Authority: 38 U.S.C. 501, 3701–3704, 3707, 3710–3714, 3719, 3720, 3729, 3762, unless otherwise noted.

2. In § 36.4306a, paragraphs (a)(3) through (a)(5) are revised and paragraphs (a)(6) and (a)(7) are added, to read as follows:

§ 36.4306a Interest rate reduction refinancing loan.

(a) * * *

(3) The monthly principal and interest payment on the new loan must be lower than the payment on the loan being refinanced, except when the term of the new loan is shorter than the term of the loan being refinanced; or the new loan is a fixed-rate loan that refinances a VA-guaranteed adjustable rate mortgage; or the increase in the monthly payments on the loan results from the inclusion of energy efficient improvements, as provided by § 36.4336(a)(4); or the loan is approved by the Secretary in advance after determining that the new loan is necessary to prevent imminent foreclosure and the veteran qualifies for the new loan under the credit standards contained in § 36.4337.

(4) The amount of the refinancing loan may not exceed:

(i) An amount equal to the balance of the loan being refinanced, which must be current, except in cases described in paragraph (a)(5) of this section, and such closing costs as authorized by § 36.4312(d) and a discount not to exceed 2 percent of the loan amount; or

(ii) In the case of a loan to refinance an existing VA-guaranteed or direct loan and to improve the dwelling securing such loan through energy efficient improvements, the amount referred to with respect to the loan under paragraph (a)(4)(i) of this section, plus the amount authorized by § 36.4336(a)(4).

(Authority: 38 U.S.C. 3703, 3710)

(5) In any case where the loan being refinanced is delinquent, the new loan will be guaranteed only if it is approved by the Secretary in advance after determining that the veteran qualifies for the loan under the credit standards contained in § 36.4337. In such cases, the term ''balance of the loan being refinanced'' shall include any past due installments, plus allowable late charges.

(6) The dollar amount of guaranty on the 38 U.S.C. 3710(a)(8) or (a)(9)(B)(i) loan may not exceed the original dollar amount of guaranty applicable to the loan being refinanced, less any dollar amount of guaranty previously paid as a claim on the loan being refinanced; and

(7) The term of the refinancing loan (38 U.S.C. 3710(a)(8)) may not exceed the original term of the loan being refinanced plus ten years, or the maximum loan term allowed under 38 U.S.C. 3703(d)(1), whichever is less. For manufactured home loans that were previously guaranteed under 38 U.S.C. 3712, the loan term, if being refinanced under 38 U.S.C. 3710(a)(9)(B)(i), may exceed the original term of the loan but may not exceed the maximum loan term allowed under 38 U.S.C. 3703(d)(1).

(Authority: 38 U.S.C. 3703(c)(1), 3710(e)(1))

* * * * *

3. In § 36.4337, paragraph (a) is revised to read as follows:

§ 36.4337 Underwriting standards, processing procedures, lender responsibility and lender certification.

(a) *Use of standards.* The standards contained in paragraphs (c) through (j) of this section will be used to determine that the veteran's present and anticipated income and expenses, and credit history are satisfactory. These standards do not apply to loans guaranteed pursuant to 38 U.S.C. 3710(a)(8) except for cases where the Secretary is required to approve the loan in advance under § 36.4306a.

(Authority: 38 U.S.C. 3703, 3710)

* * * * *

[FR Doc. 97–26614 Filed 10–7–97; 8:45 am]

BILLING CODE 8320–01–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–300552; FRL–5745–2]

RIN 2070–AB78

Glyphosate Oxidoreductase and the Genetic Material Necessary for Its Production in All Plants; Exemption From Tolerance Requirement On All Raw Agricultural Commodities

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This document establishes an exemption from the requirement of a tolerance for residues of the plant-pesticide inert ingredients glyphosate oxidoreductase (GOX) and the genetic material necessary for its production in all plants when used as plant-pesticides in or on all raw agricultural commodities (RACs). Monsanto Company submitted a petition to EPA under the Federal Food, Drug, and Cosmetic Act (FFDCA) as amended by the Food Quality Protection Act of l996 (FQPA) requesting the exemption from the requirement of a tolerance. This regulation eliminates the need to establish a maximum permissible level for residues of this plant-pesticides in or on all RACS.

