Sunshine Act Meetings

Federal Register
Vol. 51, No. 153
Friday, August 8, 1986

This section of the FEDERAL REGISTER contains notices of meetings published under the "Government in the Sunshine Act" (Pub. L. 94-409) 5 U.S.C. 552b(e)(3).

CONTENTS

1

FEDERAL RESERVE SYSTEM

TIME AND DATE: 10:00 a.m., Wednesday, August 13, 1986.

PLACE: Marriner S. Eccles Federal Reserve Board Building, C Street entrance between 20th and 21st Streets, NW., Washington, DC 20551.

STATUS: Closed.

MATTERS TO BE CONSIDERED:

1. Personnel actions (appointments, promotions, assignments, reassignments, and salary actions) involving individual Federal Reserve System employees.

2. Any items carreied forward from a previously announced meeting.

CONTACT PERSON FOR MORE INFORMATION: Mr. Joseph R. Coyne, Assistant to the Board; (202) 452–3204. You may call (202) 452–3207, beginning at approximately 5 p.m. two business days before this meeting, for a recorded anouncement of bank and bank holding company applications scheduled for the meeting.

Dated: August 5, 1986.

James McAfee,

Associate Secretary of the Board.

[FR Doc. 86–17935 Filed 8–5–86; 4:26 pm]

BILLING CODE 6210-01-M

2

FEDERAL RESERVE SYSTEM BOARD OF GOVERNORS

"FEDERAL REGISTER" CITATION OF PREVIOUS ANNOUCEMENT: 51 FR 27307, July 30, 1986.

PREVIOUSLY ANNOUNCED TIME AND DATE OF MEETING: 10:00 a.m., Wednesday, August 6,1986.

CHANGES IN THE MEETING: Addition of the following closed item(s) to the meeting:

Proposed Board comments to the Office of Management and Budget on draft legislation implementing the Report of the Task Group on Regulation of Financial Services.

CONTACT PERSON FOR MORE INFORMATION: Mr. Joseph R. Coyne, Assistant to the Board; (202) 452–3204.

Dated: August 6, 1986.

James McAfee,

Associate Secretary of the Board.

[FR Doc. 86–17982 Filed 8–6–86; 12:55 pm]

BILLING CODE 6210-01-M

Federal Register

Friday
August 8, 1986

Part II

Department of Health and Human Services

Food and Drug Administration

21 CFR Part 344

Topical Otic Drug Products for Over-the-Counter Human Use; Final Monograph; Final Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 344

[Docket No. 77N-0334]

Topical Otic Drug Products for Over-the-Counter Human Use; Final Monograph

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing a final rule in the form of a final monograph establishing conditions under which over-the-counter (OTC) topical otic drug products (drug products for the ear) are generally recognized as safe and effective and not misbranded. FDA is issuing this final rule after considering public comments on the agency's proposed regulation, which was issued in the form of a tentative final monograph, and all new data and information on topical otic drug products that have come to the agency's attention. This final monograph is part of the ongoing review of OTC drug products conducted by FDA.

EFFECTIVE DATE: August 10, 1987.

FOR FURTHER INFORMATION CONTACT: William E. Gilbertson, Center for Drugs and Biologics (HFN-210), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-295-8000.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of December 16, 1977 (42 FR 63556), FDA published, under § 330.10(a)(6) (21 CFR 330.10(a)(6)), an advance notice of proposed rulemaking to establish a monograph for OTC topical otic drug products, together with the recommendations of the Advisory Review Panel on OTC Topical Analgesic, Antirheumatic, Otic, Burn, and Sunburn Prevention Treatment Drug Products, which was the advisory review panel responsible for evaluating data on the active ingredients in this drug class. Interested persons were invited to submit comments by March 16, 1978. Reply comments in response to comments filed in the initial comment period could be submitted by April 14, 1978.

In accordance with § 330.10(a)(10), the data and information considered by the Panel were put on display in the Dockets Management Branch (HFA-305), Food and Drug Administration, Rm. 4-62, 5600 Fishers Lane, Rockville, MD 20857, after deletion of a small amount of trade secret information.

