of protective clothing as specified in the Mancozeb Registration Standard (Ref. 20). The risk to mixer/loaders was estimated to be in the range of 10^{-6} to 10^{-7} (Ref. 23). The risk to applicators ranged from 10^{-5} for airblast and ground boom application, to 10^{-7} for home users and some types of aerial application (Ref. 23). In view of the small population of applicators and mixer/loaders potentially exposed, and the relative risk range, the Agency does not believe that the oncogenicity criterion for initiation of Special Review has been

met. If as a result of comments received or further analysis it is determined that the oncogenic risk is greater than expected at this time, the Agency will incorporate that finding in subsequent regulatory decisions.

III. Use Profile and Benefits Information

A. Use Profile of the EBDC Pesticides

Approximately 18.5 million pounds of EBDC pesticide active ingredients are used annually in the United States on agricultural crops and non-agricultural use sites, based on 1985 data (Ref. 22). (These figures do not include amobam whose registrations are cancelled). In their agricultural uses, the EBDCs are broad spectrum fungicides used to prevent crop damage by fungi and to protect harvested crops from deterioration. Some EBDC pesticide products are also used as industrial biocides in some applications.

Mancozeb is registered on 28 food crops, and is used primarily on apples, grapes, potatoes, sweet corn, tomatoes, and onions. The major use sites for metiram include apples and potatoes. Maneb is registered for control of early and late blights, and is used primarily on apples, potatoes, and tomatoes. The major use sites for zineb include citrus crops, apples, mushrooms, and pears. Nabam is registered for a variety of food, field and food crop, terrestrial non-food uses, and industrial food and non-food uses; all of its uses other than industrial food and industrial non-food uses are currently suspended. Amobam was registered for use as a miticide on citrus, and as a fungicide on several fruits and vegetables.

B. Benefits Information

The Agency is soliciting the information described below to support its assessment of the benefits of the EBDC pesticides, and the economic impact of regulatory action on this group of pesticides. Because of the number of uses for which the EBDC pesticides are registered, the Agency will focus its benefits analysis during the course of this Special Review on the principal uses; i.e., those that account for a high percentage of the total amount of the EBDC pesticides used in the United States, or, in the case of agricultural use, those in which a high percentage of the total crop is treated. The Agency also encourages the submission of benefits data on all other registered agricultural and non-agricultural uses. In the absence of such benefits information for these sites, the Agency may conclude that the benefits are negligible.

The user community, other government agencies, and the interested public are encouraged to submit data to support any benefits claims on all registered uses. Persons who desire to submit benefits information should provide the following kinds of information for each use addressed, along with any other information they believe relevant and desire to include.

1. *Comparative Efficacy Reports.* The Agency is requesting all relevant field test results comparing EBDCs with possible chemical and nonchemical alternatives at recommended or reduced dosage rates and methods of application or implementation. Field tests in order to be useful should preferably not be over 10 years old and include:

a. In the case of agricultural uses, data relating to yield and quality (using current agricultural practices, plot designs, and statistical analyses) that compare the EBDC pesticides with possible alternatives.

b. Growing conditions and other pertinent factors that impact on the results of agricultural use.

c. In the case of industrial use, data relating to the results of use of the EBDC pesticides compared with possible alternatives. Include discussion of pertinent factors that impact on results of the use.

d. Data on nontarget organisms (e.g., predators, parasites, pathogens, and other introduced or endemic species) that are affected by the EBDC pesticides and other pesticides or pest management programs being tested (e.g., integrated pest management data [IPM]).

e. Information on the development of resistance by target pests to the EBDC pesticides or their alternatives.

f. Information on pest spectrum controlled by each pesticide and its alternatives including identification of primary and secondary pests.

g. Data on methods and equipment used for pesticide application.

2. *Pesticide Profile and Economics Information.* The Agency is requesting additional information concerning pesticide use practices, including the following:

a. Data on pesticide or pest management program characteristics that determine the choice of pesticides or other control strategies including their restrictions, limitations, and benefits in agricultural and industrial uses.

b. Pest management programs currently used by growers (or other users) and any other research programs which could modify pest management practices within the next several years.

c. For each use site addressed, typical use patterns of the EBDC pesticides and any alternatives preferably by target

pest(s) (as may be appropriate to the particular use site) in terms of acres treated, number of applications per season, formulations, pounds of active ingredient (quantities expressed by State or region are preferable to national totals), and application intervals, and pre-harvest intervals.

d. Actual application rate(s) (individual amount or a range where appropriate) in terms of active ingredient per acre or unit in agricultural or industrial uses.

e. Retail cost of the EBDC pesticides and alternatives in terms of dollars per acre of treatment or similar unit. When grower applied, submit use rates as specified in crop production budgets. Submit similar cost data for industrial uses of these pesticides.

f. Economic profile of current users of the EBDC pesticides and of "downstream" processors potentially affected by price or supply shifts of the crop or manufactured product or commodity in question.

g. Enterprise or crop budget data (costs and returns) for the typical user.

h. Price elasticity of demand (raw commodity and at the retail level) for the crop or manufactured product or commodity in question.

i. Information on crop or manufactured product or commodity exports and imports that has a bearing on the regulatory decision.