DATES: This regulation is effective on October 8, 1997. Written objections and requests for hearings must be received by EPA on or before December 8, 1997.

ADDRESSES: Written objections and hearing requests, identified by the docket control number OPP–300552, may be submitted to: Hearing Clerk (1900), Environmental Protection Agency, Rm. M3708, 401 M St., SW., Washington, DC 20460. Fees accompanying objections and hearing requests shall be labeled ''Tolerance Petition Fees'' and forwarded to: EPA Headquarters Accounting Operations Branch, OPP (Tolerance Fees), P.O. Box 360277M, Pittsburgh, PA 15251. A copy of any objections and hearing requests filed with the Hearing Clerk should be identified by the docket control number OPP–300552 and submitted to: Public Information and Records Integrity Branch, Information Resources and Services Division (7506C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. In person, bring a copy of objections and hearing requests to: Rm. 1132, Crystal Mall #2, 1921 Jefferson Davis Highway, Arlington, VA.

A copy of objections and hearing requests filed with the Hearing Clerk may also be submitted electronically by sending electronic mail (e-mail) to:

opp-docket@epamail.epa.gov.

Copies of objections and hearing requests must be submitted as an ASCII file avoiding the use of special characters and any form of encryption. Copies of objections and hearing requests will also be accepted on disks in WordPerfect in 5.1 file format or ASCII file format. All copies of objections and hearing requests in electronic form must be identified by the docket control number OPP–300552. No Confidential Business Information (CBI) should be submitted through e-mail. Additional information on CBI can be found in VII. of this document. Electronic copies of objections and hearing requests on this rule may be filed online at many Federal Depository Libraries. Additional information on electronic submissions can be found in Unit VIII. of this document.

FOR FURTHER INFORMATION CONTACT: By mail: Mike Mendelsohn, Biopesticides and Pollution Prevention Division, Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Office location, telephone number, and

e-mail address: 5th Floor Crystal Station, 2800 Crystal Drive, Arlington, VA , (703) 308–8715); e-mail: mendelsohn.mike@epamail.epa.gov.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of January 24, 1997 (62 FR 3682) (FRL–5380–2), EPA issued a notice pursuant to section 408(d) of FFDCA, 21 U.S.C. 346a(d) announcing the filing of a pesticide petition for an exemption from the requirement for a tolerance by Monsanto Company, 700 Chesterfield Parkway, North St. Louis, MO 63198. The notice contained a summary of the petition prepared by the petitioner and this summary contained conclusions and arguments to support its conclusion that the petition complied with the FQPA (Pub. L. 104–170). The petition requested that an exemption from the requirement of a tolerance be established for the plant-pesticides GOX and the genetic material necessary for its production in plants in or on all RACS. There were no comments or requests for referral to an advisory committee received in response to the notice of filing. The data submitted in the petition and other relevant material have been evaluated. The toxicology and other data listed below were considered in support of this exemption from the requirement of a tolerance.

I. Risk Assessment and Statutory Findings

New section 408(c)(2)(A)(I) of FFDCA allows EPA to establish an exemption from the requirement of a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the tolerance is ''safe'' to mean that ''there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information.'' This includes exposure through drinking water and in residential settings, but does not include occupational exposure. Section 408(c)(2)(B) of FFDCA requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to ''ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue...'' EPA performs a number of analyses to determine the risks from aggregate exposure to pesticide residues. First, EPA determines the toxicity of pesticides. Second, EPA examines exposure to the pesticide through food, drinking water, and through other exposures that occur as a result of pesticide use in residential settings.