The agency's proposed regulation, in the form of a tentative final monograph, for topical otic drug products was published in the **Federal Register** of July 9, 1982 (47 FR 30012). Interested persons were invited to file by September 7, 1982, written comments, objections, or requests for oral hearing before the Commissioner of Food and Drugs regarding the proposal. Interested persons were invited to file comments on the agency's economic impact determination by November 9, 1982. New data could have been submitted until September 11, 1983. Final agency action occurs with the publication of this final monograph, which is a final rule establishing a monograph for OTC topical otic drug products.

The OTC procedural regulations (21 CFR 330.10) now provide that any testing necessary to resolve the safety or effectiveness issues that formerly resulted in a Category III classification, and submission to FDA of the results of that testing or any other data, must be done during the OTC drug rulemaking process before the establishment of a final monograph. Accordingly, FDA is no longer using the terms "Category I" (generally recognized as safe and effective and not misbranded), "Category II" (not generally recognized as safe and effective or misbranded), and "Category III" (available data are insufficient to classify as safe and effective, and further testing is required) at the final monograph state, but is using instead the terms "monograph conditions" (old Category I) and "nonmonograph conditions" (old Categories II and III).

As discussed in the proposed regulaton for OTC topical otic drug products (47 FR 30013), the agency advises that the conditions under which the drug products that are subject to this monograph will be generally recognized as safe and effective and not misbranded (monograph conditions) will be effective 12 months after the date of publication in the **Federal Register**. Therefore, on or after August 10, 1987 no OTC drug product that is subject to the monograph and that contains a nonmonograph condition, i.e., a condition that would cause the drug to be not generally recognized as safe and effective or to be misbranded, may be initially introduced or initially delivered for introduction into interstate commerce unless it is the subject of an approved application. Further, any OTC drug product subject to this monograph that is repackaged or relabeled after the effective date of the monograph must be in compliance with the monograph regardless of the date the product was initially introduced or initially delivered for introduction into interstate commerce. Manufacturers are encouraged to comply voluntarily with the monograph at the earliest possible date.

In response to the proposed rule on OTC topical otic drug products, five drug manufacturers, one association for drug manufacturers, and one college of pharmacy submitted comments. Copies of comments received are on public display in the Dockets Management Branch. Any additional information that has come to the agency's attention since publication of the proposed rule is also on public display in the Dockets Management Branch.

In proceeding with this final monograph, the agency has considered all comments and the changes in the procedural regulations.

This final monograph applies only to earwax removal aids. Active ingredients for claims for the prevention of swimmer's ear and treatment of water-clogged ears were submitted in comments to the tentative final monograph. They were not included in the Panel's report, nor considered by the agency in the tentative final monograph on topical otic drug products. Therefore, in order to obtain public comment on these active ingredients and claims, the agency published a proposed rule to amend the tentative final monograph for OTC topical otic drug products to include drugs used for the prevention of swimmer's ear and the treatment of water-clogged ears in the **Federal Register** of July 30, 1986 (51 FR 27366).

I. The Agency's Conclusions on the Comments

A. General Comments on Topical Otic Drug Products

1. One comment contended that OTC drug monographs are interpretive, as opposed to substantive, regulations. The comment referred to statements on this issue submitted earlier to other OTC drug rulemaking proceedings.

The agency addressed this issue in paragraphs 85 through 91 of the preamble to the procedures for classification of OTC drug products, published in the **Federal Register** of May 11, 1972 (37 FR 9464) and in paragraph 3 of the preamble to the tentative final monograph for antacid drug products, published in the **Federal Register** of November 12, 1973 (38 FR 31260). FDA reaffirms the conclusions stated there. Subsequent court decisions have confirmed the agency's authority to issue substantive regulations by rulemaking. See, e.g., *National Nutritional Foods Association* v.

Weinberger, 512 F.2d 688, 696–98 (2d Cir. 1975) and *National Association of Pharmacetical Manufacturers* v. *FDA*, 487 F. Supp. 412 (S.D.N.Y. 1980), *Aff'd*, 637 F.2d 887 (2d Cir. 1981).

2. One comment contended that FDA does not have the authority to legislate the exact wording of OTC labeling claims to the exclusion of what the comment described as other truthful, accurate, not misleading, and intelligible labeling for the products.