IV. Duty To Submit Information on Adverse Effects

Registrants are required by section 6(a)(2) of FIFRA to submit any additional information regarding unreasonable adverse effects on man or the environment which comes to their attention at any time. For further information on this requirement consult the Agency's enforcement policy for section 6(a)(2), published in the *Federal Register* of July 12, 1979 (44 FR 40716). The registrants of EBDC pesticide products must submit immediately published or unpublished information, studies, reports, analyses, or reanalyses regarding adverse effects associated with these pesticides, their impurities, metabolites and degradation products in humans or animal species, and claimed or verified accidents to humans, domestic animals, or wildlife which have not been previously submitted to EPA. These data must be submitted with a cover letter specifically identifying the information as being submitted under section 6(a)(2) of FIFRA. In light of this Special Review and the requirements of FIFRA section 6(a)(2), the registrants must notify EPA of the results of any studies on the EBDC pesticides currently in progress to the extent specified in the

section 6(a)(2) enforcement policy cited above. Specifically, information on any adverse toxicological effects of the EBDC pesticides, their impurities, metabolites, and degradation products must be submitted.

V. Public Comment Opportunity

All registrants and applicants for registration have been notified by certified mail of the Special Review being initiated on their EBDC pesticide products. The Agency is providing a 90-day period to comment on this Notice. Comments must be submitted by [insert date 90 days from the date of this publication]. The Agency invites all interested persons to submit further information concerning the risks and benefits associated with the use of the EBDC pesticides, as discussed in this Notice. All interested persons are also invited to comment on whether the use of the EBDC pesticides satisfies any of the risk criteria listed at 40 CFR 154.7, whether risks posed by use of the EBDC pesticides are unreasonable, and what, if any, regulatory action should be taken by the Agency. All comments and information should be submitted in triplicate to the address given in this Notice under ADDRESS to facilitate the work of EPA and others interested in inspecting them. The comments and information should bear the identifying notation OPP-30000/53.

During the comment period, interested members of the public or registrants may request a meeting to discuss factual information available to the Agency, to present any factual information, to respond to presentations by other persons, or to discuss what regulatory actions should be taken regarding the EBDC pesticides. Persons interested in arranging such meetings should contact the person listed in this Notice under "FOR FURTHER INFORMATION CONTACT."

VI. Public Docket

The Agency has established a public docket [OPP-30000/53] for the EBDC pesticides Special Review. This public docket includes or will include: (1) The preliminary notification to the registrants concerning the EBDC Special Review, (2) all written comments and materials (other than claimed confidential business information) submitted to the Agency in response to the preliminary notification; (3) this Notice of Special Review and all documents specifically referenced herein; (4) the Notice of Preliminary Determination and Notice of Final Determination concerning the EBDC Special Review and all documents specifically referenced therein; (5) all

written comments or other materials (other than claimed confidential business information) concerning the EBDC Special Review submitted to the Agency by any person or party outside of government; (6) all documents or other written materials concerning the EBDC Special Review provided by the Agency to any person or party outside of government; (7) a memorandum describing each meeting concerning the EBDC Special Review between Agency personnel and any person or party outside of government; (8) any written response to the Notice of Preliminary Determination by the Secretary of Agriculture or the FIFRA Scientific Advisory Panel; (9) a transcript of all public meetings held by the Scientific Advisory Panel or the Agency concerning the EBDC Special Review; and (10) a current index of all materials in the docket. All such materials will be available for public inspection and copying at Room 236, Crystal Mall Building #2, 1921 Jefferson Davis Highway, Arlington, VA. from 8 a.m. to 4 p.m. Monday through Friday, excluding legal holidays. The Agency will also distribute a compendium of indices for new materials in Special Review dockets by mail, on a monthly basis, to those members of the public who have specifically requested such material. To request inclusion on this mailing list, contact Frances Mann (703-557-2805).

VII. References

The following list of references includes all documents cited in this Notice. These documents are part of the public docket for this Special Review (docket number OPP-30000/53). The Agency will continue to supplement the public docket with additional information as it is received.

The record includes the following information:

