the requested SIP revision. Navistar's argument that the filing of a SIP revision should suspend all Federal enforcement action would gravely undercut the enforcement requirements of the Clean Air Act, 42 U.S.C. 7413. A violator remains subject to the existing requirements of a SIP until a SIP revision is obtained. *Train* v. *Natural Resources Defense Council*, 421 U.S. 60, 92 (1975); *Duquesne Light Co.* v. *USEPA*, 698 F.2d 456, 471 (D.C. Cir. 1983); *National Resources Defense Council* v. *USEPA*, 507 F.2d 905, 915 (9th Cir. 1974).

The other fact Navistar refers to which purportedly supports its argument that there has been an improper mixture of rulemaking and enforcement is that USEPA allegedly has made a Federal court pleading part of the administrative record. Navistar cities "Record Item 261–5," which it alleges corresponds to the pleading styled, "Defendant's First Set of Requests for Admissions dated December 17, 1987." After a careful review of the index to the administrative record and the administrative record itself, USEPA can locate no such document.

In summary, the administrative record contains the very items Navistar suggests it should: "the identities of all persons involved in the Agency's review of the SIP revision and * * * memoranda, records of conversations, or other documents reflecting that review" (Navistar comment, page 23). USEPA's rulemaking on Navistar's site-specific RACT SIP revision has been completely independent of its enforcement action as mandated by the law. *See Bethlehem Steel* v. *USEPA*, 638 F.2d 994 (7th Cir. 1980).

Conclusion

USEPA is disapproving this revision because the State has not demonstrated that Navistar's compliance schedule is expeditious, that meeting the existing SIP limit is technically or economically infeasible, and that the revision will not jeopardize attainment or maintenance.

Under section 307(b)(1) of the Act, petitions for judicial review of this action must be filed in the United States Court of Appeals for the appropriate circuit by November 13, 1989. This action may not be challenged later in proceedings to enforce its requirements. (See 307(b)(2).)

This action has been classified as a Table 2 action by the Regional Administrator under the procedures published in the **Federal Register** on January 19, 1989 (54 FR 2214–2225). On January 6, 1989, the Office of Management and Budget waived Table 2 and 3 SIP revisions (54 FR 2222) from the requirements of section 3 of Executive Order 12291 for a period of two years.

List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Ozone, Carbon monoxide, Hydrocarbon, Intergovernmental offices.

Authority: 42 U.S.C. 7401–7642.

Dated: August 31, 1989.

Frank M. Covington,

Acting Regional Administrator.

PART 52—APPROVAL AND PROMULGATION OF IMPLEMENTATION PLANS

Subpart KK—Ohio

Title 40 of the Code of the Federal Regulations, chapter 1, part 52, is amended as follows:

1. The authority citation for part 52 continues to read as follows:

Authority: 42 U.S.C. 7401–7642.

2. Section 52.1885 is amended by adding paragraph (p) to read as follows:

§ 52.1885 Control strategy: Ozone.

* * * * *

(p) Disapproval—On March 10, 1986, the Ohio Environmental Protection Agency (OEPA) submitted a site-specific revision to the Ohio ozone SIP for volatile organic compound emissions from Navistar's (Formerly called International Harvester) one surface coating line at its Body plant and nine lines at its Assembly plant. Both plants are located in Springfield, Clark County, Ohio. Clark County is designated nonattainment for the pollutant ozone under section 107 of the Clean Air Act (40 CFR 81.336).

[FR Doc. 89–21459 Filed 9–12–89; 8:45 am]

BILLING CODE 6560–50–M

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40 CFR Part 799

[OPTS–42099A; FRL–3645–8]

Methyl Ethyl Ketoxime; Final Test Rule

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: EPA is issuing this final test rule under section 4 of the Toxic Substances Control Act (TSCA), requiring manufacturers and processors of methyl ethyl ketoxime (MEKO, CAS No. 96–29–7) to perform testing for health effects. The testing requirements include oncogenicity, mutagenicity, developmental toxicity, reproductive toxicity, neurotoxicity, and pharmacokinetics. For the pharmacokinetics test only, EPA will finalize the test standard and reporting requirement in a separate final rule.

DATES: In accordance with 40 CFR 23.5, this rule shall be promulgated for purposes of judicial review at 1 p.m. eastern (daylight or standard as appropriate) time on September 27, 1989. This rule should become effective on October 27, 1989.

FOR FURTHER INFORMATION CONTACT: Michael M. Stahl, Director, Environmental Assistance Division (TS–799), Office of Toxic Substances, Rm. EB–44, 401 M St., SW., Washington, DC 20460, (202) 554–1404, TDD: (202) 554–0551.

SUPPLEMENTARY INFORMATION: EPA is issuing a final test rule under section 4(a) of TSCA to require health effects testing for MEKO.

I. Introduction

A. Test Rule Development Under TSCA

This final rule is part of the overall implementation of section 4 of TSCA (Pub. L. 94–469, 90 Stat. 2003 *et seq.*, 15 U.S.C. 2601 *et seq.*), which contains authority for EPA to require the development of data relevant to assessing the risk to health and environment posed by exposure to particular chemical substances or mixtures (chemicals).

Under section 4(a) of TSCA, EPA must require testing of a chemical to develop data if the Administrator makes certain findings as described in TSCA under section 4(a)(1) (A) or (B). Detailed discussions of the statutory section 4 findings are provided in the EPA's first and second proposed test rules which were published in the **Federal Register** of July 18, 1980 (45 FR 48510) and June 5, 1981 (46 FR 30300).

B. Regulatory History

The Interagency Testing Committee (ITC) designated MEKO for priority testing consideration in its 19th Report, published in the **Federal Register** of November 14, 1986 (51 FR 41417). The ITC recommended that MEKO be considered for health effects testing. EPA responded to the ITC's recommendations for MEKO by publishing a notice of proposed rulemaking in the **Federal Register** of September 15, 1988 (53 FR 35838), which proposed that MEKO be tested for oncogenicity, mutagenicity, reproductive toxicity, developmental toxicity, neurotoxicity, and pharmacokinetics. The proposed rule contained a chemical profile of MEKO, a discussion of EPA's TSCA section 4(a) findings, and the proposed test standards and reporting requirements.

II. Response to Public Comments

EPA received written comments on the MEKO proposed test rule from Allied-Signal, Inc. (Allied), Huls America Inc. (Huls), Cosan Chemical Corp. (Cosan), and ICI Americas Inc. (ICI). A public meeting was also requested by Allied and was held on December 15, 1988 (Ref. 18). Allied submitted additional comments on human exposure to MEKO (Ref. 21) and on the economic impact of the rule (Ref. 23). The comments submitted by these companies and the EPA's response are contained in the public record for this rule (Ref. 24)

A. Route of Administration

Huls believes that all major toxicity tests should be conducted by the inhalation route and that inhalation is the major route of human exposure to MEKO. Allied believes the oncogenicity test should be conducted by inhalation.

EPA believes that, in addition to inhalation exposure, dermal contact may also be an important route of exposure to MEKO (Refs. 3 and 11). EPA has no information at this time to reject the inhalation route for the oncogenicity, in vivo mammalian cytogenetics, and neurotoxicity studies, and the final rule has been modified to allow either inhalation or oral routes for these tests. EPA believes there will be severe methodological problems associated with performing the developmental and reproductive toxicity tests by the inhalation route. The most serious problem is that dosing the dams by inhalation requires prolonged separation from their offspring (Ref. 40). Because the reproductive land developmental studies are complimentary, EPA has concluded that they should be conducted by the same route.

B. Oncogenicity

Huls believes acetoxime is not a good analogue because MEKO is asymmetrical and because acetoxime may be an atypical homologue.

EPA believes that, although acetoxime is symmetrical and the first member of a homologous series, it is still a good analogue for MEKO and is adequate for the finding that MEKO may present an unreasonable risk of injury to human health. Structurally, MEKO differs from acetoxime by a single methyl group, both chemicals are relatively water soluble and both exhibit similar acute toxicity (Ref. 24).

Allied believes the study by Mirvish concerning acetoxime and the positive results from a mouse lymphoma mutagenicity study are not an adequate basis for requiring a bioassay.

EPA has concluded that the Mirvish study of acetoxime, while not sufficient for use in quantitative risk assessment, is sufficient to raise concern for the possible oncogenicity of MEKO. EPA's use of structure-activity relationships (SAR) in supporting the section 4(a)(1)(A) TSCA finding was upheld by the D.C. Circuit Court of Appeals in a case reviewing the final rule for 2-Ethylhexanoic Acid (EHA, Ref. 39). The court stated, "But Congress explicitly contemplated that EPA would base test rules on comparisons among structurally similar chemicals" (Ref. 41). In addition, the Third Circuit has suggested that "structure-activity relationships" be used even when there is uncertainty and that such uncertainty may "highlight the need for testing" (Ref. 42).

EPA believes the positive results from the mouse lymphoma study of MEKO provide further evidence that MEKO may be oncogenic.

Allied indicates that neither of the hypothesized metabolites of MEKO, methyl ethyl ketone (MEK), or hydroxylamine, have been implicated in a positive carcinogenic response.

EPA believes MEKO itself may be oncogenic. This alone is sufficient for EPA's findings under TSCA section 4(a)(1)(A). Furthermore, even if the metabolites are not carcinogenic, there is no assurance that the parent compound (MEKO) is not.

Allied believes that, because tumors were observed in male rates in the study of acetoxime, the male rat would be an adequate subject for testing MEKO, and testing females is not necessary.

EPA disagrees. Testing experience and standard scientific references indicate there may be substantial sex-related differences in sensitivity to different compounds, EPA is requiring that females as well as males be tested.

Allied expressed general concern for the unnecessary sacrifice of animals.

EPA shares this concern, and has made every effort to design studies which economize on the number of animals while providing adequate numbers for acceptable statistical analysis. Industry may further reduce the number of animals by submitting study plans which use satellite groups or the same animals for different measurements, wherever feasible. EPA also notes that there are presently no alternatives to whole-animal testing for the toxicological endpoints required by this rule.

Allied and Huls believe there is no justification for using two species in any oncogenicity study of MEKO. They believe testing should be limited to the rat because the mouse is a poor test species for a substance where they believe the liver is the sole target organ. Huls is concerned about using the B6C3F1 mouse.

EPA disagrees. It has not been established that the liver is the only target for possible MEKO oncogenicity. EPA requires data from two species under its cancer risk assessment guidelines. Thus, a negative single species test would be insufficient evidence to exonerate MEKO. This requirement is consistent with those of the EPA Office of Pesticide Programs and the Organization for Economic Cooperation and Development (OECD).