During the course of the OTC drug review, the agency has maintained that the terms that may be used in an OTC drug product's labeling are limited to those terms included in a final OTC drug monograph. (This policy has become known as the "exclusivity policy.") The agency's position has been that it is necessary to limit the acceptable labeling language to that developed and approved through the OTC drug review process in order to ensure the proper and safe use of OTC drugs. The agency has never contended, however, that any list of terms developed during the course of the review exhausts all the possibilities of terms that appropriately can be used in OTC drug labeling. Suggestions for additional terms or for other labeling changes may be submitted as comments to proposed or tentative final monographs within the specified time periods or through petitions to amend monographs under § 330.10(a)(12). For example, the labeling in this final monograph has been expanded and revised in response to comments received.

During the course of the review, FDA's position on the "exclusivity policy" has been questioned many times in comments and objections filed in response to particular proceedings and in correspondence with the agency. The agency has also been asked by The Proprietary Association to reconsider its position. In a notice published in the **Federal Register** of July 2, 1982 (47 FR 29002), FDA announced that a hearing would be held to assist the agency in resolving this issue. On September 29, 1982, FDA conducted an open public forum at which interested parties presented their views. The forum was a legislative type administrative hearing under 21 CFR Part 15 that was held in response to a request for a hearing on the tentative final monographs for nighttime sleep-aides and stimulants (published in the **Federal Register** of June 13, 1978; 43 FR 25544).

After considering the testimony presented at the hearing and the written comments submitted to the record, in the **Federal Register** of April 22, 1985 (50 FR 15810), FDA proposed to change its exclusivity policy for the labeling of OTC drug products. In the **Federal Register** of May 1, 1986 (51 FR 16258), the agency published a final rule changing the exclusivity policy and establishing three alternatives for stating the indications for use in OTC drug labeling. Under the final rule, the label and labeling of OTC drug products are required to contain in a prominent and conspicuous location, either: (1) The specific wording on indications for use established under an OTC drug monograph, which may appear within a boxed area designated "APPROVED USES"; (2) other wording describing such indications for use that meets the statutory prohibitions against false or misleading labeling, which shall neither appear within a boxed area nor be designated "APPROVED USES"; or (3) the approved monograph language on indications, which may appear within a boxed area designated "APPROVED USES," plus alternative language describing indications for use that is not false or misleading, which shall appear elsewhere in the labeling. All required OTC drug labeling other than indications for use (e.g., statement of identity, warnings, and directions) must appear in the specific wording established under an OTC drug monograph.

In the tentative final monograph (47 FR 30020), supplemental language relating to indications had been proposed and captioned as *Other Allowable Statements*. Under FDA's revised exclusivity policy (51 FR 16258), such statements are included at the tentative final stage as examples of other truthful and nonmisleading language that would be allowed elsewhere in the labeling without prior FDA review. In accordance with the revised exclusivity policy, such statements would not be included in a final monograph. However, the agency has decided that, because these additional terms have been reviewed by FDA, they should be incorporated, wherever possible, in final OTC drug monographs under the heading "Indications" as part of the indications developed under that monograph.

3. One comment from a small manufacturer stated that the 12-month period of time provided for manufacturers to comply with the final monograph is too restrictive. The company requested that this time period be expanded to 18 months or at least long enough to use existing supplies of cartons and labels. The company explained that to keep costs as low as possible, labels are ordered in large quantities that will provide an 18-month supply. Consequently, meeting the present 12-month requirement could result in the manufacturer having a surplus of unusable labels. The company argued that the cost of unusable labels could increase company costs, thus increasing the cost of the product to the consumer and possibly adversely affecting sales of the product.

In some advance notices of proposed rulemaking previously published in the OTC drug review, the agency suggested a 6-month effective date for monograph conditions. However, as explained in the tentative final monograph (proposed rule) for OTC topical otic drug products (47 FR 30012), the agency concluded that, generally, it is more reasonable to have a final monograph be effective 12 months after the date of its publication in the **Federal Register**. The agency believes that this period of time should enable most manufacturers to reformulate, relabel, or take other steps necessary to comply with a new monograph with a minimum disruption of the marketplace, thereby reducing economic loss and ensuring that consumers have continued access to safe and effective OTC drug products. However, in an assessment of the economic impacts of the OTC drug review, the agency concluded that although the OTC drug review was not a major rule as defined in Executive Order 12291, significantly large impacts might be experienced by some small firms in some years (Ref. 1).