1. EPA, Preliminary Notification letter (March 31, 1987).
2. EPA, Decision Document: Final Resolution of Rebuttable Presumption Against Registration (October 14, 1982).
3. Haines, L., Dithane M-45 Percutaneous Absorption in Rats (1980) (unpublished).
4. EPA, Reassessment of Dietary Exposure of Mancozeb and Ethylene thiourea (November 19, 1986).
5. EPA, Mancozeb Task 2: Residue Chemistry Chapter (August 15, 1986).
6. EPA, Mancozeb Task 4: Update of the Registration Standard—Product and Residue Chemistry Chapters (December 15, 1986).
7. EPA, Memorandum, Harold Day to Anne Barton (December 19, 1986); Memorandum, Harold Day to Anne Barton (August 8, 1986).
8. EPA, Use Practices Report on Mancozeb (July 3, 1986).
9. EPA, Guidance for the Reregistration of Pesticide Products Containing Nabam as the Active Ingredient (April 1987).
10. Graham, S. L., et al., "Effects of Prolonged Ethylene Thiourea Ingestion on the Thyroid of the Rat", 13 *Food Cosmetic Toxicology* 493 (1975).
11. Ulland, S. M., et al., "Thyroid Cancer in Rats from Ethylene Thiourea Intake", 49 *Journal of the National Cancer Institute* 583 (1972).
12. EPA, Peer Review of Ethylenethiourea (December 2, 1986).
13. Innes, J. R. M., et al., "Bioassay of Pesticides and Industrial Chemicals for Tumorigenicity in Mice: A Preliminary Note", 42 *Journal of the National Cancer Institute* 1101 (1969).
14. Comments received in response to EPA preliminary notification letter (March 31, 1987).
15. EPA, Toxicology Branch Rebuttal to Company Comments in Response to Grassley-Allen Letter on the EBDC's (May 22, 1987).
16. Khera, K.S., "Ethylenethiourea: Teratogenicity Study in Rats and Rabbits", 7 *Teratology* 243 (1973).
17. Teramoto, S., Shingu, A., Kameda, M., and Saito, "Teratogenicity Studies with Ethylenethiourea in Rats, Mice, and Hamsters", 18 *Congenital Anomalies* 11 (1978).
18. Freudenthal, R. I., Kirchner, G.A., Persing, R.L., and Baron, R.L., "Dietary Subacute Toxicity of Ethylene Thiourea in the Rat", 1 *Journal Environmental Pathology and Toxicology* 147 (1977).
19. Graham, S.L., and Hansen, W.H., "Effects of Short-Term Administration of Ethylenethiourea upon Thyroid Function of the Rat", 7 *Bulletin of Environmental Contamination Toxicology* 19 (1972).
20. EPA, Guidance for the Reregistration of Pesticide Products Containing Mancozeb as the Active Ingredient (April 1987).
21. DiDonato, L.J., Longacre, S.L., Mancozeb pharmacokinetic study in rats (May 21, 1985) (unpublished).
22. EPA, Preliminary Quantitative Usage Analysis for Mancozeb (Feb. 5, 1986), Metiram (Jan. 14, 1986) Maneb (Feb. 28, 1986), Nabam (Dec. 1985), Zineb (May 7, 1985).
23. EPA, Dietary and Worker Exposure and Risk Analyses for Mancozeb and Ethylene Thiourea (ETU), (April 1, 1987).

Dated: July 10, 1987.

John A. Moore,

Assistant Administrator for Pesticides and Toxic Substances.

[FR Doc. 87-16316 Filed 7-15-87; 10:15 am]

BILLING CODE 6560-50-M

43 CFR Part 3190

Friday
July 17, 1987

Part VI

Department of the Interior

Bureau of Land Management

43 CFR Part 3190

Delegation of Authority, Cooperative Agreements, and Contracts for Oil and Gas Inspections by Non-Federal Employees; Final Rulemaking

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[Circular No. 2599; AA-540-07-4111-02]

43 CFR Part 3190

Delegation of Authority, Cooperative Agreements, and Contracts for Oil and Gas Inspections by Non-Federal Employees

AGENCY: Bureau of Land Management, Interior.

ACTION: Final rulemaking.

SUMMARY: This final rulemaking establishes administrative procedures for programs for the inspection of federally supervised oil and gas leases by other than Federal employees. These procedures are designed to implement certain provisions of the Federal Oil and Gas Royalty Management Act of 1982. While Subpart 3190 establishes a framework for all such programs, the specific procedures in Subpart 3191 apply only to delegations of authority to States under section 205 of the Act.

EFFECTIVE DATE: August 17, 1987.

ADDRESS: Any inquiries or suggestions should be sent to: Director (540), Bureau of Land Management, Room 303 Premier Building, 1800 C Street NW., Washington, DC 20240.

FOR FURTHER INFORMATION CONTACT: Susan Pepperney, (202) 653-2200.

SUPPLEMENTARY INFORMATION: A proposed rulemaking to establish a new Part 3190 in Group 3100, implementing the authority contained in the Federal Oil and Gas Royalty Management Act (30 U.S.C. 1701 *et seq.*) relating to programs for the inspection of federally supervised oil and gas leases by other than Federal employees, was published in the Federal Register on October 14, 1986 (51 FR 36565). Comments were invited for a period of 60 days ending December 15, 1986, during which period a total of 21 comments were received, with 9 from business entities, 3 from Indian Tribes, 2 from law firms representing tribes and 1 from a law firm representing a corporation, 2 from State government agencies, 2 from Federal Government agencies, 1 from a business association, and 1 from an individual. Each of the comments has been given careful consideration during the decisionmaking process on this final rulemaking.

Several comments expressed general support or general opposition to the proposed rulemaking. These do not require specific discussion in the **SUPPLEMENTARY INFORMATION** except to state that promulgation of these

regulations is necessary for the orderly execution of the Federal Oil and Gas Royalty Management Act. Most of the comments contained discussion of specific sections of the proposed rulemaking and in many instances recommended changes, some of which have been adopted in this final rulemaking. This preamble will discuss only those sections that were the subject of specific comments or were changed.