EPA has not specified the strain of mouse for testing MEKO, however, the National Toxicology Program (NTP) concluded that even with the variable rate of background liver tumors in males, the B6C3F1 mouse is an acceptable species for oncogenicity studies (Ref. 19). EPA would consider the variable rate of background tumors with other evidence in estimating potential human risk from MEKO.

Huls believes that the reporting requirements should be extended to 65 months if conducted in only the rat and 79 months if both rat and mouse are used.

EPA does not believe that MEKO presents special testing problems requiring an extension of the reporting requirements.

C. Mutagenicity

Allied believes that because the mouse lymphoma assay conducted on MEKO was negative with activation, MEKO would be deactivated by enzymes in vivo.

EPA believes the positive results from this mouse lymphoma study, without activation, indicate that MEKO can potentially cause mutagenic effects. The negative result obtained by using enzymes in vitro does not necessarily predict how MEKO would react in vivo, nor how it would be processed by human enzyme systems. This information must be obtained through further testing. In addition, EPA found that hydroxylamine, a possible metabolite of MEKO, and hydroxylamine hydrochloride, a structurally related chemical, are mutagenic in a variety of test systems (Refs. 6 and 7). Therefore, MEKO may also be mutagenic. Allied noted that hydroxylamine is active in vitro but not in vivo. Further, hydroxylamine, a product of normal cell metabolism, is endogenously present in humans where it apparently does not have mutagenic effect.

EPA believes in vitro studies indicate that hydroxylamine is intrinsically

mutagenic, and are sufficient to raise concern for MEKO. Further study is needed to determine the mutagenic risk of MEKO itself.

Allied requests that in vitro cytogenetics, sister chromatid exchange, and Ames *Salmonella* studies of MEKO being conducted by NTP be evaluated before conducting mutagenicity studies of MEKO.

EPA's tiered testing system for both gene mutations and chromosomal aberrations is explained in detail in the final test rules for C9 aromatic hydrocarbon fraction (40 CFR 799.2175; 50 FR 20662; May 17, 1985), and diethylenetriamine (40 CFR 799.1575; 50 FR 21398; May 23, 1985).

NTP has indicated that the in vitro cytogenetics and the in vitro sister chromatid exchange studies conducted by NTP are negative (Ref. 31). EPA has not reviewed the studies but will do so when they are available. However, regardless of the results of NTP's testing, both the sex-relinked recessive lethal assay in *Drosophila* and an in vivo mammalian bone marrow cytogenetics test are required to confirm the negative.

D. Developmental and Reproductive Toxicity

Allied proposed that a protocol combining developmental toxicity, neurotoxicity, and reproductive toxicity be devised.

EPA believes that a combined protocol testing for neurotoxicity, developmental toxicity, and reproductive toxicity will compromise the results of these studies. Developmental and reproductive tests require different exposure periods and different dose levels. Neurotoxicity tests also require longer exposure times than the developmental test (Ref. 24, 25, and 40). Theoretically, the neurotoxicity and reproductive studies could be combined. However, at this time, the commenter failed to establish that it can be done successfully.

Allied disagrees with EPA's interpretation of data used to support the need for reproductive toxicity testing of MEKO.

Although EPA believes data from the 13-week subchronic toxicity study (Ref. 30) are inadequate to prove that MEKO causes hypospermatogenesis, these data strongly suggest that MEKO may cause adverse effects on male reproductive organs (Ref. 25).

Allied questions EPA's use of Ramaija's study with hydroxylamine (Ref. 31) to support the need for reproductive toxicity testing, and especially the use of spermatogenesis staging studies.

Although the Ramaija data do not prove conclusively that hydroxylamine is a reproductive toxicant, EPA believes the data suggest that hydroxylamine has adverse effects on spermatogenesis and embryonic viability. These study results support concern for the potential reproductive toxicity of hydroxylamine, and hence of MEKO. We also believe that if reproductive toxicity testing is to be conducted, it would be prudent to include the "histopathology of the tests with staging of the sperm" as outlined in the proposed rule. We do not concur with Allied that staging of sperm is only appropriate for compounds that are metabolized slowly. The purpose of the staging study is to determine if a particular stage of sperm development is uniquely sensitive to the toxic effects of a compound. For this purpose quantitation is not necessary. Since spermatogenesis is a continual process, and not a cyclic process, all stages of sperm development will be present and exposed to a compound even if the compound is metabolized and eliminated rapidly. Although the data from the study by Ramaija are of limited value because of the high doses used, they do not provide suggestive evidence that specific stages of sperm development may be more sensitive to the effects of hydroxylamine than other stages.

Allied questions EPA's use of the available information on hydroxylamine as support for developmental toxicity testing of MEKO.

EPA considers none of the studies available on the developmental toxicity of hydroxylamine to be adequate for risk assessment. However, these data are considered sufficient to raise concern for the developmental toxicity potential of hydroxylamine. Since hydroxylamine is a possible metabolite of MEKO, EPA believes MEKO may also be developmentally toxic.

Allied considered the results of two developmental toxicity tests (Ref. 16) to be contradictory and thus insufficient to support developmental toxicity testing.

EPA disagrees (Ref. 25). Both studies demonstrated increased frequencies of skeletal anomalies and grossly malformed fetuses. Because MEKO is structurally related to the chemicals from these studies, MEKO may cause similar effects.

E. Neurotoxicity

Allied and Huls believe that existing data for MEKO indicate it is unlikely that MEKO will cause neurotoxic effects.

As a matter of testing policy, the substantial production, the substantial potential exposure to MEKO, and the lack of adequate neurotoxicity data justify definitive testing under TSCA. The available data are limited (Refs. 1, 16 and 24). There is no evidence that other than gross cage side observations were conducted in any of the existing studies, and EPA believes data from these studies is inadequate for evaluating the potential for neurotoxic effects from MEKO.

If neurotoxicity testing is to be conducted, Huls recommends that satellite groups be added to the subchronic probe study for the oncogenicity test to conserve animals.

As prescribed in 40 CFR 798.6400, the neurotoxicity tests may be combined with any other toxicity test as long as one of the requirements of either are violated by the combination.

Huls commented that, only if pathologic evidence from examination of a variety of neurologic tisses provides reason for concern, should the additional proposed neurotoxicity testing be required.

No data were provided by the commenters to support their contention that a persistent nervous system effect must have a basis in observable pathology. EPA does not agree that only those chemicals that test positive for neuropathological effects warrant testing for functional or behavioral type effects. The National Academy of Sciences also supports the consideration of both behavior and pathology in evaluation of neurotoxic effects (Refs. 43, 44, 45).

Allied believes that EPA has not considered the availability of contract laboratories to conduct the neurotoxicity studies.

EPA has determined that laboratories are available to complete the neurotoxicity testing requirements for the MEKO final rule (Ref. 38).

F. Pharmacokinetics

Allied believes that the pharmacokinetics test guideline has not undergone full scientific and technical evaluation and comment.

Because numerous comments were received on the generic pharmacokinetics guideline published in the MEKO proposed rule (53 FR 35838; September 15, 1988), EPA has decided to reevaluate the pharmacokinetics test standard and reporting requirements for MEKO. EPA plans to promulgate the pharmacokinetics test standard and related reporting requirements for MEKO in a separate rule.

G. Exposure

Allied contends that MEKO has insufficient exposure potential to pose

unreasonable risk of injury since workplace exposure is controlled during manufacture, and consumer and occupational exposure to MEKO from paint is low. In support of this claim, Allied submitted the results of an exposure study (Ref. 21).

EPA has reviewed this study (Ref. 20) and has found that the methodology used by Allied in developing exposure estimates was similar to the methodology used by EPA. Furthermore, the MEKO exposure levels and number of people exposed agree with or exceed those previously estimated by EPA. EPA has found that individual exposure estimates can vary a great deal with small changes in the assumptions used for the calculations. Exposure to MEKO is a range of values depending upon factors like ventilation, application method, duration, amount of paint used, and others. Moreover, as risk is a function of toxicity and exposure, levels of exposure have no meaning for determining risk until testing is conducted to determine the toxicity of a chemical. EPA believes the potential exposure to MEKO both with regard to the large numbers of individuals exposed and the duration and levels to which they are exposed are sufficient to support the TSCA section 4 (a)(1) (A) and (B) findings.

H. Economic Impact

Allied believes that the cost of testing will force Allied to abandon its production of MEKO. They state that price competition for Meko is keen, and foreign suppliers respond aggressively to opportunities to gain market share.

EPA believes that even though the annualized costs of testing may appear high relative to the product price, other factors indicate that the potential for economic impact is moderate. Because there are no cost-effective substitutes for MEKO, the price of MEKO can be increased to cover the cost of testing. In addition, because small quantities are used in paints, the increased cost of MEKO would have little effect on retail paint prices. EPA believes the market for alkyd resin paints is relatively stable, and alkyd resin paint manufacturers will continue to use MEKO in their formulations. In addition, EPA believes the market structure of MEKO may change, but the market will support testing for MEKO, and MEKO will continue to be available to domestic users.

EPA cost reimbursement procedures subject all manufacturers and importers, under the rule, to the same requirements for cost reimbursement. EPA has not received adequate information for evaluating the cost structure of foreign suppliers or of Allied. Foreign suppliers could use subsidies, as Allied has claimed, to increase market share. But, EPA believes subsidies could be used independent of a test rule for MEKO.

Allied believes the anti-skinning agent market will be eliminated in 5 years and that a 5-year amortization period will more than double EPA's estimated annual burden.

EPA notes there is some indication of a possible decline in the demand for alkyd resin paints, but does not believe that the anti-skinning market will be eliminated in 5 years. Nonetheless, EPA used Allied's estimate of a 5-year amortization period as a worst case scenario. The increase does not appropach the price of the substitutes for MEKO. No data have been provided to EPA to justify use of a 5-year amortization period.

Allied claims key economic determinants of competition profitability, and historical price competition were neglected in EPA's economic analysis.

EPA requested information on cost structure, profitability, and historical price competition (Ref. 26). Additional information provided to EPA was inadequate to change EPA's analysis of economic impact. However, EPA acknowledges that Allied may leave the MEKO market.

Allied believes the total cost of testing will be $2.3 million.

EPA estimates that testing will cost between $1.4 and $1.9 million. Allied has not substantiated its claim for higher costs; and, without further information, EPA cannot justify using higher cost estimates. Nonetheless, using Allied's cost figures does not significantly change the economic viability of MEKO and does not change the conclusion of the economic analysis.