Nevertheless, FDA has a statutory mandate to assure that OTC drug products are safe and effective for their intended use and are properly labeled. The statute does not allow FDA to waive these important public health considerations even though additional costs may be incurred by a manufacturer in order to achieve compliance with a monograph.

Reference

(1) "Assessment of the Economic Impacts of the OTC Drug Review Process," Docket No. 82N–0143, Dockets Management Branch.

4. One comment questioned the meaning of the word "effective." The comment asked FDA to consider whether consumer acceptance and usage of a product, without the use of coercive advertising, indicates some effectiveness of the product. The comment stated that some drugs are more effective than others and questioned whether this means that the less effective drugs are considered as being not effective at all.

As defined in § 330.10(a)(4)(ii), effectiveness means a reasonable expectation that, in a significant proportion of the target population, the pharmacological effect of the drug, when

used under adequate directions for use and warnings against unsafe use, will provide clinically significant relief of the type claimed. The regulation provides that reports of significant human experience during marketing may be used to corroborate controlled clinical investigations and other studies, in order to establish general recognition of the effectiveness of a drug. However, isolated case reports, random experience, and reports lacking the details that permit scientific evaluation are not considered. Without more substantive data, mere consumer acceptance and usage of a product is not enough to constitute proof of effectiveness.

With regard to the comment's inquiry concerning "less effective drugs," the agency does not consider the comparative efficacy of a drug in determining general recognition of effectiveness; it only considers that the drug has been shown to be effective based on the standards discussed above.

B. Comments on Topical Otic Drug Ingredients

5. One manufacturer expressed concern about the agency's decision to reclassify glycerin as an earwax removal aid from Category I to Category III "so that studies may be performed to establish effectiveness." The manufacturer stated that in response to the advance notice of proposed rulemaking on OTC topical otic drugs, it reformulated its earwax product to contain only glycerin as an active ingredient. The propylene gylcol in the product was removed. However, the comment asserted that because of the reclassification of glycerin to Category III, the expensive process of reformulation and relabeling will have to be repeated. The comment maintained that it is unfair and costly for the agency to urge manufacturers to comply with advance proposals and then change the Panel's recommendation.

Since the beginning of the OTC drug review, the agency has stated that a panel's findings are prepared independently of FDA and do not necessarily reflect the agency's position. Although the agency encourages manufacturers to comply voluntarily with a panel's recommendations in formulating and labeling their products prior to the effective date of a final monograph, manufacturers are at risk because a panel's recommendation may be accepted, rejected, or modified by the agency in the tentative final and final monographs. This concept was discussed in the preamble to each Panel's report including the report on OTC otic drug products. (See, e.g., 42 FR 63556.) The agency does not modify a panel's recommendations arbitrarily. Before making any change, the agency carefully considers all relevant data and information.

The agency reclassified glycerin as an earwax removal aid from Category I to Category III in the tentative final monograph because there were no well-controlled studies that demonstrated effectiveness. The only published effectiveness study cited by the Panel (42 FR 63562) was an in vitro study that showed that glycerin had no effect on earwax after 60 minutes and caused only surface softening of earwax after 24 hours (47 FR 30014). Therefore, there was no basis for the agency to accept the Panel's Category I classification of glycerin as an earwax removal aid. In addition, because no data were submitted after publication of the tentative final monograph to establish the effectiveness of glycerin as an earwax removal aid, it is not being included in this final monograph.

This final monograph is effective 12 months after the date of publication in the **Federal Register**. Thus, manufacturers will have a reasonable period of time to reformulate and relabel currently marketed products to comply with the monograph.

C. Comments on Labeling of Topical Otic Drug Products

6. Two comments disagreed with the agency's proposed substitution of the word "doctor" for "physician" in OTC drug labeling. One comment stated that because "physician" is a term that is recognized by people of all ages and social and economic levels, there is no need for the change, which would be costly and provide no benefit. The comment further contended that physician is a more accurate term, whereas "doctor" is a broad term that could confuse and mislead the lay person into taking advice on medication from persons other than medical doctors, such as optometrists, podiatrists, and chiropractors. The other comment favored the use of easily understood language in labeling, but noted that both "doctor" and "physician" are accurate and meaningful and argued that the use of either term should be allowed.