Section 3190.0-1—Purpose

One comment stated that this and other sections in Subpart 3190 should be rewritten to apply only to States. The proposed rulemaking contained only Subpart 3190, which is a general section addressing delegation of authority, cooperative agreements, and contracts, and Subpart 3191, which covers delegations of authority. Although Subpart 3191 pertains only to delegations, which are applicable only to States, Subpart 3190 is a general introduction not only to Subpart 3191, but also to Subparts 3192 and 3193 on cooperative agreements and contracts, which will be published later. Since cooperative agreements and contracts may be arranged with Indian tribes and States, it would be inappropriate to limit the scope of Subpart 3190 to States. It was also deemed more efficient to have 1 general subpart rather than 3 to reduce duplication. The comment has not been adopted in the final rulemaking.

Another comment suggested that § 3190.0-1 could be interpreted to include as a purpose of Part 3190 provision of procedures for delegations of authority for inspection, enforcement and investigation activities related to surface management and drilling operations as well as verification of oil and gas production. The comment requested that delegations be restricted to the authority to verify production. Although delegations are limited by the terms of this section to "activities related to oil and gas operations in Federal and Indian lands under the provisions of the Federal Oil and Gas Royalty Management Act," which emphasizes oil and gas production and product accountability, this section has been amended in the final rulemaking to make it clear that activities to be carried out under delegations and other transfers are restricted to producing leases.

Section 3190.0-5—Definitions

Several comments addressed the Definitions section of the proposed rulemaking. One suggested that a definition of "enforcement" should be added, because enforcement is one of the functions subject to delegation. This

suggestion has been adopted. Another suggested that a definition for "Indian lands" should be added as well, and that the term should include lands whose surface only is owned by Indian Tribes, with minerals reserved to the United States. The definition of Indian lands provided in FOGMA has been added. Instances where the surface is Indian land with minerals reserved to the United States will be considered on a case-by-case basis.

One comment pointed out that the Osage Tribe of Indians, by virtue of the terms of the Act of June 28, 1906 (34 Stat. 539), are not subject to the proposed rulemaking, and urged that the final rulemaking should state this explicitly. This suggestion has been adopted in the final rulemaking.

One comment suggested that the regulations should include a narrowly drawn definition of "proprietary data". This suggestion has been adopted in the final rulemaking.

Section 3190.1—Proprietary Data

Two comments questioned the provision in § 3190.1(a)(4) that requires Indian Tribes to "waive sovereign immunity by express consent for wrongful disclosure" of proprietary data made available to them pursuant to a cooperative agreement. The comments expressed concern that this provision would be an unlawful infringement on Tribal self-government. The requirement for Tribes to waive sovereign immunity by "express consent for wrongful disclosure" is specified in the Act. In order to benefit from receiving proprietary data, a Tribe should be willing to be held responsible for its wrongful disclosure. A waiver of sovereign immunity limited to the consequences of a specified act or class of acts does not compromise the general sovereign immunity of a Tribe. The comments are not adopted in the final rulemaking.

One comment expressed concern about the possibility that proprietary data may be inadvertently disclosed when provided to non-Federal employees. This possibility is the reason that both the statute and this rulemaking provide that those receiving such data are required to accept liability for wrongful disclosure.

One comment suggested that proprietary data should not be made available unless the recipient demonstrates that the persons who receive it, as well as being directly involved in an investigation under 30 U.S.C. 1732, also "have a need to know." This suggestion has been adopted in the final rulemaking.

The same comment suggested that a new section should be inserted providing that disclosure of confidential data may not be compelled under State law. This comment has been adopted, and a new § 3190.1(b)(2) has been added in the final rulemaking.

Section 3190.2-3—Audits

One comment recommended that this section include a requirement that those conducting audits under delegations, contracts, or cooperative agreements, comply with generally accepted accounting principles, auditing standards, and industry ethical standards. Audits referred to in this section are those of funds paid to States, Tribes, and contractors, not audits of oil and gas lessees. The provision has been edited to make its application more clear, but there is no need to refer to energy industry ethical standards.

Section 3190.2-2—Funding

One comment opposed the provision in § 3190.2-2(b)(2) that the cost incurred by a party to a cooperative agreement may be reimbursable up to 50 percent, while, under § 3190.2-2(b)(1), the costs of a party to which a delegation of authority has been made may be reimbursable up to 100 percent. The comment argued that this would be unfair to tribes, which are eligible only to enter cooperative agreements and are not as well funded as States, which are eligible to be delegated authority and collect the majority of taxes from production on Indian land. This rule is consistent with the 50 percent funding provided for cooperative agreements by the Minerals Management Service (MMS) at 30 CFR 228.105. MMS pointed to the cooperative nature of this activity as support for 50 percent, rather than 100 percent, funding. 49 FR 37336, 37342 (September 21, 1984). More recently, the Secretary of the Interior affirmed the policy reflected in this regulation in his response to the recommendations of the Royalty Management Advisory Committee on funding guidelines. Since the Tribes receive the full financial benefit from their mineral resources, no change is made in the final rulemaking in response to these comments.