II. Aggregate Risk Assessment and Determination of Safety

Consistent with section 408(b)(2)(D) of FFDCA, EPA has reviewed the available scientific data and other relevant information in support of this action and considered its validity, completeness, and reliablitiy and the relationship of this information to human risk. EPA has sufficient data to assess the hazards of glyphosate oxidoreductase (GOX), and to make a determination on aggregate exposure, consistent with section 408(c)(2) of FFDCA, for an exemption from the requirement of a tolerance for residues GOX in or on all RACS. EPA's assessment of the dietary exposures and risks associated with establishing the exemption follows.

A. Toxicological Profile

Glyphosate oxidoreductase (GOX) catalyzes the conversion of glyphosate to aminomethylphosphonic acid (AMPA) and glyoxylate in a 1:1 stoichiometry while consuming ½ mole of oxygen as a cosubstrate. GOX requires flavin adenine dinucleotide (FAD) and magnesium for activity; therefore, it is more appropriately designated an apoenzyme.

The gene for Gox was originally isolated from Achromobacter sp. Strain LBAA. The GOX protein was then sequenced and the gene was synthesized with an added signal sequence and the codons modified in the guanine and cytosine nucleic acid (GC) content to yield higher plant expression. Two modified GOX proteins are specified in this rule. They are designated GOX and GOXv247. Both versions have an identifier of ''(M4–C1)'' in the data submissions which indicates that the protein was expressed in *E. coli* for testing purposes. The GOX protein retains the same amino acid sequence as the native protein and has additional four amino acid sequence *N*-terminus (reminanats of an added signal sequence). In GOXv247, the gene sequence of the native protein was altered resulting in changes to three amino acids in the sequence of the resulting protein along with the remains of the added signal sequence mentioned previously. These changes did not negatively affect the enzymatic activity of either protein.

The GOX variants GOX and GOXv247, expressed in *E. coli* and originating from the synthetic GOX gene optimized for protein expression in plants, showed similarity to the native GOX protein when expressed in *E. coli*. These similarities are seen as comparable molecular weights, immunoreactivity, amino acid sequence and enzymatic activity.

The data submitted regarding potential health effects of GOX and GOXv247 includes information on the characterization of the expression of GOX in corn, the acute oral toxicity of GOX and GOXv247, and *in vitro* digestibility studies of the proteins. The applicability of the results of these studies to evaluate human risk and the validity, completeness, and reliability of the available data from the studies were considered.

Both variants of the GOX protein (GOX and GOXv247) are rapidly degraded in simulated gastric fluid (GF) and simulated intestinal fluid (IF). After a fifteen-second incubation in GF, both variants have less than 90% of their initial protein epitopes by western blot analysis. Enzyme activity loss is also greater than 90% in both GOX variants when assayed after a 1-minute incubation in GF. Similar results are seen in simulated IF. Western blot assays show that both variants are greater than 90% degraded by 30-second incubation in IF. However, the enzyme activity assays show that the GOX activity lasts longer in IF than variant GOXv247. After a 10-minute IF incubation, the activity decreased to about 48% of initial for GOX whereas GOXv247 was already greater than 90% inactive.

Two findings, found in the *in vitro* digestibility studies, that are remarkable are: GOXv247 displays a more rapid degradation in the IF compared to unaltered GOX, apparently due to the single amino acid substitutions; and antibody recognition is lost prior to a significant loss of enzyme activity indicating that western blots may not always accurately track functional protein degradation.

None of the amino acid sequences of known allergens or proteins involved in coeliac disease were shown to have similarity to the GOX protein as defined by eight identical and contiguous amino acids in a sequence. However, the assertion that a lack of allergenicity can be established by comparison of sequences to known allergens is questionable. While this is the best approximation at present, there is no scientific basis to assume that the presence of eight contiguous and homologous amino acids in a protein will predict its allergenicity. The assumption is based on the finding that the presence of an eight amino acid sequence in one allergen was associated with the epitope responsible for IgE recognition. Alteration of this sequence

reduced IgE binding and hence allergenicity. The converse experiment, to introduce the sequence into a non-allergenic protein and create an allergen, has not been attempted experimentally.