The agency recognizes that the term "doctor" is not a precise synonym for the word "physician," but believes that the terms are frequently used interchangeably by consumers and that the word "doctor" is likely to be more commonly used and better understood by consumers. In an effort to simplify OTC drug labeling, the agency proposed in a number of tentative final monographs to substitute the word "doctor" for "physician." Based on comments submitted following publication of these tentative final monographs, the agency has determined that final monographs will give manufacturers the option of using either the word "physician" or the word "doctor." This final monograph includes that option.

7. One comment suggested that, in the interest of consumer education, the warning, "Never use instruments such as cotton swabs, toothpicks, or hairpins to remove wax from ear canal" be required. To preclude the use of unsafe instruments to remove the earwax softened by carbamide peroxide, the comment also suggested that the phrase "the only medically approved way for safely removing earwax" be permitted in the labeling of carbamide peroxide that is packaged with a rubber bulb ear syringe for the purpose of flushing the ear.

The comment submitted no data in support of its request. Based on data and information that are available, the agency concludes that the warnings proposed in the tentative final monograph adequately inform consumers how to use these products safely and that it is unnecessary to require the comment's suggested warning in the labeling of topical otic drug products. However, as long as the required warning appears on the product's label, the agency has no objection to the information described in the comment also appearing in some other portion of the label. Such information may not appear in any portion of the labeling that is required by the monograph.

The phrase "the only medically approved way for safely removing earwax" is not being included in the monograph for use in labeling unit packages containing carbamide peroxide and a rubber bulb ear syringe. By appearing on such packages, the phrase would imply that a rubber bulb ear syringe used in conjunction with carbamide peroxide constitutes the only medically approved way of safely removing earwax. In fact, carbamide peroxide alone may safely remove earwax.

The agency stated in the tentative final monograph that the use of an irrigation syringe in the ear should be limited as much as possible (47 FR 30018). The directions in § 344.50(d) for using a rubber bulb ear syringe are include in the monograph only to assist in the removal of any earwax that may

remain after 4 days of treatment with carbamide peroxide. The agency therefore objects to any labeling that might infer that a rubber bulb ear syringe must be used to remove earwax safely.

8. Two comments suggested that the warning in § 344.50(c)(3) that states "Do not use for more than 4 days; if excessive earwax remains after use of this product, consult a doctor" be revised because it does not indicate clearly that the 4-day limitation applies to each episode of excessive earwax. One comment pointed out that many individuals are subject to chronic accumulation of earwax and will, accordingly, use these products routinely for recurring accumulation. Therefore, the comments suggested that the warning be revised by adding a phrase such as "for each occurrence of accumulated earwax" or "during any episode" to make it clearer to the user that the 4-day limitation applies to each episode of excessive earwax.

The agency believes that the present warning in § 344.50(c)(3), concerning the limitation of use for not more than 4 days, in conjunction with the directions for use in § 344.50(d), which instruct consumers to use the product twice daily for up to 4 days, is adequate to inform consumers that the 4-day limitation applies to each episode of excessive earwax accumulation. The labeling of many OCT drug products contains limitations on the number of days that the product should be used, and the agency believes that it is reasonable to expect that consumers will understand that the 4-day limitation applies to each episode of excessive earwax.

9. One comment stated that anhydrous glycerin can cause a painful, burning sensation in the eyes, and suggested that the labeling instructions should anticipate accidental contact. The comment recommended that the proposed warning in § 344.50(c)(4) "Avoid contact with the eyes," be expanded by adding the following sentences: "If accidental contact occurs, wash eye with water. Consult physician if pain or irritation persists."

The agency concludes that it is not necessary to expand the warning in § 344.50(c)(4) because glycerin does not cause any serious effects. Although anhydrous glycerin can cause irritation and stinging of the eyes, anhydrous glycerin has accepted medical usage as an agent to facilitate ophthalmoscopic examination and to reduce corneal edema (Refs. 1, 2, and 3). Accordingly, the agency is not expanding the warning in the monograph as suggested by the comment. As long as the required warning appears on the products's label, the agency has no objection to the statements described in the comment also appearing in some other portion of the label.