Section 3190.3—Sharing of Civil Penalties

Several comments addressed this section of the proposed rulemaking, which would provide that 50 percent of any civil penalties collected should be retained by the United States, with the remaining 50 percent going to the State or Indian Tribe, and that the amount paid to the State or Tribe would be deducted from the amounts

appropriated for that entity to conduct inspections. The comments feared that this provision would provide little incentive for Tribes to pursue civil penalties, and argued that penalties collected by Tribal inspections should accrue entirely to Tribes conducting inspections on their own land. One comment urged explicitly that a distinction should be drawn between Federal lands and Indian lands, and that penalties from the latter should be distributed to the beneficial owners of the lands. Another comment feared that the provision for sharing civil penalties will lead to abuses. The distribution of civil penalties provided for in this rulemaking is required by statute. No change is made in the final rulemaking in response to these comments.

Section 3191.1—Petition for Delegation

Two comments urged that Indian Tribes should be eligible for delegations of authority. This suggestion cannot be adopted because section 205 of FOGMA does not provide for delegation of authority of Tribes.

One comment suggested that this section should provide that delegations of authority are allowed for auditing leases, rather than for enforcing the law, to be consistent with 30 U.S.C. 1735. Another stated that section 205(a) unequivocally limits the Secretary's delegation authority to conducting inspections, audits, and investigations. It is the policy of the Department of the Interior to include enforcement as a delegable activity. It is not specifically prohibited in the Act. Enforcement is an integral part of the inspection process that is the subject of delegations. Requiring enforcement by separate Federal personnel would be wasteful and fragment the program. Further, it would be needlessly burdensome upon the industry to subject operators to inspection by one agency and enforcement by another. The comment is not adopted in the final rulemaking.

Section 3191.1-3—Action Upon Petition

One comment addressed this section, stating that paragraph (c) implies piecemeal regulation that will result in duplication and additional burdens on operators and the oil industry. Actually, this paragraph expressly provides for coordination between delegated and non-delegated functions to avoid unreasonable burdens on lessees. The section is adopted as proposed.

Section 3191.1-4—Public Hearing on Petition

One comment urged that the notice of proposed delegation published in the Federal Register contain all the

information, terms, and provisions of the proposed delegation in order to allow public and industry scrutiny of the entire matter before such delegations are implemented. This comment is adopted in the final rulemaking, which has been amended to make it clear that the proposed delegations will be published in full in the Federal Register, with an opportunity for public comment.

Section 3191.2—Terms of Delegation

One comment stated that this section, particularly paragraphs (f) through (i), would cause inconsistent actions and confusion for States, operators, and the oil and gas industry, if abused. The comment conceded that the intent of the section appears meritorious. The Department of the Interior will monitor all delegations as part of its oversight program, insuring that States do not abuse their delegated authority.

Section 3191.3—Termination and Reinstatement

One comment stated that there is no statutory provision for a State to submit a correction plan for deficiencies in delegation programs, as provided for in § 3131.3-1(d), and no statutory provision for reinstatement of a terminated delegation, as provided for in § 3191.3-2. The comment stated that these provisions could result in delays and extensions that could burden lessees. The Department of the Interior has determined that there should be a mechanism for correction deficiencies in a State program before permanently revoking the delegation of authority. Therefore, a policy decision was made to allow States to correct deficiencies. The requirement in § 3191.3-2(b) that a State be fully capable of resuming the activities carried out under the delegation will reduce movement of the program back and forth between the Federal and State agencies.

Editorial changes have been made as necessary.

The principal authors of this final rulemaking are Susan Pepperney and Stephen Spector of the Energy and Minerals Staff, assisted by the staff of the Division of Legislation and Regulatory Management, Bureau of Land Management.

It is hereby determined that this rulemaking does not constitute a major Federal action significantly affecting the quality of the human environment and that no detailed statement pursuant to section 102(2)(C) of the National Environmental Policy Act of 1969 (42 U.S.C. 4332(2)(C)) is required.

The Department of the Interior has determined that this document is not a

major rule under Executive Order 12291 and that it will not have a significant economic effect on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*).

This rulemaking will not have a significant economic effect on the States involved because they will be reimbursed for costs incurred as required by the Federal Oil and Gas Royalty Management Act of 1982.

This final rulemaking will not have a major impact on Federal and Indian lessees. Much of the information required by State regulatory agencies from a lessee or operator is essentially a duplicate of that presently required by the United States. In addition, under the existing system, a lessee or operator is often required to comply with 2 sets of operating regulations and is subject to twice the regulatory presence. The reduction in duplication of effort by State and Federal Governments resulting from this final rulemaking should result in less burdensome conditions for a lessee or operator.

This rule does not contain information collection requirements which require approval by the Office of Management and Budget under 44 U.S.C. 3501 *et seq.* The information collection requirements contained in 43 CFR Part 3190 require fewer than 10 responses annually. Of the 29 States eligible to participate in the delegation of authority or cooperative agreement programs authorized by this part, only 2 States have expressed interest in a delegation of authority and only 1 State has expressed interest in a cooperative agreement. The Bureau of Land Management currently has non-funded cooperative agreements with 3 Indian Tribes and has received indications of interest from 3 additional Tribes. Therefore, it is anticipated that participants in any of the programs authorized by this part will be less than 10 annually.

List of Subjects in 43 CFR Part 3190

Administrative practice and procedure, Government contracts, Indian lands—mineral resources, Intergovernmental relations, Mineral royalties, Oil and gas production, Public lands—mineral resources, Reporting and recordkeeping requirements.