III. Final Test Rule for MEKO

A. Findings

Although findings under either section 4(a)(1) (A) or (B) may independently support testing, EPA is basing its oncogenicity, mutagenicity, developmental toxicity, reproductive toxicity, neurotoxicity, and pharmacokinetics testing for MEKO on the authority of section 4(a)(1) (A) and (B) of TSCA.

Under section 4(a)(1)(B)(i) of TSCA, EPA finds that MEKO is produced in substantial quantities and there may be substantial human exposure to MEKO during its manufacture, processing, and use.

Although the total annual production of MEKO is confidential business information (CBI), public information indicates the total imports and domestic annual production are in excess of 5 million pounds per year (Ref. 2). Over two million consumers may be exposed to MEKO through use of oil-based paints. In addition, consumers may be exposed to MEKO through use of household cleaning products and adhesives, caulking, and repair products (Refs. 3, 4, and 9). An estimated 900,000 professional painters may be routinely exposed to MEKO through use of oil-based paints (Ref. 14), and an estimated 12,000 workers in 1,500 plants may be exposed through manufacture and processing of MEKO (Refs. 10 and 11). EPA finds that this production volume and potential exposure to large numbers of consumers and workers constitutes sufficient basis for making a finding under section 4(a)(1)(B)(i) of TSCA.

Under section 4(a)(1)(A)(i), EPA finds that the manufacture, processing, and use of MEKO may present an unreasonable risk of injury to human health due to its potential to cause oncogenic, mutagenic, reproductive, developmental, and subchronic effects. The finding for potential oncogenic risk is based upon data which indicate that acetoxime, a structural analogue of MEKO, caused benign and carcinogenic hepatocellular tumors in mice (Refs. 5 and 8). In addition, MEKO is positive in the mouse lymphoma gene mutation test (Ref. 28) which also raises concern that MEKO may be oncogenic.

The finding for potential mutagenic risk is based on data indicating that MEKO caused gene mutations in a mouse lymphoma test (Ref. 28). In addition, data on hydroxylamine, a possible metabolite of MEKO, indicates hydroxylamine is mutagenic in various systems (Refs. 6 and 7). Because there is concern for potential mutagenicity from hydroxylamine, there is concern for potential mutagenci risk from MEKO.

The finding for potential reproductive risk is based on adverse effects on the tests of rats from a 90-day exposure to MEKO (Ref. 6). In addition, hydroxylamine, a possible metabolite of MEKO, appears to adversely affect spermatogenesis, mammary gland development, prolactin levels, estrous cycle, and development of Graafian follicles (Refs. 5, 6, 30, 31, and 37). These results suggest potential reproductive risk from MEKO.

The finding for potential developmental risk is based on data from tests on MEK, a possible metabolite of MEKO, which indicate that MEK causes skeletal and soft tissue abnormalities in rats at 1,000 ppm and soft tissue abnormalities in rats at 3,000 ppm (Ref. 13). In addition, data on

hydroxylamine (Refs. 5, 6, 30, 32, 37, and 39), another possible metabolite of MEKO, suggest that hydroxylamine is developmentally toxic. These studies on the metabolites of MEKO suggest that MEKO may also potentially cause developmental effects.

The finding for potential blood effects risk is based on data from a 90-day oral toxicity study of MEKO (Ref. 30) which suggest that MEKO induces hemolytic anemia in the rat with compensatory erythropoiesis as described in unit II.E.3. of the proposed rule (53 FR 35838; September 15, 1988), and supports concern for the risk of blood effects from MEKO.

Although the available data on blood effects are adequate for risk assessment, it may be in the interest of those subject to this rule to further assess blood effects. The 90-day subchronic study (Ref. 30) does not provide a no-observed-adverse-effect level (NOAEL) for blood effects for MEKO. Uncertainty factors would be added to the lowest-observed-adverse-effect level (LOAEL) to establish acceptable levels of exposure. Testing to determine the NOAEL for blood effects associated with subchronic and chronic exposure would reduce the uncertainty in evaluating these effects.

The NOAEL for blood effects could be established in the subchronic range-finding studies for the MEKO oncogenicity test. These data should be developed according to the test guidelines at 40 CFR 798.2650, modified to direct specific attention towards the hematology profile. Hematology determinations (hematocrit, hemoglobin concentrations, erythrocyte count, total and differential leukocyte count, and a measure of clotting potential such as clotting time, prothrombin time, thromboplastin time, or platelet count, and certain clinical biochemistry determinations on blood) could be made on all groups, including controls, at day 30 and at day 90 of the test period for the rat. A chronic NOAEL for blood effects could be obtained by modifying the oncogenicity study to include hematology and blood biochemistry. This could be accomplished by modifying the oncogenicity test guideline at 40 CFR 798.3300 to include hematology determinations and certain clinical biochemistry determinations on blood for rats, in accordance with 40 CFR 798.3320, the combined chronic toxicity/oncogenicity test guideline. Satellite groups of rats may be necessary to avoid stress to the test animals from blood sampling and to provide sufficient animals for adequate blood collections.

The findings for the potential health effects as listed above along with the exposure cited above (Refs. 2, 3, 4, 9, 10, 11, and 14) are sufficient to support EPA's finding that the manufacturing, processing, and use of MEKO may present an unreasonable risk of injury to human health.

Under section 4(a)(1) (A)(ii) and (B)(ii), EPA finds that there are insufficient data and experience from which the potential oncogenicity, mutagenicity, reproductive toxicity, developmental toxicity, and neurotoxicity from manufacturing, processing, and use of MEKO can reasonably be determined or predicted.

Under section 4(a)(1) (A)(iii) and (B)(iii), EPA finds that testing of MEKO is necessary to develop such data for oncogenicity, mutagenicity, reproductive toxicity, developmental toxicity, and neurotoxicity. EPA believes the data resulting from this testing will be relevant to a determination as to whether manufacturing, processing, and use of MEKO does or does not present an unreasonable risk of injury to human health.

Because of the concerns for oncogenicity, mutagenicity, blood effects, reproductive toxicity, and developmental toxicity for the described exposures to MEKO, EPA finds that pharmacokinetics testing is necessary. Pharmacokinetics data will be used for making extrapolations of toxicologic data from species to species, from route to route of administration, and from high to low doses. Pharmacokinetics data will be used to detect differences between sexes relative to the metabolic processes of absorption, tissue distribution, biotransformation and excretion. In addition, these data will show if metabolic processes are modified by different routes of administration or by repeated dosing.

B. Required Testing and Test Standards

On the basis of the findings presented in Unit III.A. of this preamble, EPA is requiring that health effects testing be conducted for MEKO. The tests shall be conducted in accordance with EPA's TSCA Good Laboratory Practice Standards in 40 CFR part 792 and in accordance with specific test standards based on the guidelines set forth in 40 CFR part 798, or other published test methods as specified in this test rule and enumerated in the following Table.

REQUIRED TESTING, TEST STANDARDS AND REPORTING REQUIREMENTS FOR MEKO

Test	Test standard (40 CFR citation)	Reporting deadline for final report [1]	Number of interim (6 month) reports required
Health Effects:			
Oncogenicity, oral/inhalation	§ 798.3300	53	8
Developmental toxicity, oral	§ 798.4900	15	2
Reproductive toxicity, oral	§ 798.4700	29	4
Sex-linked recessive lethal assay in *Drosophila*	§ 798.5275	18	2
In vivo mammalian bone marrow cytogenetics tests:			
Chromosomal analysis, oral/inhalation	§ 798.5385	14/17	2
or			
Micronucleus assay, oral/inhalation	§ 798.5395	18/17	2
Functional observational battery: Acute and subchronic, oral/inhalation	§ 798.6050	18/21	2
Motor activity test: Acute and subchronic, oral/inhalation	§ 798.6200	18/21	2
Neuropathology: Subchronic oral/inhalation	§ 798.6400	18/21	2
Pharmacokinetics [2]	([3])	([3])	

[1] Number of months, beginning with the effective date of this rule. These reporting requirements have been adjusted from those specified in the proposed rule to be consistent with other test rules under section 4 and to allow additional time if inhalation testing is conducted.
[2] Pharmacokinetics test standard and reporting requirements will be promulgated at a later date.
[3] [Reserved].

The health effects tests to be conducted for MEKO are: (1) An oral or inhalation 2-year oncogenicity study, using the guideline at 40 CFR 798.3300; (2) an oral 2-species developmental toxicity study using the guideline at 40 CFR 798.4900; (3) an oral 2-generation reproductive toxicity study using the guideline at 40 CFR 798.4700 and including histopathology of the ovaries, and vaginal cytology for the last 3 weeks prior to mating to monitor the estrus cycle; (4) sex-linked recessive lethal gene mutation assay in *Drosophila* using the guideline at 40 CFR 798.5275, (5) oral or inhalation in vivo mammalian bone marrow cytogenetics test using the guideline for either the chromosomal analysis at 40 CFR 798.5385 or the micronucleus assay at 40 CFR 798.5395; and (6) acute and subchronic (90-day) oral or inhalation neurotoxicity tests, including: a functional observational battery using the guideline at 40 CFR 798.6050, and a motor activity test using the guideline at 40 CFR 798.6200, and subchronic neuropathology using the guideline at 40 CFR 798.6400.

The test guideline for the two-generation reproductive toxicity test (40 CFR 798.4700) in the test standard for MEKO is modified as follows: The integrity of the various cell stages of spermatogenesis shall be determined, with particular attention directed toward achieving optimal quality in the fixation and embedding. Preparations of testicular and associated reproductive organ samples for histology should follow the recommendations of Lamb and Chapin (Ref. 46), or an equivalent procedure. Histopathology of the testes shall be conducted on all P and F_1 adult males at the time of sacrifice, and histological analyses shall include evaluations of the spermatogenic cycle, i.e., the presence and integrity of the 14 cell stages. These evaluations should follow the guidance provided by Clermont and Percy (Ref. 47). Information shall also be provided regarding the nature and level of lesions observed in control animals for comparative purposes.

Data on female cyclicity shall be obtained by performing vaginal smears and cytology in parental (P) and first generation (F_1) females over the last 3 weeks prior to mating. The cell staging technique of Sadleir (Ref. 33), and the vaginal smear method in Hafez (Ref. 34), or equivalent methods should be used. Data shall be provided on whether the animal is cycling and the cycle length.