The acute oral toxicity test of bacterially-derived GOX and GOXv247 proteins showed no test substance related deaths at doses of 91.3 milligrams per kilogram (mg/kg) and 104 µg/kg respectively. Expression data on the GOX protein expressed in corn grains ranges from undetectable levels to a high of 11.70 micro grams per gram (mg/g) freshweight. This indicates that it would require 8,547 kg corn grain per kg bodyweight to receive the 100 mg/kg dose that was administered to the mice.

However, residue chemistry data were not required for a human health effects assessment of the subject plant-pesticide inert ingredients because of the lack of mammalian toxicity. Both available information concerning the dietary consumption patterns of consumers (and major identifiable subgroups of consumers including infants and children) and safety factors which, in the opinion of experts qualified by scientific training and experience to evaluate the safety of food additives, are generally recognized as appropriate for the use of animal experimentation data were not evaluated because the lack of mammalian toxicity at high levels of exposure demonstrate the safety of the product at levels above possible maximum exposure levels. This is similar to the Agency position regarding toxicity and the requirement of residue data for the microbial Bacillus thuringiensis. [See 40 CFR 158.740(b).] For microbial products, further toxicity testing to verify the observed effects and clarify the source of the effects (Tiers II and III) and residue data are triggered by significant acute effects in studies such as the mouse oral toxicity study.

The acute oral toxicity data submitted support the prediction that the GOX proteins would be non-toxic to humans. When proteins are toxic, they are known to act via acute mechanisms and at very low dose levels [Sjoblad, Roy D., *et al.* ''Toxicological Considerations for Protein Components of Biological Pesticide Products,'' Regulatory Toxicology and Pharmacology 15, 3-9 (1992)]. Therefore, since no effects were shown to be caused by the plant-pesticides, even at relatively high dose levels, the GOX protein is not considered toxic.

Adequate information was submitted to show that the GOX test materials derived from microbial cultures was biochemically and, functionally similar to the proteins produced by the plant-pesticide inert ingredient in corn. Production of microbially produced protein was chosen in order to obtain sufficient material for testing. In addition, the i*n vitro* digestibility studies indicate the proteins would be rapidly degraded following ingestion.

The genetic material necessary for the production of the plant-pesticides active and inert ingredients are the nucleic acids (DNA) which comprise genetic material encoding these proteins and) their regulatory regions. ''Regulatory regions'' are the genetic material that control the expression of the genetic material encoding the proteins, such as promoters, terminators, and enhancers. DNA is common to all forms of plant and animal life and the Agency knows of no instance where these nucleic acids have been associated with toxic effects related to their consumption as a component of food. These ubiquitous nucleic acids as they appear in the subject plant-pesticide inert ingredient have been adequately characterized by the applicant. Therefore, no mammalian toxicity is anticipated from dietary exposure to the genetic material necessary for the production of the subject active and inert plant pesticidal ingredients.

B. Sensitivity of Subgroups

The Agency has considered available information on the variability of the sensitivities of major identifiable subgroups of consumers including infants and children and the physiological differences between infants and children and adults and effects of in utero exposure to the plant-pesticides. Since GOX is a protein, allergenic sensitivities were considered. Current scientific knowledge suggests that common food allergens tend to be resistant to degradation by heat, acid, and proteases, are glycosylated and are present at high concentrations in the food. Data has been submitted which demonstrate that the GOX proteins are rapidly degraded by gastric fluid *in vitro* and are non-glycosylated. Thus, the potential for the GOX proteins to be a food allergens is minimal.

C. Cumulative Effects

The Agency has considered available information on the cumulative effects of such residues and other substances that have a common mode toxicity. These considerations included the cumulative effects on infants and children of such residues and other substances with a common mechanism of toxicity. Because there is no indication of mammalian toxicity to these plant-pesticides, there are no cumulative effects.