Under the authority of the Mineral Leasing Act of 1920, as amended and supplemented (30 U.S.C. 181 *et seq.*), the Mineral Leasing Act for Acquired Lands of 1947, as amended (30 U.S.C. 351–359), the Act of March 3, 1909, as amended (25 U.S.C. 396), the Act of May 11, 1938, as amended (25 U.S.C. 396a–396q), the Act of February 19, 1891, as amended (25 U.S.C. 397), the Act of May 29, 1924 (25 U.S.C. 398), the Act of March 3, 1927

(25 U.S.C. 398a–398e), the Act of June 30, 1919, as amended (25 U.S.C. 399), and the Federal Oil and Gas Royalty Management Act of 1982 (30 U.S.C. 1701 *et seq.*), Group 3100, Subchapter C, Chapter II of Title 43 of the Code of Federal Regulations is amended by adding a new Part 3190 as set forth below:

May 11, 1987.

J. Steven Griles,

Assistant Secretary of the Interior.

PART 3190—DELEGATION OF AUTHORITY, COOPERATIVE AGREEMENTS AND CONTRACTS FOR OIL AND GAS INSPECTION

Subpart 3190—Delegation of Authority, Cooperative Agreements and Contracts for Oil and Gas Inspections; General

Sec.

3190.0-1 Purpose.

3190.0-3 Authority.

3190.0-4 Objective.

3190.0-5 Definitions.

3190.0-7 Cross references.

3190.1 Proprietary data.

3190.2 Recordkeeping, funding and audit.

3190.2-1 Recordkeeping.

3190.2-2 Funding.

3190.2-3 Audit.

3190.3 Sharing of civil penalties.

Subpart 3191—Delegation of Authority

3191.1 Petition for delegation.

3191.1-1 Petition.

3191.1-2 Eligibility.

3191.1-3 Action upon petition.

3191.1-4 Public hearing on petition.

3191.2 Terms of delegation.

3191.3 Termination and reinstatement.

3191.3-1 Termination.

3191.3-2 Reinstatement.

3191.4 Standards of delegation.

3191.5 Delegation for Indian lands.

3191.5-1 Indian lands included in delegation.

3191.5-2 Indian lands withdrawn from delegation.

Authority: The Mineral Leasing Act of 1920, as amended and supplemented (30 U.S.C. 181 *et seq.*), the Mineral Leasing Act for Acquired Lands of 1947, as amended (30 U.S.C. 351–359), the Act of March 3, 1909, as amended (25 U.S.C. 396), the Act of May 11, 1938, as amended (25 U.S.C. 396a–396q), the Act of February 18, 1891, as amended (25 U.S.C. 397), the Act of May 29, 1924 (25 U.S.C. 398), the Act of March 3, 1927 (25 U.S.C. 398a–398e), the Act of June 30, 1919, as amended (25 U.S.C. 399) and the Federal Oil and Gas Royalty Management Act of 1982 (30 U.S.C. 1701 *et seq.*).

Subpart 3190—Delegation of Authority, Cooperative Agreements and Contracts for Oil and Gas Inspections; General

§ 3190.0-1 Purpose.

The purpose of the part is to provide procedures for approval, implementation

and administration of delegations of authority, cooperative agreements and contracts for inspection, enforcement and investigative activities related to oil and gas production operations on Federal and Indian lands under the provisions of the Federal Oil and Gas Royalty Management Act of 1982 (30 U.S.C. 1701 *et seq.*).

§ 3190.0-3 Authority.

The Federal Oil and Gas Royalty Management Act of 1982 (30 U.S.C. 1701 *et seq.*).

§ 3190.0-4 Objective.

The objective of this part is to assure that delegations of authority, cooperative agreements and contracts as provided for under the Federal Oil and Gas Royalty Management Act are carried out in accordance with the provisions of the Act and this title.

§ 3190.0-5 Definitions.

As used in this part, the term:

(a) "Inspection" means the examination of oil and gas lease sites, records or motor vehicle documentation by an authorized representative of the Secretary of the Interior to determine if there is compliance with applicable regulations, Onshore Oil and Gas orders, approvals, Notices to Lessees and Operators, approvals, other written orders, the mineral leasing laws, and the Federal Oil and Gas Royalty Management Act.

(b) "Investigation" means any inquiry into any action by or on behalf of a lessee or operator of a Federal or Indian lease, or transporter of oil from such lease.

(c) "Contractor" means any individual, corporation, association, partnership, consortium or joint venture who has contracted to carry out activities under this part.

(d) "Enforcement" means action taken by an authorized representative of the Secretary in order to obtain compliance with applicable regulations, Onshore Oil and Gas Orders, Notices to Lessees and Operators, approvals, other written orders, the mineral leasing laws, and the Federal Oil and Gas Royalty Management Act.

(e) "Indian lands" means any lands or interests in lands of an Indian tribe or an Indian allottee held in trust by the United States or which is subject to Federal restriction against alienation, including mineral resources and mineral estates reserved to an Indian tribe or Indian allottee in the conveyance of a surface or nonmineral estate, except that such term does not include any lands subject to the provisions of

section 3 of the Act of June 28, 1906 (34 Stat. 539).