Such information may not appear in any portion of the labeling that is required by the monograph.

References

(1) Smith, M. B., "Ocular Toxicity," Publishing Sciences Group, Acton, MA, p. 54, 1976.

(2) "AMA Drug Evaluations—1983," 5th Ed., American Medical Association, Chicago, IL, pp. 506–507, 1983.

(3) Gennaro, A., editor, "Remington's Pharmaceutical Sciences," 17th Ed., Mack Publishing Co., Easton, PA, p. 1308, 1985.

10. One comment stated that the directions for use of an ear syringe could be more instructive to the user and suggested that the directions in § 344.50(d) be worded as follows: "Any wax remaining after treatment should be removed once a day by gently flushing the ear with warm (body temperature) water, using a soft rubber bulb ear syringe. Place tip of washer at outer edge of ear canal."

The agency believes that the directions as proposed in the tentative final monograph are sufficient for OTC use of earwax removal aids. The agency does not agree with the comment's wording "Any wax remaining after treatment should be removed once a day . . ." because such information is misleading and implies that the ear syringe should be used each day after the treatment, whereas the ear syringe should only be used after treatment is completed if there is still wax remaining in the ear after 4 days of treatment.

In addition, the agency believes that the term "warm water" is understood by consumers and that it is not necessary to require in the monograph that the term "(body temperature)" be added to the directions. Manufacturers may, however, add terms such as "(body temperature)" to the directions of products if they believe that they enhance consumer understanding. They may also add additional information in the directions regarding the proper use of the bulb ear syringe, such as suggested by the comment, provided that the information is true and not misleading. Therefore, the agency's proposed directions in § 344.50(d) will be included in the final monograph without revision.

11. Three comments objected to the directions statement in § 344.50(d), "Children under 12 years of age: consult a doctor." The comments contended that the agency's basis for this age restriction, i.e., that the studies submitted in support of the use of carbamide peroxide in children were supervised by a physician (47 FR 30017), is not valid. The comments stated that all clinical studies are professionally supervised and that these studies were conducted under the supervision of a physician not because of safety concerns, but to assure that they were conducted under controlled conditions to support efficacy and to monitor any side effects that might occur. The comments contended that the studies demonstrate that earwax removal aid products can be safely used in children 2 to under 12 years of age.

One of the comments stated that restricting the use of carbamide peroxide in children under 12 years of age will force consumers to use primitive methods for removal of earwax in this age group. Another comment from a manufacturer stated that the Panel's and the agency's concerns that parents would unnecessarily use earwax removal aids to routinely clean the ears of their children are unfounded. The manufacturer explained that there is a target population of individuals who chronically accumulate earwax and who would derive benefit from cleaning the ears to prevent irritation and potential subsequent infection. The manufacturer submitted a summary of the results of a 1980 opinion poll which indicated that, in 5 percent of the surveyed families, earwax buildup occurred in children 12 years of age or under (Ref. 1). The manufacturer also stated that in the past 18 months it had received only one product-related report associated with the use of its earwax removal aid product in children per 2 million bottles sold and argued that "such a rate of reported occurrence does not indicate a need to restrict the use of the drug to adults and children 12 and over."

In the tentative final monograph for topical otic drug products, the agency stated that an earwax removal aid should not be used in children unless a physician has made a determination that there is a need to use such a product (47 FR 30017). This was based on the fact that earwax is derived from the watery secretions of the apocrine glands and the oily secretions of the sebaceous glands (Ref. 2) and on the fact that the apocrine glands are not active until puberty (42 FR 63558). Thus, these directions were proposed because excessive earwax is less likely to occur in children under 12 years of age, not because physicians had supervised the clinical studies and examined the ears of children as alleged by the comment.