P and F_1 females shall continue to be exposed to MEKO for at least an additional 2 weeks following weaning of offspring to permit them to begin cycling once again. They shall then be sacrificed and their ovaries shall be serially sectioned with a sufficient number of sections examined to adequately detail oocyte and follicular morphology. The methods of Mattison and Thorgiersson (Ref. 35) and Pederson and Peters (Ref. 36) may provide guidance. The strategy for sectioning and evaluation is left to the discretion of the investigator, but shall be described in detail in the protocol and final report. The nature and background level of lesions in the control tissue shall also be noted. Gross and histopathologic evaluations shall be conducted on the mammary glands in F_1 females and second generation (F_2) pups sacrificed at weaning and in adult (F_1) females at the termination of the study. Any abnormalities shall be described in the final report.

An in vitro mammalian cytogenetics assay, and a sister chromatid exchange test on MEKO were conducted by NTP, which indicates that both of these tests were negative (Ref. 31). NTP is also conducting a gene mutation assay in *Salmonella*. EPA will evaluate this information along with lower-tier mutagenicity data developed through this test rule to determine if the mouse visible specific locus assay, the rodent dominant lethal assay, the rodent heritable translocation assay, or other mutagenic testing is necessary for MEKO. These upper-tier mutagenic tests are not being required at this time. EPA is requiring that the TSCA Health Effects Testing Guidelines referenced in the table, including all modifications made herein, be the test standards for the required tests for MEKO. The TSCA testing guidelines for health effects testing specify generally accepted minimum conditions for determining the health effects for substances such as MEKO to which humans are exposed.

C. Test Substance

EPA is requiring that MEKO of at least 99 percent purity be used as the test substance. MEKO of this purity is commercially available. EPA has specified a relatively pure substance for teting because EPA is interested in evaluating the effects attributable to MEKO itself.

D. Persons Required to Test

Section 4(b)(3)(B) of TSCA specifies that the activities for which EPA makes section 4(a) findings (manufacture, processing, distribution in commerce, use, and/or disposal) determine who bears the responsibility for testing a chemical. Manufacturers and persons who intend to manufacture the chemical are required to test if the findings are based on manufacturing ("manufacture" is defined in section 3(7) of TSCA to include "import"). Processor and persons who intend to process the chemical are required to test if the findings are based on processing. Manufacturers and processors and persons who intend to manufacture or process the chemical are required to test if exposure giving rise to the potential risk occurs during distribution in commerce, use, or disposal of the chemical.

Because EPA has found that there are insufficient data and experience to reasonably determine or predict the effects of the manufacture, processing, and use of MEKO on human health, EPA is requiring persons who manufacture and/or process, or who intend to manufacture and/or process MEKO, including persons who manufacture or process or intend to manufacture or process MEKO as a byproduct, or who import or intend to import products which contain MEKO, at any time from the effective date of the final test rule to the end of the reimbursement period be subject to the testing requirements contained in this final rule. Persons who manufacture, import, or process MEKO only as an impurity are not subject to these requirements. The end of the reimbursement period shall be at least 5 years after the last final report is submitted, but if it takes longer than 5 years to develop the data, the reimbursement period shall be extended an amount of time equal to that which was required to develop the data.

Because TSCA contains provisions to avoid duplicative testing, not every person subject to this rule must individually conduct testing. Section 4(b)(3)(A) of TSCA provides that EPA may permit two or more manufacturers or processors who are subject to the rule to designate one such person or a qualified third person to conduct the tests and submit data on their behalf. Section 4(c) provides that any person required to test may apply to EPA for an exemption from the requirement. EPA promulgated procedures for applying for TSCA section 4(c) exemptions in 40 CFR part 790.

Manufacturers (including importers) subject to this rule are required to submit either a letter of intent to perform testing or an exemption application within 30 days after the effective date of the final test rule. The required procedures for submitting such letters and applications are described in 40 CFR part 790.

Processors subject to this rule, unless they are also manufacturers, are not required to submit letters of intent or

exemption applications, or to conduct testing, unless manufacturers fail to submit notices of intent to test or later fail to sponsor the required tests. EPA expects that the manufacturers will pass an appropriate portion of the costs of testing on to processors through the pricing of their products or other reimbursement mechanisms. If manufacturers perform all the required tests, processors will be granted exemptions automatically. If manufacturers fail to submit notices of intent to test or fail to sponsor all the required tests, EPA will publish a separate notice in the **Federal Register** to notify processors to respond: this procedure is described in 40 CFR part 790.

EPA is not requiring the submission of equivalence data as a condition for exemption from the required testing for MEKO. As noted in Unit IV.B., EPA is interested in evaluating the effects attributable to MEKO itself and has specified a relatively pure substance for testing.

Manufacturers and processors subject to this test rule shall comply with the test rule development and exemption procedures in 40 CFR part 790 for single-phase rulemaking.

E. Reporting Requirements

All data developed under this rule shall be reported in accordance with TSCA Good Laboratory Practice (GLP) Standards which appear in 40 CFR part 792.

In accordance with 40 CFR part 790 under single-phase rulemaking procedures, test sponsors are required to submit individual study plans at least 45 days prior to the initiation of each test.

EPA is required by TSCA section 4(b)(1)(C) to specify the time period during which persons subject to a test rule must submit test data. EPA's reporting requirements for each of the test standards are specified in the table in Unit III.B. Note that longer reporting periods are provided for inhalation tests to calibrate and set up inhalation chambers. Progress reports for all tests are required at 6-month intervals starting 6 months from the effective date of the final test rule.

TSCA section 14(b) governs EPA disclosure of test data submitted pursuant to section 4 of TSCA. Upon receipt of test data required by this rule, EPA will publish a notice of receipt in the Federal Register as required by section 4(d).

Persons who export a chemical which is subject to a section 4 test rule are subject to the export reporting requirements of section 12(b) of TSCA. Final regulations interpreting the requirements of section 12(b) are in 40 CFR part 707. In brief, as of the effective date of the final test rule, an exporter of MEKO must report to EPA the first annual export or intended export of MEKO to each country. EPA will notify the foreign country concerning the test rule for the chemical.

F. Enforcement Provisions

EPA considers failure to comply with any aspect of a section 4 rule to be a violation of section 15 of TSCA. Section 15(1) of TSCA makes it unlawful for any person to fail or refuse to comply with any rule or order issued under section 4. Section 15(3) of TSCA makes it unlawful for any person to fail or refuse to: (1) Establish or maintain records, (2) submit reports, notices, or other information, or (3) permit access to or copying of records required by TSCA or any rule issued under TSCA. Section 15(4) makes it unlawful for any person to fail or refuse to permit entry or inspection as required by TSCA section 11. Section 11 applies to any "* * * establishment, facility, or other premises in which chemical substances or mixtures are manufactured, processed, stored, or held before or after their distribution in commerce * * *" EPA considers a testing facility to be a place where the chemical is held or stored and, therefore, subject to inspection. Laboratory inspections and data audits will be conducted periodically in accordance with the authority and procedures outlined in TSCA section 11 by duly designated representatives of the EPA for the purpose of determining compliance with the final rule for MEKO. These inspections may be conducted for purposes which include verification that testing has begun, schedules are being met, and reports accurately reflect the underlying raw data, interpretations, and evaluations, and to determine compliance with TSCA GLP Standards and the test standards established in the rule.

EPA's authority to inspect a testing facility also derives from section 4(b)(1) of TSCA, which directs EPA to promulgate standards for the development of test data. These standards are defined in section 3(12)(B) of TSCA to include those requirements necessary to assure that data developed under test rules are reliable and adequate, and to include such other requirements as are necessary to provide such assurance. EPA maintains that laboratory inspections are necessary to provide this assurance.

Violators of TSCA are subject to criminal and civil liability. Persons who submit materially misleading or false information in connection with the requirement of any provision of this rule may be subject to penalties which may be calculated as if they never submitted their data. Under the penalty provisions of section 16 of TSCA, any person who violates section 15 of TSCA could be subject to a civil penalty of up to $25,000 for each violation with each day of operation in violation constituting a separate violation. This provision applies primarily to manufacturers who fail to submit a letter of intent or an exemption request and continue manufacturing after the deadlines for such submissions. This provision also applies to processors who fail to submit a letter of intent or an exemption application and continue processing after EPA has notified them of their obligation to submit such documents (see 40 CFR 790.46(b)). Knowing or willful violations could lead to the imposition of criminal penalties of up to $25,000 for each day of violation, imprisonment for up to 1 year, or both. In determining the amount of penalty, EPA will take into account the seriousness of the violation and the degree of culpability of the violator, as well as all the other factors listed in TSCA section 16. Other remedies are available to EPA under section 17 of TSCA, such as seeking an injunction to restrain violations of TSCA section 4.

Individuals as well as corporations could be subject to enforcement actions. Sections 15 and 16 of TSCA apply to "any person" who violates provisions of TSCA. EPA may, at its discretion, proceed against individuals as well as companies themselves. In particular, this includes individuals who report false information or who cause it to be reported. In addition, the submission of false, fictitious, or fraudulent statements is a violation under 18 U.S.C. 1001.

IV. Economic Analysis

To assess the potential economic impact of this rule, EPA has prepared an economic analysis (Ref. 2) that evaluates the potential for significant economic impact on the industry as a result of the required testing. The economic analysis estimates the costs of conducting the required testing and evaluates the potential for significant adverse economic impact as a result of these tests costs by examining four market characteristics of MEKO: Price sensitivity of demand, industry cost characteristics, industry structure, and market expectations. Since, in the case of MEKO, preliminary analysis indicated some potential for significant economic impact, a more comprehensive and detailed analysis was conducted to

more precisely predict the magnitude and distribution of the expected impact.

Total testing costs for MEKO are estimated to range from $1.4 to $1.9 million. To predict the financial decision making practices of manufacturing firms, these costs have been annualized. Annualized costs are compared with annual revenue as an indication of potential impact. The annualized costs represent equivalent constant costs which would have to be recouped each year of the payback period to finance the testing expenditure in the first year. EPA recognizes that inhalation exposure during toxicity testing is more expensive than oral dosing. However, since exercising this option is voluntary, its cost has not been included in the economic analysis.

The annualized test costs, calculated using a cost of capital of 7 percent over a period of 15 years, range from $150,000 to $205,000. Though the annualized unit costs of the tests relative to the product price of MEKO appear to be high, EPA believes that the potential for adverse economic impact is moderate. This conclusion is based on the following observations: Demand for MEKO appears to be inelastic with respect to price in its largest end use as an antiskinning agent in alkyd paints because of the higher price of substitutes, and the market for MEKO appears to be stable.