D. Aggregate Exposures

The Agency has considered available information on the aggregate exposure levels of consumers (and major identifiable subgroups of consumers) to the pesticide chemical residue and to other related substances. These considerations include dietary exposure under the tolerance exemption and all other tolerances or exemptions in effect for the plant-pesticides chemical residue, and exposure from non-occupational sources. Exposure via the skin or inhalation is not likely since the plant-pesticides are contained within plant cells which essentially eliminates these exposure routes or reduces these exposure routes to negligible. Oral exposure, at very low levels, may occur from ingestion of processed food products and drinking water. However a lack of mammalian toxicity and the digestibility of the plant-pesticides has been demonstrated. Regarding exposure via residential or lawn use to infants and children, the Agency concludes that such exposure would present no risk due to the lack of toxicity.

Section 408 of FFDCA provides that EPA shall apply an additional 10-fold margin of exposure (MOE) (safety) for infants and children in the case of threshold effects to account for pre- and post-natal toxicity and the completeness of the database unless EPA determines that a different MOE (safety) will be safe for infants and children. In this instance EPA believes there is reliable data to support the conclusion that the plant-pesticides are not toxic to mammals, including infants and children, and thus there are no threshold effects of concern. As a result, the provision requiring an additional MOE does not apply.

III. Endocrine Effects

EPA does not have any information regarding endocrine effects for these kinds of pesticides at this time. The Agency is not requiring information on the endocrine effects of these plant-pesticides at this time; and Congress allowed 3 years after August 3, 1996, for the Agency to implement a screening and testing program with respect to endocrine effects.

IV. Analytical Method

The Agency is establishing an exemption from the requirement of a tolerance without numerical limitation; therefore, it has concluded that an analytical method is not required for enforcement purposes for GOX and the genetic material necessary for their production.

V. Conclusion

There is a reasonable certainty that no harm will result from aggregate exposure to the U.S. population, including infants and children, to the GOX protein and the genetic material necessary for that production. This includes all anticipated dietary exposures and all other exposures for which there is reliable information. The Agency has arrived at this conclusion because, as discussed above, no toxicity to mammals has been observed for the plant-pesticides. As a result, EPA establishes an exemption from tolerance requirements pursuant to section 408(j)(3) of FFDCA for GOX and the genetic material necessary for their production in all plants.

Glyphosate Oxidoreductase [GOX or GOXv247] and the genetic material necessary for its production in all plants are exempt from the requirement of a tolerance when used as plant-pesticide inert ingredients in all plant RACs. ''Genetic material necessary for its production'' means the genetic material which comprise genetic material encoding the GOX proteins and their regulatory regions. ''Regulatory regions'' are the genetic material that control the expression of the genetic material encoding the GOX proteins, such as promoters, terminators, and enhancers.

VI. Objections and Hearing Requests

The new FFDCA section 408(g) provides essentially the same process for persons to ''object'' to a regulation for an exemption from the requirement of a tolerance issued by EPA under new section 408(d) of FFDCA as was provided in the old section 408 and in section 409 of FFDCA. However, the period for filing objections is 60 days, rather than 30 days. EPA currently has procedural regulations which governs the submission of objections and hearing requests. These regulations will require some modification to reflect the new law. However, until those modifications can be made, EPA will continue to use those procedural regulations with appropriate adjustments to reflect the new law.

Any person may, by December 8, 1997 file written objections to any aspect of this regulation and may also request a hearing on those objections. Objections and hearing requests must be filed with the Hearing Clerk, at the address given under the ''ADDRESSES'' section (40 CFR 178.20). A copy of the objections and/or hearing requests filed with the Hearing Clerk should be submitted to the OPP docket for this rulemaking. The objections submitted must specify the provisions of the regulation deemed objectionable and the grounds for the objections (40 CFR 178.25). Each objection must be accompanied by the fee prescribed by 40 CFR 180.33(i). If a hearing is requested, the objections must include a statement of the factual issue(s) on which a hearing is requested, the requestor's contentions on such issues, and a summary of any evidence relied upon by the objector (40 CFR 178.27). A request for a hearing will be granted if the Administrator determines that the material submitted shows the following: There is a genuine and substantial issue of fact; there is a reasonable possibility that available evidence identified by the requestor would, if established, resolve one or more of such issues in favor of the requestor, taking into account uncontested claims or facts to the contrary; and resolution of the factual issue(s) in the manner sought by the requestor would be adequate to justify the action requested (40 CFR 178.32).