(f) "Proprietary data" means information obtained from a lessee that constitutes trade secrets, or commercial or financial information that is privileged or confidential, or other information that may be withheld under the Freedom of Information Act (5 U.S.C. 552(b)).

§ 3190.0-7 Cross references.

- (a) 25 CFR 211.18; 212.24; 213.34.
- (b) 30 CFR Part 229.
- (c) 43 CFR Part 3160.

§ 3190.1 Proprietary data.

With regard to any data or information obtained by a State, Indian tribe or individual, whether under a delegation of authority, cooperative agreement or contract, the following applies:

(a) Proprietary data shall be made available to a State or Indian tribe pursuant to a cooperative agreement under the provisions of 30 U.S.C. 1732 if such State or Indian tribe:

- (1) Consents in writing to restrict the dissemination of such information to such persons directly involved in an investigation under 30 U.S.C. 1732 who need the information to conduct the investigation;
- (2) Agrees in writing to accept liability for wrongful disclosure;
- (3) In the case of a State, the State demonstrates that such information is essential to the conduct of an investigation or to litigation under 30 U.S.C. 1734; and
- (4) In the case of an Indian tribe, the tribe demonstrates that such information is essential to the conduct of an audit or investigation and waives sovereign immunity by express consent for wrongful disclosure.

(b)(1) Any person or State that obtains proprietary data pursuant to a delegation of authority, cooperative agreement or contract under this part is subject to the same provisions of law with respect to the disclosure of such information as would apply to any officer or employee of the United States.

(2) Disclosure of proprietary data obtained pursuant to a delegation of authority, cooperative agreement, or contract under this part may not be compelled under State law.

§ 3190.2 Recordkeeping, funding and audit.

§ 3190.2-1 Recordkeeping.

(a) Records and accounts relating to activities under delegations of authority, cooperative agreements or contracts shall be identified in the delegation, cooperative agreement or contract.

(b) All records and other materials relating to a delegation of authority, cooperative agreement or contract shall be maintained by the State, Indian Tribe or contractor for a period of 6 years from the date they are generated or such other period as may be specified in the delegation, cooperative agreement or contract.

§ 3190.2-2 Funding.

(a) States and Tribes shall provide adequate funding for administration and execution of activities carried out under a delegation or cooperative agreement.

(b) Reimbursement for allowable costs incurred by a State, Indian tribe or contractor as a result of activities carried out under a delegation of authority, cooperative agreement or contract shall be as negotiated, with the following limitations:

- (1) Up to 100 percent for a delegation of authority; or
- (2) Up to 50 percent for a cooperative agreement.

(c) Funding shall be subject to the availability of funds.

(d) States, Indian tribes or contractors shall maintain financial records relating to the funds received and expended under a delegation of authority, cooperative agreement or contract as specified in the delegation of authority, cooperative agreement or contract.

(e) Reimbursement shall be at least quarterly and only shall be made upon submission of an invoice or request for reimbursement to the authorized officer.

§ 3190.2-3 Audit.

In maintaining financial records relating to the funds received and expended under a delegation of authority, cooperative agreement, or contract, States, Indian tribes and contractors shall comply with generally accepted accounting principles and audit requirements established by the Department of the Interior and Bureau of Land Management.

§ 3190.3 Sharing of civil penalties.

Fifty percent of any civil penalty collected by the United States as a result of activities carried out by a State under a delegation of authority or a State or Indian tribe under a cooperative agreement shall be payable to that State or Indian tribe upon receipt by the United States. Such amount shall be deducted from compensation due to the State or Indian tribe by the United States under the delegation of authority or cooperative agreement.

Subpart 3191—Delegation of Authority

§ 3191.1 Petition for delegation.

§ 3191.1-1 Petition.

The Governor or other authorized official of any eligible State may request in writing that the Director delegate all or part of his/her authority and responsibility for inspection, enforcement and investigation on oil and gas leases on Federal lands within the State and on Indian lands within the State where the affected Indian tribe or Indian allottee has given written permission for such inspection, enforcement and investigation. Requests by a State for delegation of other activities may be granted by the Director with the approval of the Secretary.

§ 3191.1-2 Eligibility.

Any State with producing oil or gas leases on Federal or Indian lands may request a delegation of authority.

§ 3191.1-3 Action upon petition.

Upon request for a delegation of authority, the Director shall determine if:

(a) The State has proposed an acceptable plan for carrying out the delegated activities and will provide adequate resources to achieve the purposes of 30 U.S.C. 1735. This plan shall, at a minimum:

(1) Identify specific authorities and responsibilities for which the State is requesting a delegation of authority and whether it is applicable to Federal lands only or includes Indian lands;

(2) Provide evidence of written permission of the affected Indian tribe(s) or allottee(s) for such lands;

(3) Include specifics for carrying out the delegated activities;

(4) Indicate the inspector resources for carrying out the delegated activities and documentation of inspector qualifications;

(5) Describe the proposed record keeping for funding purposes;

(6) Detail the frequency and method of payment; and

(7) Include copies of any non-Federal forms that are to be used.