Refer to the economic analysis which is contained in the public record for this rulemaking for a complete discussion of test cost estimation and potential for economic impact resulting from these costs (Ref. 2). Some of the information reviewed in the economic analysis is confidential business information and not available for public review. However, consideration of this information does not change the conclusions of the economic analysis.

V. Availability of Test Facilities and Personnel

Section 4(b)(1) of TSCA requires EPA to consider the reasonably foreseeable availability of the facilities and personnel needed to perform the testing required under the rule. Therefore, EPA conducted a study to assess the availability of test facilities and personnel to handle the additional demand for testing services created by section 4 test rules. Copies of the study, Chemical Testing Industry: Profile of Toxicological Testing (PB 82–140773), can be obtained through the National Technical Information Service (NTIS), 5285 Port Royal Road, Springfield, VA 22161 or the docket for this rule. On the basis of this study, EPA believes that there will be available test facilities and personnel to perform the testing specified in this rule.

EPA has recently reviewed the availability of contract laboratory facilities to conduct the neurotoxicity testing requirements (Ref. 38) and believes that facilities will be available for conducting these tests. The laboratory review indicates that few laboratories are currently conducting these tests according to TSCA test guidelines and TSCA GLP Standards. However, the barriers faced by testing laboratories to gear up for these tests are not formidable. Laboratories will need to invest in testing equipment and personnel training, but EPA believes that these investments will be recovered as the neurotoxicity testing program under TSCA section 4 continues. EPA's expectations of laboratory availability were borne out under the testing requirements of the C_9 aromatic hydrocarbon fraction test rule at 40 CFR 799.2175. Pursuant to that rule, the manufacturers were able to contract with a laboratory to conduct the testing according to TSCA test guidelines and TSCA GLP Standards.

VI. Rulemaking Record

EPA has established a record for this rulemaking proceeding (docket number OPTS–42099A). This includes:

A. Supporting Documentation

(1) **Federal Register** notices pertaining to this rule consisting of:

(a) Notice containing the ITC's recommendation of MEKO to the Priority List (50 FR 41417; Nov. 14, 1986) and comments on MEKO in response to that notice.

(b) Methyl Ethyl Ketoxime; Proposed Test Rule and Proposed Pharmacokinetics Test Guideline (53 FR 35838; September 15, 1988).

(c) Rule requiring TSCA section 8(a) and 8(d) reporting on MEKO (51 FR 41328; Nov. 14, 1986).

(d) TSCA test guidelines cited as test standards for this rule, 40 CFR part 798.

(e) Final rule on Ethyltoluenes, Trimethylbenzenes, and the C_9 Aromatic Hydrocarbon Fraction (50 FR 20662; May 17, 1985).

(f) Final rule on Diethylenetriamine (50 FR 21398, May 23, 1985).

(2) Communications before final rulemaking, consisting of:

(a) Written public comments and letters.

(b) Meeting summaries.

(c) Telephone contact reports.

(3) Reports—published and unpublished factual materials including: Chemical Testing Industry: Profile of Toxicological Testing (October, 1981).

B. References

(1) U.S. Environmental Protection Agency (USEPA). Technical Support in Response to Public Comments: Methyl Ethyl Ketoxime. Syracuse Research Corporation. Contract number 68D80117. Office of Toxic Substances, Washington, DC. (December 12, 1986).

(2) USEPA Economic Impact Analysis of Proposed Test Rule for Methyl Ethyl Ketoxime. Mathtech, Inc. Contract number 68–02–4209. Office of Toxic Substances, Washington, DC. (1989).

(3) USEPA. Consumer Exposure to Methyl Ethyl Ketoxime from Use of Alkyl Paint. Intragency memorandum from P. Kennedy, Exposure Evaluation Division, to B. Carton, Test Rules Development Branch, Office of Toxic Substances, Washington, DC. (September 30, 1987).

(4) USEPA. National Household Survey of Interior Painters. Westat, Inc. Office of Toxic Substances. Exposure Evaluation Division. Washington, DC. (July 1987).

(5) USEPA. Validation of Toxicity Studies on MEKO and Policy Paper on Acetoxime. Intra-agency memorandum from P. Fenner-Crisp, Health and Environmental Review Division, to G. Timm, Test Rules Development Branch, Office of Toxic Substances. (September 24, 1987).

(6) USEPA. Chemical Hazard Information Profile, Hydroxylamine. Prepared by Science Applications, Inc., Oak Ridge TN, for the Office of Toxic Substances. Washington, DC. (September 11, 1984).

(7) USEPA. Review of Genotoxicity Sections of CHIP on Hydroxylamine. Intra-agency memorandum from Michael C. Cimino, Health and Environmental Review Division, to William Thompson, Health and Environmental Review Division. Office of Toxic Substances, Washington, DC. (April 7, 1986).

(8) USEPA. Basis for Conclusion that Acetoxime and Methyl Ethyl Ketoxime are Possible Human Carcinogens. Intra-agency memorandum from Don Clay, Director, Office of Toxic Substances, to John A. Moore, Assistant Administrator for Pesticides and Toxic Substances, Washington, DC. (January 29, 1985).

(9) U.S. Consumer Product Safety Commission. CHIP Data Request, Interagency memorandum from E.W. Leland, to M. Wind, through W.R. Hobby, Washington, DC (October 11, 1985).

(10) National Occupational Hazard Survey Trade Name Ingredient Database. Copy of computer printout for 2-butanone, oxime, Washington, DC (May 10, 1985 and July 23, 1985).

(11) USEPA. Methyl Ethyl Ketoxime, Assessment of Occupational Exposure and Environmental Release of MEKO. Intra-agency memorandum from Greg Macek, Economics and Technology Division, to John Walker, Test Rules Development Branch. Office of Toxic Substances, Washington, DC (July 16, 1986).

(12) Kurita, H. "Experimental studies on methyl ethyl ketoxime toxicity". Department of Hygiene, Nagoya University School of Medicine. "Nagoya Journal of Medical Science" 29: 393–418 (1967).

(13) National Toxicology Program. Yang, R.S.H. "The toxicology of methyl ethyl ketone." "Residence Reviews", Volume 97. Springer-Verlag, New York Inc. P.O. Box 12233, Research Triangle Park, NC 27709 (1986).

(14) Stoecklein, P. Estimate for the number of commercial painters in the U.S. Letter from P. Stoecklein, American Painting Contracting, St. Louis, MO to L. Borghi, Dynamac Corporation, Rockville, MD (September 25, 1986).

(15) ICI Americas, Inc., Central Toxicology Laboratory. Letter from P.L. Patten to D. Farrar Re: Methyl Ethyl Ketoxime Proposed Pharmacokinetic Test Guideline, Wilmington, DE (November 18, 1988).

(16) Allied Signal, Inc. EPA's Proposed TSCA section 4 Test Rule for Methyl Ethyl Ketoxime, and Proposed Pharmacokinetics Test Guideline, Letter from P. Milley, Manager Oximes, Allied Signal, Inc., to USEPA, Washington, DC (November 14, 1988).

(17) Huls America, Inc. Document Control Number OPTS-42099 Proposed Test Rule for Methyl Ethyl Ketoxime, Letter from John Hodgson, Huls America, Inc., to USEPA, Washington, DC (November 14, 1988).

(18) USEPA. Transcript of Proceedings in the Matter of: Request to Present Oral Comments on MEKO. Heritage Reporting Corporation, Official Reporters, 1220 L St. NW, Washington, DC (December 15, 1988).

(19) National Toxicology Program. Maronpot, R.R. "Liver lesions in B6C3F1 Mice, Experience and Position." Research Triangle Park, NC (1987).

(20) USEPA. Arthur D. Little Report on MEKO Exposure. Intra-agency memorandum from P. Kennedy, Exposure Evaluation Division, to R. Jones, Test Rules Development Branch, Office of Toxic Substances, Washington, DC (January 30, 1989).

(21) Allied Signal, Inc. Exposure Evaluation for Methyl Ethyl Ketoxime in Paint Manufacture and Application. Report prepared by Arthur D. Little Inc., Morristown, NJ (January 16, 1989).

(22) Cosan Chemical Corp. Comments on methyl ethyl ketoxime; proposed rule, Washington, DC (November 11, 1988).

(23) Allied Signal Inc. Economic Matters Associated With Allied's Production and Sales of MEKO, Letter from P. Milley, Allied Signal Inc. to E. Coe, Regulatory Impacts Branch, Office of Toxic Substances, Washington, DC (January 9, 1989).

(24) Syracuse Research Inc. Technical Support in Response to Public Comments: Methyl Ethyl Ketoxime, Contract No. 68D80117, Task B-04, Office of Toxic Substances, Washington, DC (1989).

(25) USEPA. Response to Public Comments on Developmental and Reproductive Toxicity of MEKO, Intra-agency memorandum, from M. Campbell, Health and Environmental Review Division to R. Jones, Test Rules Development Branch, Office of Toxic Substances, Washington, DC (1989).

(26) USEPA. Request for Economics Information to Update EPA's Economic Analysis for MEKO, Letter from E. Coe, Regulatory Impacts Branch, to P. Milley, Allied Signal Inc., Morristown, NJ (December 20, 1988).

(27) National Cancer Institute (NCI). Mouse Lymphoma genesis Assay with No. 88080 (ML-NCI No. 160) Report prepared by Microbiological Associates under contract No. NO1-CP-41004, Silver Spring, MD (December 11, 1985).

(28) Allied Signal, Inc. Methyl Ethyl Ketoxime (MEKO), Letter from J.B. Charm, Corporate Product Safety, Allied Corporation, Morristown, NJ to R. Jones, USEPA, Washington, DC (March 5, 1984).

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(37) USEPA. Review of Strategy on Proposed Testing of MEKO. Intra-agency memorandum from E. Francis, Health and Environmental Review Division, to C.C. Lee, Health and Environmental Review Division, Office of Toxic Substances, Washington, DC. (September 16, 1987).

(38) USEPA. Evaluation of TSCA Test Guidelines for Neurotoxicity Testing. Mathtech, Inc. Contract number 68-02-4235. Regulatory Impacts Branch, Office of Toxic Substances, Washington, DC. (April 4, 1987).

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(40) USEPA. HERD review of the MEKO final rule. Intra-agency memorandum from P. Fenner-Crisp, Director Health and Environmental Review Division to R. Jones, Test Rules Development Branch. Office of Toxic Substances. Washington DC. (April 26, 1989).