VII. Confidential Business Information

Information submitted in connection with an objection or hearing request may be claimed confidential by marking any part or all of that information as CBI. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2. A copy not contain CBI must be submitted for inclusion in the public record. Information not marked confidential may be disclosed publicly by EPA without prior notice.

VIII. Public Record and Electronic Submissions

EPA has established a record for this rulemaking under docket control number OPP–300552 (including any comments and data submitted electronically). A public version of this record, including printed, paperversions of electronic comments, which does not in include any information claimed as CBI, is available for inspection from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The public record is located in Room 1132 of the Public Information and Records Integrity Branch, Information Resources and Services Division (7506C), Office of Pesticide Programs, Environmental Protection Agency, Crystal Mall #2, 1921 Jefferson Davis Highway, Arlington, VA.

Electronic comments may be sent directly to EPA at:

opp-docket@epamail.epa.gov.

Electronic comments must be submitted as an ASCII file avoiding the use of special characters and any form of encryption.

The official record for this rulemaking, as well as the public version, as described above, will be kept in paper form. Accordingly, EPA will transfer any copies of objections and hearing requests received electronically into printed, paper form as they are received and will place the paper copies in the official rulemaking record. The official rulemaking record is the paper record maintained at the Virginia address in ''ADDRESSES'' at the beginning of this document.

IX. Regulatory Assessment

This final rule establishes an exemption from the tolerance requirement under FFDCA section 408(d) in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled Regulatory Planning and Review (58 FR 51735, October 4, 1993). This final rule does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA), 44U.S.C. 3501 *et seq.*, or impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (P.L. 104–4). Nor does it require any prior consultation as specified by Executive Order 12875, entitled Enhancing the Intergovernmental Partnership (58 FR 58093, October 28, 1993), or special considerations as required by Executive Order 12898, entitled Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations (59 FR 7629, February 16, 1994), or require OMB review in accordance with Executive Order 13045, entitled Protection of Children from Environmental Health Risks and Safety Risks (62 FR 19885, April 23, 1997).

In addition, since tolerances and exemptions that are established on the basis of a petition under FFDCA section 408(d), such as the exemption in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*) do not apply. Nevertheless, the Agency previously assessed whether establishing tolerances, exemptions from tolerances, raising tolerance levels or expanding exemptions might adversely impact small entities and concluded, as a generic matter, that there is no adverse economic impact. The factual basis for the Agency's generic certification for tolerance actions published on May 4, 1981 (46 FR 24950), and was provided

to the Chief Counsel for Advocacy of the Small Business Administration.

X. Submission to Congress and the General Accounting Office

Under 5 U.S.C. 801(a)(1)(A), as added by the Small Business Regulatory Enforcement Fairness Act of 1996, the Agency has submitted a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the General Accounting Office prior to publication of this rule in today's **Federal Register**. This is not a ''major rule'' as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: September 25, 1997.

Stephen L. Johnson,

Acting Director, Office of Pesticide Programs.

Therefore, 40 CFR chapter I is amended as follows:

PART 180—[AMENDED]

1. The authority citation for part 180 continues to read as follows:

Authority: 21 U.S.C. 346a and 371.

2. Section 180.1190 is added to subpart D to read as follows:

§ 180.1190 Glyphosate Oxidoreductase [GOX or GOXv247] and the genetic material necessary for its production in all plants; exemption from the requirement of a tolerance.

Glyphosate Oxidoreductase [GOX or GOXv247] and the genetic material necessary for its production in all plants are exempt from the requirement of a tolerance when used as plant-pesticide inert ingredients in all plant RACs. *Genetic material necessary for its production* means the genetic material which comprise genetic material encoding the GOX proteins and their regulatory regions. *Regulatory regions* are the genetic material that control the expression of the genetic material encoding the GOX proteins, such as promoters, terminators, and enhancers.