(b) The State has demonstrated that it will effectively and faithfully administer the rules and regulations of the Department of the Interior in accordance with the provisions of 30 U.S.C. 1735.

(c) The delegation will be carried out in coordination with activities retained by the Bureau so that such delegation will not create an unreasonable burden on any lessee.

§ 3191.1-4 Public hearing on petition.

Prior to the granting of any delegation of authority, the notice of proposed delegation shall be published in the Federal Register. The Federal Register notice shall provide an opportunity for a public hearing in the affected State.

§ 3191.2 Terms of delegation.

(a) Delegations shall be continuing, contingent upon available funding, providing that there is an annual finding by the Director that the provisions of the delegation and the mineral leasing laws are still being carried out and that the requirements of § 3191.1-3 (a), (b) and (c) of this title are still in effect.

(b) Authority delegated to a State under this subpart shall not be redelegated.

(c) The State regulatory authority shall maintain sufficient qualified, personnel to comply with the terms and purpose of the delegation.

(d) Inspection identification cards shall be issued by the authorized officer to all certified State inspectors for the purpose of identifying the bearer as an authorized representative of the Secretary. Identification cards remain the property of the United States.

(e) The delegation shall provide for coordination with designated offices of the Bureau of Land Management, the Minerals Management Service, and, where appropriate, the Bureau of Indian Affairs, Forest Service, and other surface management agencies.

(f) The delegation shall provide for annual program review.

(g) The delegation shall provide for annual budget and program reporting in conjunction with the Federal Budget process.

(h) The Director reserves the right to make inspections on Federal and Indian leases inspected by a State under this subpart for the purpose of evaluating the manner in which the delegation is being carried out.

(i) The Director reserves the right to act independently to carry out his/her responsibilities under the law.

§ 3191.3 Termination and reinstatement.**§ 3191.3-1 Termination.**

(a) The delegation may be terminated by mutual written consent at any time.

(b) The Director may revoke a delegation if it is determined that the State has failed to meet the minimum

standards for complying with the delegated authority.

(c) Prior to any action to revoke a delegation, the Director shall notify the State in writing of the deficiencies in the program leading to such revocation.

(d) Upon notification of intent to revoke a delegation, the State shall have 30 days to respond with a plan to correct the cited deficiencies. If the Director determines that the plan of correction is acceptable, the Director shall then approve the plan and specify the timeframe within which the cited deficiencies shall be corrected.

(e) In the event the Director makes a determination to revoke a delegation of authority, the State shall be provided an opportunity for a hearing prior to final action.

§ 3191.3-2 Reinstatement.

Terminated delegations of authority may be reinstated as set out below;

(a) For a delegation terminated by mutual consent under § 3191.3-1(a) of this title, the State shall apply for reinstatement by filing a petition with the Director, who shall determine whether such reinstatement should be granted.

(b) For a delegation of authority revoked by the Director, the State shall file a petition requesting reinstatement. In applying for reinstatement, the State shall provide written evidence that it has remedied all defects for which the delegation was revoked and that it is fully capable of resuming the activities carried out under the delegation. Upon receipt of the petition, the following actions shall be taken:

(1) The authorized officer, after review of the petition, may recommend approval of the reinstatement but shall provide proof that the deficiencies have been corrected and that the State is fully capable of carrying out the delegation.

(2) The Director shall review the petition and the recommendation of the authorized officer and may approve the reinstatement of a delegation upon a determination that the findings of the authorized officer are acceptable.

§ 3191.4 Standards of delegation.

(a) The Director shall establish minimum standards to be used by a State in carrying out activities established in the delegation.

(b) The delegation shall identify functions, if any, that are to be carried out jointly.

(c) A delegation shall be made in accordance with the requirements of this section.

(d) Copies of delegations shall be on file in the Washington Office of the Bureau and shall be available for public inspection.

§ 3191.5 Delegation for Indian lands.**§ 3191.5-1 Indian lands included in delegation.**

(a) No activity under a delegation made under this subpart may be carried out on Indian lands without the written permission of the affected Indian tribe or allottee.

(b) A State requesting a delegation involving Indian lands shall provide, as evidence of permission, a written agreement signed by an appropriate official(s) of the Indian tribe for tribal lands, or by the individual allottee(s) or their representative(s) for allotted lands. The agreement shall at a minimum specify the type and extent of activities to be carried out by the State under the agreement, and provisions for State access to carry out the specified activities.

(c) Delegations covering Indian lands shall be separate from delegations covering Federal lands.

§ 3191.5-2 Indian lands withdrawn from delegation.

(a) When an Indian tribe or allottee withdraws permission for a State to conduct inspection and related activities on its lands, the Indian tribe or allottee shall provide written notice of its withdrawal of permission to the State.

(b) Immediately upon receipt of a notice of withdrawal of permission, the State shall provide written notification of said notice to the authorized officer, who immediately shall take all necessary action to provide for inspection and enforcement activities on the affected Indian lands.

(c) No later than 120 days after receipt of a notice of withdrawal of permission draw from an Indian tribe or allottee, the delegation on the lands covered by the notice shall terminate.

(d) Upon termination of a delegation covering Indian lands, appropriate changes in funding shall be made by the authorized officer.

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