(41) *Chemical Manufacturers Association* v. *USEPA*. 859 F.2d 977, (D.C. Cir. 1988).

(42) *Ausimont USA Inc.* v. *USEPA*, 838 F.2d 93, 98 (3rd Cir. 1988).

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Confidential business information (CBI), while part of the record is not available for public review. A public version of the record, from which CBI has been deleted, is available for inspection in the TSCA Public Docket Office, Rm. G-004, NE Mall, 401 M Street SW., Washington, DC, from 8 a.m. to 4 p.m., Monday through Friday, except legal holidays.

VII. Other Regulatory Requirements

A. Executive Order 12291

Under Executive Order 12291, EPA must judge whether a rule is "major" and therefore subject to the requirement of a Regulatory Impact Analysis. EPA has determined that this test rule is not major because it does not meet any of the criteria set forth in section 1(b) of the Order; i.e., it will not have an annual effect on the economy of at least $100 million, will not cause a major increase in costs or prices, and will not have a significant adverse effect on competition or the ability of U.S. enterprise to compete with foreign enterprises.

This rule was submitted to the Office of Management and Budget (OMB) for review as required by Executive Order 12291. Any written comments from OMB to EPA, and any EPA response to those comments, are included in the rulemaking record.

B. Regulatory Flexibility Act

Under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*, Pub. L. 96-354, September 19, 1980), EPA is certifying that this test rule will not have a significant impact on a substantial number of small businesses because: (1) They are not likely to perform testing themselves, or to participate in the

organization of the testing effort; (2) they will experience only very minor costs, if any, in securing exemption from testing requirements; and (3) they are unlikely to be affected by reimbursement requirements.

C. Paperwork Reduction Act

OMB has approved the information collection requirements contained in this final rule under the provisions of the Paperwork Reduction Act of 1980 (44 U.S.C. 3501 *et seq.*, Pub. L. 96–511, December 11, 1980), and has assigned OMB control number 2070–0033.

Public reporting burden for this collection of information is estimated to total 12,534 hours and to average 1,253 hours per test, including time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments or information, including suggestions for reducing this burden, to Chief, Information Policy Branch, PM–223, U.S. Environmental Protection Agency, 401 M Street SW., Washington, DC 20460; and to the Office of Information and Regulatory Affairs, Office of Management and Budget, Washington, DC 20503.

List of Subjects in 40 CFR Part 799

Testing, Environmental protection, Hazardous substances, Chemicals, Recordkeeping and reporting requirements.

Dated: August 28, 1989.

Victor J. Kimm,

Acting Assistant Administrator for Pesticides and Toxic Substances.

Therefore, 40 CFR part 799 is amended as follows:

PART 799—[AMENDED]

1. The authority citation for part 799 continues to read as follows:

Authority: 15 U.S.C. 2603, 2611, and 2625.

2. By adding new § 799.2700, to read as follows:

§ 799.2700 Methyl ethyl ketoxime.

(a) *Identification of test substance.* (1) Methyl ethyl ketoxime (MEKO, CAS No. 96–29–7) shall be tested in accordance with this section.

(2) MEKO of at least 99 percent purity shall be used as the test substance.

(b) *Persons required to submit study plans, conduct tests, and submit data.* All persons who manufacture (including import) or process or intend to manufacture or process MEKO, including persons who manufacture or process or intend to manufacture or process MEKO as a byproduct, or who import or intend to import products which contain MEKO, after the date specified in paragraph (e) of this section to the end of the reimbursement period, shall submit letters of intent to conduct testing, submit study plans, conduct tests and submit data, or submit exemption applications, as specified in this section, subpart A of this part, and parts 790 and 792 of this chapter for single-phase rulemaking. Persons who manufacture, import, or process MEKO only as an impurity are not subject to these requirements.

(c) *Health effects testing*—(1) *Pharmacokinetics testing*—(i) *Required testing.* Pharmacokinetics testing shall be conducted with MEKO in accordance with paragraph (c)(1)(ii) of this section.

(ii) [Reserved.]

(2) *Oncogenicity*—(i) *Required testing.* Oncogenicity testing shall be conducted in accordance with § 798.3300 of this chapter.

(ii) *Route of administration.* MEKO shall be administered either orally or by inhalation.

(iii) *Reporting requirements.* (A) Oncogenicity testing shall be completed and a final report submitted to EPA within 53 months of the date specified in paragraph (e) of this section.

(B) Interim progress reports shall be submitted to EPA at 6-month intervals, beginning 6 months after the date specified in paragraph (e) of this section, until submission of the final report to EPA.

(3) *Developmental toxicity*—(i) *Required testing.* Developmental toxicity testing shall be conducted in a rodent and a nonrodent mammalian species in accordance with § 798.4900 of this chapter.

(ii) *Route of administration.* MEKO shall be administered orally.

(iii) *Reporting requirements.* (A) Developmental toxicity testing shall be completed and a final report submitted to EPA within 15 months of the date specified in paragraph (e) of this section.

(B) Interim progress reports shall be submitted to EPA at 6-month intervals, beginning 6 months after the date specified in paragraph (e) of this section.

(4) *Reproductive toxicity*—(i) *Required testing.* (A) Reproductive toxicity testing shall be conducted orally in accordance with § 798.4700 of this chapter except for the provisions in paragraphs (c) (8)(iii) and (9)(i) of § 798.4700.

(B) For the purpose of this section, the following provisions also apply:

(*1*) The following organs and tissues, or representative samples thereof, shall be preserved in a suitable medium for possible future histopathological examination: Vagina, uterus, oviducts, ovaries, testes, epididymides, vas deferens, seminal vesicles, prostate, pituitary gland, and, target organ(s) of all P and F_1 animals selected for mating.

(*2*)(*i*) Full histopathology shall be conducted on the organs and tissues listed in paragraph (c)(4)(i)(B)(*1*) of this section for all high dose and control P and F_1 animals selected for mating.

(*ii*) The integrity of the various cell stages of spermatogenesis shall be determined, with particular attention directed toward achieving optimal quality in the fixation and embedding. Preparations of testicular and associated reproductive organ samples for histology should follow the recommendations of Lamb and Chapin (1985) under paragraph (d)(1) of this section, or an equivalent procedure. Histopathology of the testes shall be conducted on all P and F_1 adult males at the time of sacrifice, and histological analyses shall include evaluations of the spermatogenic cycle, i.e., the presence and integrity of the 14 cell stages. These evaluations should follow the guidance provided by Clermont and Percy (1957) under paragraph (d)(2) of this section. Information shall also be provided regarding the nature and level of lesions observed in control animals for comparative purposes.

(*iii*) Data on female cyclicity shall be obtained by conducting vaginal cytology in P and F_1 females over the last 3 weeks prior to mating; the cell staging technique of Sadleir (1978) and the vaginal smear method in Hafez (1978) under paragraphs (d)(3) and (d)(7) of this section, respectively, or equivalent methods should be used. Data shall be provided on whether the animal is cycling and the cycle length.

(*iv*) P and F_1 females shall continue to be exposed to MEKO for at least an additional 2 weeks following weaning of offspring to permit them to begin cycling once again. They shall then be sacrificed and their ovaries shall be serially sectioned with a sufficient number of sections examined to adequately detail oocyte and follicular morphology. The methods of Mattison and Thorgiersson (1979) and Pederson and Peters (1968) under paragraphs (d) (4) and (5) of this section, respectively, may provide guidance. The strategy for sectioning and evaluation is left to the discretion of the investigators, but shall be described in detail in the study plan and final report. The nature and background level of lesions in control tissue shall also be noted.

(*v*) Gross and histopathologic evaluations shall be conducted on the mammary glands in F_1 females and F_2

pups sacrificed at weaning and in adult F_1 females at the termination of the study. Any abnormalities shall be described in the final report.

(ii) *Reporting requirements.* (A) Reproductive toxicity testing shall be completed and a final report submitted to EPA within 29 months of the date specified in paragraph (e) of this section.

(B) Interim progress reports shall be submitted to EPA at 6-month intervals, beginning six months after the date specified in paragraph (e) of this section until submission of the final report to EPA.

(5) *Mutagenic effects—gene mutations*—(i) *Required testing.* The sex-linked recessive lethal assay in *Drosophila* shall be conducted with MEKO in accordance with § 798.5275 of this chapter.

(ii) *Reporting requirements.* (A) The sex-linked recessive lethal assay in *Drosophila* shall be completed and a final report submitted to EPA within 18 months of the date specified in paragraph (e) of this section.

(B) Interim progress reports shall be submitted to EPA at 6-month intervals beginning 6 months after the date specified in paragraph (e) of this section.

(6) *Mutagenic effects—chromosomal aberrations*—(i) *Required testing.* (A) An in vivo mammalian bone marrow cytogenetics test shall be conducted with MEKO in accordance with either § 798.5385 (chromosomal analysis) of this chapter, or § 798.5395 (micronucleus assay) of this chapter except for the provisions in paragraphs (d)(5) (ii), (iii), and (iv) of §§ 798.5385 and 798.5395.

(B) For the purpose of this section, the following provisions also apply if § 798.5385 of this chapter is used in conducting the test:

(*1*) *Dose levels and duration of exposure.* At least three dose levels shall be tested. The highest dose tested shall be the maximum tolerated dose or that dose producing some signs of cytotoxicity (e.g., partial inhibition of mitosis) or shall be the highest dose attainable. Under oral administration, animals shall be exposed once per day for 5 consecutive days. Under administration by inhalation, animals shall be exposed 6 hours per day for 5 consecutive days.

(*2*) *Route of administration.* Animals shall be exposed to MEKO either orally or by inhalation.

(C) For the purpose of this section, the following provisions also apply if § 798.5395 of this chapter is used in conducting the test:

(*1*) *Dose levels and duration of exposure.* At least three dose levels shall be tested. The highest dose tested shall be the maximum tolerated dose or that dose producing some signs of cytotoxicity (e.g., a change in the ratio of polychromatic to normochromatic erythrocytes) or shall be the highest dose attainable. Under oral administration animals shall be exposed once per day for 5 consecutive days. Under administration by inhalation, animals shall be exposed 6 hours per day for 5 consecutive days.

(*2*) *Route of administration.* Animals shall be exposed to MEKO either orally or by inhalation.

(ii) *Reporting requirements.* (A) The oral in vivo mammalian cytogenetics test shall be completed and a final report submitted to EPA within 14 months of the date specified in paragraph (e) of this section. The inhalation in vivo mammalian cytogenetics test shall be completed and a final report submitted to EPA within 17 months of the date specified in paragraph (e) of this section.