[FR Doc. 97–26190 Filed 10–7–97; 8:45 am]

BILLING CODE 6560–50–F

DEPARTMENT OF THE INTERIOR

Office of the Secretary

43 CFR Part 36

RIN 1093–AA07

Transportation and Utility Systems In and Across, and Access Into, Conservation System Units in Alaska

AGENCY: Office of the Secretary, Interior.

ACTION: Final rule.

SUMMARY: The Department of the Interior is implementing this final rule to revise and simplify the regulatory definition of the term ''economically feasible and prudent alternative route'' as used in the review of proposed transportation and utility systems in Alaska under Title XI of the Alaska National Interest Lands Conservation Act (ANILCA).

DATES: *Effective date:* This rule becomes effective November 7, 1997.

Compliance date: This rule will apply to agency decisionmaking under ANILCA Title XI beginning November 7, 1997.

FOR FURTHER INFORMATION CONTACT: David A. Funk, Alaska Field Office, National Park Service, 2525 Gambell Street, Room 107, Anchorage, AK 99503–2892. Phone: (907) 257–2589.

SUPPLEMENTARY INFORMATION:

Background

On December 2, 1980, the Alaska National Interest Lands Conservation Act (ANILCA) was signed into law as Public Law 96–487 (94 Stat. 2371, 16 U.S.C. 3101, *et seq.*). Title XI of ANILCA, which is entitled ''Transportation and Utility Systems In and Across, and Access Into, Conservation System Units,'' established guidelines and procedures for submitting and processing applications for transportation and utility systems (TUS) in Alaska when any portion of the route or the system will be within any conservation system unit, national recreation area, or national conservation area. In addition, Title XI authorizes special access, temporary access, and access to inholdings.

On July 15, 1983, the Department of the Interior (Department) proposed comprehensive regulations to implement ANILCA Title XI on lands in Alaska under the jurisdiction of the National Park Service (NPS), the U.S. Fish and Wildlife Service (FWS), and the Bureau of Land Management (BLM) (48 FR 32506). On September 4, 1986, the Department published final Title XI regulations (51 FR 31619).

In early 1987, the Trustees for Alaska and other groups (Trustees) sued the Department to challenge the Title XI regulations as exceeding the authority granted to the Department by ANILCA. Parties intervening in the case included Arctic Slope Regional Corporation, the Alaska Miners Association, the Alaska Forest Association, and the Resource Development Council for Alaska, Inc. In orders dated April 29, 1991, and March 16, 1993, the U.S. District Court for the District of Alaska granted summary judgment to the Department. The Trustees appealed the lower court's decision to the U.S. Court of Appeals for the Ninth Circuit, which assigned the case to a mediator to explore whether review and possible revision of the Title XI regulations might provide a basis for settlement.

On September 17, 1996, the Department proposed (61 FR 48873) one revision to the 1986 regulations in order to improve the regulations' workability and reduce the opportunities for delays in decisionmaking. The proposal followed substantial review and consultation with interested parties both within and outside the Department. The proposal provided an additional advantage of offering a focus for the consensus necessary to settle the longstanding litigation. The litigation was dismissed on August 30, 1996, subject to reinstatement if the final regulations differed from the proposal.

The Department did not propose any other revisions of the Title XI regulations. Thus, for example, the 1986 regulations implementing the Title XI provisions concerning access to inholdings, special access, and temporary access will remain intact. Also, the Department did not propose any changes to the regulatory provisions governing access to subsistence resources under Title VIII of ANILCA (*see* 36 CFR 13.46 (NPS) and 50 CFR 36.12 (FWS)). Finally, neither the proposed nor this final rule concerns recognition or management of R.S. 2477 rights-of-way.

Summary of Public Comments

Six comments were received in response to publication of the proposed rule. None of the responses objected to the proposed revision of 43 CFR 36.2(h).

The Alaska Department of Law stated that the revision would be consistent with the August 30, 1996, Order issued by the United States Court of Appeals for the Ninth Circuit in *Trustees for Alaska* v. *United States Department of the Interior,* No. 93–35493 (Trustees). The Department of Law added, however, that the State does not necessarily concur with the facts and