(B) Interim progress reports shall be submitted to EPA at 6-month intervals, beginning 6 months after the date specified in paragraph (e) of this section.

(7) *Neurotoxicity*—(i) *Required testing*—(A) *Functional observational battery.* (*1*) A functional observational battery shall be conducted with MEKO in accordance with § 798.6050 of this chapter except for the provisions in paragraphs (d) (4)(ii), (5), and (6) of § 798.6050.

(*2*) For the purpose of this section, the following provisions also apply:

(*i*) *Route of exposure.* Animals shall be exposed either orally or by inhalation.

(*ii*) *Lower doses.* The data from the lower doses shall show either graded dose-dependent effects in at least two of all the doses tested, including the highest dose, or no neurotoxic (behavioral) effects at any dose tested.

(*iii*) *Duration and frequency of exposure.* For the oral acute testing, animals shall be exposed once. For the oral subchronic testing, animals shall be exposed once per day 5 days per week for a 90-day period. For the inhalation acute testing, animals shall be exposed for 6 hours for 1 day. For the inhalation subchronic testing, animals shall be exposed 6 hours per day 5 days per week for a 90-day period.

(B) *Motor activity.* (*1*) A motor activity test shall be conducted with MEKO in accordance with § 798.6200 of this chapter except for provisions in paragraphs (d) (4)(ii), (5), and (6) of § 798.6200.

(*2*) For the purpose of this section, the following provisions also apply:

(*i*) *Route of exposure.* Animals shall be exposed either orally or by inhalation.

(*ii*) *Lower doses.* The data from the lower doses shall show either graded dose-dependent effects in at least two of all the doses tested including the highest dose, or no neurotoxic (behavioral) effects at any dose tested.

(*iii*) *Duration and frequency of exposure.* For the acute oral testing, animals shall be exposed once. For the oral subchronic testing, animals shall be exposed once per day 5 days per week for a 90-day period. For the acute inhalation testing, animals shall be exposed for 6 hours for 1 day. For the inhalation subchronic testing, the animals shall be exposed for 6 hours per day 5 days per week for a 90-day period.

(C) *Neuropathology.* (*1*) A neuropathology test shall be conducted with MEKO in accordance with § 798.6400 of this chapter except for the provisions in paragraphs (d) (4)(ii), (5), (6), and (8)(iv)(C) of § 798.6400.

(*2*) For the purpose of this section, the following provisions also apply:

(*i*) *Route of exposure.* Animals shall be exposed either orally or by inhalation.

(*ii*) *Lower doses.* The data from the lower doses shall show either graded dose-dependent effects in at least two of all the doses tested including the highest dose, or no neurotoxic (behavioral) effects at any dose tested.

(*iii*) *Duration and frequency of exposure.* Animals shall be exposed orally once per day 5 days per week for a 90-day period; or if exposed by inhalation, for 6 hours per day 5 days per week for a 90-day period.

(*iv*) *Clearing and embedding.* After dehydration, tissue specimens shall be cleared with xylene and embedded in paraffin or paraplast except for the sural nerve which should be embedded in plastic. Multiple tissue specimens (e.g., brain, cord, ganglia) may be embedded together in one single block for sectioning. All tissue blocks shall be labeled to provide unequivocal identification. A suggested method for plastic embedding is described by Spencer et al. in paragraph (d)(6) of this section.

(ii) *Reporting requirements.* (A) The neurotoxicity tests required under this paragraph (c)(7) and administered orally shall be completed and the final results submitted to EPA within 18 months of the date specified in paragraph (e) of this section. The neurotoxicity tests required under this paragraph (c)(7) and administered by inhalation shall be

completed and the final results submitted to EPA within 21 months of the date specified in paragraph (e) of this section.

(B) Interim progress reports shall be submitted to EPA at 6-month intervals beginning 6 months after the date specified in paragraph (e) of this section until submission of the final report to EPA.

(d) *References.* For additional background information, the following references should be consulted.

(1) Lamb, J. and Chapin, R.E. "Experimental models of male reproductive toxicology." In: "Endocrine Toxicity." Thomas, J.A., Korach, K.S., and McLachlan, J.A., eds. New York, NY: Raven Press. pp. 85–115. (1985).

(2) Clermont, Y. and Percey, B. "Quantitative study of the cell population of the seminiferous tubules in immature rats." "American Journal of Anatomy." 100:241–267. (1957).

(3) Sadleir, R.M.F.S. "Cycles and seasons." In: "Reproduction in Mammals: I. Germ Cells and Fertilization." Austin, R. and Short R.V., eds. New York, NY: Cambridge Press. Chapter 4. (1978).

(4) Mattison, D.R. and Thorgiersson, S.S. "Ovarian aryl hydrocarbon hydroxylase activity and primordial oocyte toxicity of polycyclic aromatic hydrocarbons in mice." "Cancer Research." 39:3471–3475. (1979).

(5) Pederson, T. and Peters, H. "Proposal for classification of oocytes and follicles in the mouse ovary." "Journal of Reproduction and Fertility." 17:555–557. (1968).

(6) Spencer, P.S., Bischoff, M., and Schaumburg, H.H. "Neuropathological methods for the detection of neurotoxic disease." In: "Experimental and Clinical Neurotoxicology." Spencer, P.S. and Schaumburg, H.H., eds. Baltimore, MD: Williams and Wilkins, pp. 743–757 (1980).

(7) Hafez, E.S., ed., "Reproduction and Breeding Techniques for Laboratory Animals." Chapter 10. Philadelphia: Lea and Febiger. (1970).

(e) *Effective dates.* (1) The effective date of this final rule is October 27, 1989.

(2) The guidelines and other test methods cited in this section are referenced here as they exist on October 27, 1989.

(Information collection requirements have been approved by the Office of Management and Budget under Control Number 2070-0033).

[FR Doc. 89–21497 Filed 9–12–89; 8:45 am]

BILLING CODE 6560–50–M

GENERAL SERVICES ADMINISTRATION

41 CFR Part 301–4

[FTR Amendment 1]

Federal Travel Regulation

AGENCY: Federal Supply Service, GSA.

ACTION: Final rule.

SUMMARY: This final rule amends the Federal Travel Regulation to increase the mileage reimbursement rate from 22.5 cents to 24 cents per mile for use of privately owned automobiles when authorized as advantageous to the Government. This FTR amendment reflects the results of the General Services Administration's (GSA's) report to Congress on the investigation of the cost of operating privately owned automobiles.

EFFECTIVE DATE: This final rule is effective for travel performed on or after September 17, 1989.

FOR FURTHER INFORMATION CONTACT: Raymond F. Price, Jr., Travel Management Division (FBT), Washington, DC 20406, telephone FTS 557–1253 or commercial (703) 557–1253.

SUPPLEMENTARY INFORMATION: The Travel Expense Amendments Act of 1975 (Pub. L. 94–22, May 19, 1975) authorizes the Administrator of General Services to issue regulations prescribing, within statutory limits, mileage allowance rates. GSA is required by law to periodically investigate the cost of operating privately owned vehicles (automobiles, airplanes, and motorcycles) to employees while on official travel and report the results of these investigations to the Congress. GSA reported the results of the December 1988 investigation of the cost of operating privately owned automobiles to the Congress indicating that the governing regulation would be revised to reflect an increase in the mileage allowance for use of privately owned automobiles. Necessary adjustments are reflected in this amendment to the FTR.

GSA has determined that this rule is not a major rule for the purposes of Executive Order 12291 of February 17, 1981, because it is not likely to result in an annual effect on the economy of $100 million or more, a major increase in costs to consumers or others, or significant adverse effects. GSA has based all administrative decisions underlying this rule on adequate information concerning the need for, and consequences of, this rule; has determined that the potential benefits to society from this rule outweigh the potential costs and has maximized the net benefits; and has chosen the alternative approach involving the least net cost to society.

List of Subjects in 41 CFR Part 301–4

Government employees, Travel, Travel allowances, Travel and transportation expenses.

For the reasons set out in the preamble, 41 CFR part 301–4 is amended as follows:

PART 301–4—REIMBURSEMENT FOR USE OF PRIVATELY OWNED CONVEYANCES

1. The authority citation for part 301–4 continues to read as follows:

AUTHORITY: 5 U.S.C. 5701–5709; E.O. 11609, July 22, 1971 (36 FR 13747).

2. Section 301–4.2 is amended by revising paragraphs (a)(2), (d)(1), and (d)(2) to read as follows:

§ 301–4.2 When use of a privately owned conveyance is advantageous to the Government.

(a) * * *

(2) For use of a privately owned automobile: 24 cents per mile.

* * * * *

(d) * * *

(1) *Round trip instead of taxicab to carrier terminals.* Instead of using a taxicab under § 301–2.3(c), payment on a mileage basis at the rate of 24 cents per mile and other allowable costs as set forth in § 301–4.1(c) shall be allowed for the round-trip mileage of a privately owned automobile used by an employee going from either the employee's home or place of business to a terminal or from a terminal to either the employee's home or place of business. However, the amount of reimbursement for the round trip shall not in either instance exceed the taxicab fare, including tip, allowable under § 301–2.3(c) for a one-way trip between the applicable points.

(2) *Round trip instead of taxicab between residence and office on day of travel.* Instead of using a taxicab under § 301–2.3(d) (in connection with official travel requiring at least one night's lodging), payment on a mileage basis at the rate of 24 cents per mile and other allowable costs as set forth in § 301–4.1(c) shall be allowed for round-trip mileage of a privately owned automobile used by an employee going from the employee's residence to the employee's place of business or returning from place of business to residence on a day travel is performed. However, the amount of reimbursement for the round trip shall not exceed the taxicab fare, including tip, allowable

under § 301–2.3(d) for a one-way trip between the points involved.

* * * * *

Dated: August 24, 1989.

Richard G. Austin,

Acting Administrator of General Services.

[FR Doc. 89–21478 Filed 9–12–89; 8:45 am]

BILLING CODE 6820–24–M

41 CFR Parts 302–6 and 302–12

[FTR Amendment 2]

Federal Travel Regulation

AGENCY: Federal Supply Service, GSA.

ACTION: Final rule.

SUMMARY: Because of a change in the law, this final rule amends the Federal Travel Regulation to authorize, under certain conditions, reimbursement of allowable residence transaction expenses for employees transferred from an official station in a foreign area to a different nonforeign area official station than the one from which the employee was transferred when assigned to the foreign post of duty.

EFFECTIVE DATE: This final rule is effective for employees whose effective date of transfer (date the employee reports for duty at the new nonforeign area official station) is on or after February 19, 1988.

FOR FURTHER INFORMATION CONTACT: Doris L. Jones, Regulations Branch (FBTR), Washington, DC 20406, telephone FTS 557–1253 or commercial (703) 557–1253.

SUPPLEMENTARY INFORMATION: The Continuing Resolution for fiscal year 1988, Public Law 100–202 (101 Stat. 1329–430, 431) December 22, 1987, authorized new relocation benefits for certain transferred employees. Section 628 of that law amended 5 U.S.C. 5724a to specifically authorize, under certain specified conditions, reimbursement of allowable residence transaction expenses for employees transferred from an official station in a foreign area to a different nonforeign area official station than the one the employee left when transferred to the foreign post of duty.

The General Services Administration has determined that this rule is not a major rule for the purposes of Executive Order 12291 of February 17, 1981, because it is not likely to result in an annual effect on the economy of $100 million or more; a major increase in costs to consumers or others; or significant adverse effects. The General Services Administration has based all administrative decisions underlying this rule on adequate information concerning the need for, and consequences of, this rule; has determined that the potential benefits to society from this rule outweigh the potential costs; has maximized the net benefits; and has chosen the alternative approach involving the least net cost to society.

List of Subjects in 41 CFR Parts 302–6 and 302–12

Government employees, Transfers, Relocation allowances and entitlements.

For the reasons set out in the preamble, 41 CFR parts 302–6 and 302–12 are amended as follows:

PART 302–6—ALLOWANCE FOR EXPENSES INCURRED IN CONNECTION WITH RESIDENCE TRANSACTIONS

1. The authority citation for part 302–6 continues to read as follows:

Authority: 5 U.S.C. 5721–5734; 20 U.S.C. 905(a); E.O. 11609, July 22, 1971 (36 FR 13747).

2. Section 302–6.1 is amended by revising the introductory text, paragraphs (a), (b), (c), (d), and (e)(1), and by adding paragraph (g) to read as follows:

§ 302–6.1 Conditions and requirements under which allowances are payable.

To the extent allowable under this part 302–6, the Government shall reimburse an employee for expenses required to be paid by him/her in connection with the sale of one residence at his/her old official station, for purchase (including construction) of one dwelling at his/her new official station, or for the settlement of an unexpired lease involving his/her residence or a lot on which a mobile home used as his/her residence was located at the old official station provided the conditions set forth in this section are met:

(a) *Transfers covered—agreement required.* A permanent change of station is authorized or approved and, except as provided in paragraph (g) of this section, the old and new official stations are located within the 50 States, the District of Columbia, the territories and possessions of the United States, the Commonwealth of Puerto Rico, or the former Canal Zone area (i.e., areas and installations in the Republic of Panama made available to the United States under the Panama Canal Treaty of 1977 and related agreements (as described in section 3(a) of the Panama Canal Act of 1979)), and the employee has signed an agreement as required in § 302–1.5. (See exclusions in § 302–6.4.)

(b) *Location and type of residence.* The residence or dwelling is the residence as described in § 302–1.4(j), which may be a mobile home and/or the lot on which such mobile home is located or will be located. These criteria also apply to the former nonforeign area official station residence of employees who are eligible for residence transaction expenses under paragraph (g) of this section (see definition in paragraph (g)(1)(i) of this section).

(c) *Title requirements.* The title to the residence or dwelling at the old or new official station, or the interest in a cooperatively owned dwelling or in an unexpired lease, is in the name of the employee alone, or in the joint names of the employee and one or more members of his/her immediate family, or solely in the name of one or more members of his/her immediate family. For an employee to be eligible for reimbursement of the costs of selling a dwelling or terminating a lease at the old official station, the employee's interest in the property must have been acquired prior to the date the employee was first officially notified of his/her transfer to the new official station. In the case of employees covered by paragraph (g) of this section, the employee's interest must have been acquired prior to the date the employee was first officially notified of his/her transfer to the foreign area.

(d) *Occupancy requirements.* The dwelling for which reimbursement of selling expenses is claimed was, except as provided in paragraph (g) of this section, the employee's residence at the time he/she was first officially notified by competent authority of his/her transfer to the new official station.

(e) *Time limitation*—(1) *Initial period.* The settlement dates for the sale and purchase or lease termination transactions for which reimbursement is requested are not later than 2 years after the date that the employee reported for duty at the new official station. For employees eligible under paragraph (g) of this section, new official station means the official station to which the employee reports for duty when reassigned or transferred from a foreign area.

* * * * *

(g) *Transfer from a foreign area to a nonforeign area*—(1) *Definitions.* For purposes of this paragraph (g), the following definitions apply:

(i) *Former nonforeign area official station.* This term means the official station from which the employee was transferred when assigned to the post of duty in the foreign area.

(ii) *Nonforeign area.* Nonforeign area includes the United States, its territories or possessions, the Commonwealth of Puerto Rico, or the former Canal Zone

area (i.e., areas and installations in the Republic of Panama made available to the United States pursuant to the Panama Canal Treaty of 1977 and related agreements (as described in section 3(a) of the Panama Canal Act of 1979)).

(iii) *Foreign area.* Foreign area refers to any area not defined as a nonforeign area.

(2) *Applicability.* The provisions of this part 302–6 are applicable, as specified in this paragraph (g), to employees who have completed an agreed upon tour of duty in a foreign area and instead of being returned to the former nonforeign area official station, are reassigned or transferred in the interest of the Government to a different nonforeign area official station than the official station from which the employee was transferred when assigned to the foreign post of duty. The distance between the former and new official station must meet the mileage criteria specified in § 302–1.7 for short distance transfers.

(3) *Authorized reimbursement.* Generally, an employee is required to serve at least one tour of duty in a foreign area and retain a residence in a nonforeign area with the expectation of returning to the former official station in the nonforeign area. However, there are instances when an employee completes a tour of duty in a foreign area and is subsequently transferred to a different official station or post of duty in a nonforeign area than the one from which he/she transferred when assigned to the foreign post of duty. When this type of transfer is authorized or approved, reimbursement is allowable for real estate expenses required to be paid by the employee in connection with:

(i) The sale of the residence (or the settlement of an unexpired lease) at the official station from which the employee was transferred when he/she was assigned to a post of duty located in a foreign area; and

(ii) The purchase of a residence at the new official station when the employee is transferred in the interest of the Government from a post of duty located in a foreign area to a nonforeign area official station (other than the official station from which he/she was transferred when assigned to the foreign post of duty).

(4) *Reimbursement limitations.* Reimbursement under this paragraph (g) is prohibited for any sale (or settlement of an unexpired lease) or purchase transaction that occurs prior to the employee's first being officially notified (generally in the form of a change of official station travel authorization) that instead of returning to the former nonforeign area official station, he/she will be reassigned or transferred to a different nonforeign area official station than the one from which he/she was transferred when assigned to the foreign post of duty.

(5) *Service agreement required.* A signed service agreement shall be required as prescribed in § 302.1.5 for any employee who is eligible for reimbursement of residence transaction expenses authorized under this paragraph (g).

PART 302–12—USE OF RELOCATION SERVICE COMPANIES

3. The authority citation for Part 302–12 continues to read as follows:

Authority: 5 U.S.C. 5721–5734; 20 U.S.C. 905(a); E.O. 11609, July 22, 1971 (36 FR 13747); E.O. 12466, February 27, 1984 (49 FR 7349); E.O. 12522, June 24, 1985 (50 FR 26337).

4. Section 302–12.4 is amended by revising paragraph (b)(3) to read as follows:

§ 302–12.4 General conditions and limitations for eligibility.

* * * * *

(b) * * *

(3) Employees assigned or transferred to or from a post of duty in a foreign area except employees eligible for reimbursement of residence transaction expenses as provided in § 302.6.1(g).

Dated: August 24, 1989.

Richard G. Austin,

Acting Administrator of General Services.

[FR Doc. 89–21479 Filed 9–12–89; 8:45 am]

BILLING CODE 6820–24–M

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

43 CFR Public Land Order 6747

[ID–943–09–4214–10; IDI–27036]

Partial Revocation of Secretarial Order Dated October 8, 1921; Idaho

AGENCY: Bureau of Land Management, Interior.

ACTION: Public Land Order.

SUMMARY: This order revokes a Secretarial order which withdrew 80 acres of National Forest System land from surface entry for use by the U.S. Forest Service for Stock Driveway No. 48 in the Sawtooth National Forest. The land is not needed for the purpose for which it was withdrawn. This action will open the land to surface entry and allow for a proposed exchange. The land will remain closed to mining and mineral leasing due to an overlapping withdrawal.

EFFECTIVE DATE: October 13, 1989.

FOR FURTHER INFORMATION CONTACT: Larry Lievsay, BLM Idaho State Office, 3380 Americana Terrace, Boise, Idaho 83706, 208–334–1735.

By virtue of the authority vested in the Secretary of the Interior by section 204 of the Federal Land Policy and Management Act of 1976, 90 Stat. 2751; 43 U.S.C. 1714, it is ordered as follows:

1. The Secretarial order dated October 8, 1921, is hereby revoked insofar as it affects the following described land:

Boise Meridian

T. 7 N., R. 14 E.,
Sec. 24, W½SE¼.

The area described contains 80 acres in Blaine County.

2. At 9:00 a.m. on October 13, 1989, the land described shall be opened to such forms of disposition as may by law be made of National Forest System land, subject to valid existing rights, the provisions of existing withdrawals, other segregations of record, and the requirements of applicable law. The land will remain closed to mining and mineral leasing.

Dated: September 1, 1989.

Frank A. Bracken,

Under Secretary of the Interior.

[FR Doc. 89–21506 Filed 9–12–89; 8:45 am]

BILLING CODE 4310–GG–M

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR 217 and 227

Sea Turtle Conservation; Shrimp Trawling Requirements

AGENCY: National Marine Fisheries Service, NOAA, Commerce.

ACTION: Reinstatement of regulations.

SUMMARY: NOAA published an interim final rule on August 10, 1989, as a temporary substitute for the rule that requires shrimp fishermen in the Gulf of Mexico (Gulf) and the Atlantic Ocean off the coast of the southeastern United States to use Turtle Excluder Devices (TEDs) to reduce incidental captures of endangered and threatened species of sea turtles during shrimp fishing operations. The interim final rule allowed shrimp fishermen in offshore waters to choose between continuing to use TEDs or to restrict trawling times to specific 105-minute periods. That rule expired on September 8, 1989, at 12:01