The agency recognizes that some children under 12 years of age may have excessive earwax accumulation as indicated by the submitted opinion poll (Ref. 1). However, in cases where children under 12 years of age are suspected of having excessive earwax accumulation, a physician should be consulted to make a professional diagnosis and to recommend the proper treatment. A physician's diagnosis is particularly important in children under 12 years of age because young children may not often exhibit symptoms of serious ear problems or are unable to describe the symptoms of abnormal conditions to their parents. For example, the symptoms of otitis media (an inflammatory condition of the middle ear that occurs most often during childhood) include pain, hearing loss, and fever. However, in chronic serous otitis media there is impaired hearing, but the child may not have acute symptoms and pain is usually absent (Ref. 2). Such ear disorders would be difficult for parents to distinguish from excessive earwax. These ear disorders are serious and can result in hearing loss if untreated. Therefore, it is especially important for a physician to determine the appropriate treatment for the child's condition. The physician may recommend use of an OTC earwax removal aid if it is appropriate.

The agency does not believe that advising consultation with a doctor for children under 12 years of age, in the labeling of earwax removal aids, would force consumers to use primitive methods to remove excessive earwax in children in this age group. On the contrary, this direction should alert consumers to consult a physician before routinely cleaning the ears of children with an earwax removal aid, which might not be necessary and might delay needed medical attention. The direction thus promotes better ear care. Therefore, the agency is including in § 344.50(d) of this final monograph a direction restricting the use of an earwax removal aid to adults and children over 12 years of age.

References

(1) Comment No. C00009, Docket No. 77N-0334, Dockets Management Branch.

(2) Miller, K. O., "Otic Products," *in* "Handbook of Nonprescription Drugs," 7th Ed., American Pharmaceutical Association, Washington, pp. 402–403 and 406–408, 1982.

12. One comment disagreed with the proposed directions statement in § 344.50(d) for earwax removal aids that reads "Children under 12 years of age: consult a doctor." The comment suggested that the statement be revised to read: "Children under 12 should be supervised in the use of this product. For children under 2, there is no recommended dosage except under the advice and supervision of a doctor."

The agency does not agree with the comment's suggested revision. As stated in comment 11 above, earwax removal aids should not be used in children under 12 years of age except as recommended by a physician. If a physician recommends that an earwax removal aid be used in a child under 12 years of age, the agency expects that the child would be supervised in the use of the product.

II. Summary of Significant Change From the Proposed Rule

In accord with the revised "exclusivity" policy, the agency is amending § 344.50(b) under the heading "Indications" to include some of the supplemental language that was previously included in the "Other Allowable Statements" section of the tentative final monograph (see comment 2 above). The resulting indication which includes the additional optional terms "soften" and "loosen" reads as follows: "For occasional use as an aid to" (which may be followed by: "soften, loosen, and") "remove excessive wax."

III. The Agency's Final Conclusions on OTC Topical OTIC Drug Products

Based on the available evidence, the agency is issuing a final monograph establishing conditions under which OTC topical otic drug products are generally recognized as safe and effective and not misbranded. Specifically, the agency has determined that the only ingredient that has been determined to be monograph condition is carbamide peroxide 6.5 percent formulated in an anhydrous glycerin vehicle. Glycerin, antipyrine, and benzocaine, which were also considered in this rulemaking, have been determined to be nonmonograph ingredients. All other ingredients are considered nonmonograph ingredients. Any drug product marketed for use as an OTC topical otic drug that is not in conformance with the monograph (21 CFR Part 344) will be considered a new drug within the meaning of section 201(p) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 321(p)) and misbranded under section 502(a) of the act (21 U.S.C. 352(a)) and may not be marketed for this use unless it is the subject of an approved NDA.

No comments were received in response to the agency's request for specific comment on the economic impact of this rulemaking (47 FR 30019). The agency has examined the economic consequences of this final rule in conjunction with other rules resulting from the OTC drug review. In a notice published in the **Federal Register** of February 8, 1983 (48 FR 5806), the agency announced the availability of an assessment of these economic impacts. The assessment determined that the combined impacts of all the rules resulting from the OTC drug review do not constitute a major rule according to the criteria established by Executive Order 12291. The agency therefore concludes that no one of these rules, including this final rule for OTC topical otic drug products, is a major rule.

The economic assessment also concluded that the overall OTC drug review was not likely to have a significant economic impact on a substantial number of small entities as defined in the Regulatory Flexibility Act, Pub. L. 96–354. That assessment included a discretionary Regulatory Flexibility Analysis in the event that an individual rule might impose an unusual or disproportionate impact on small entities. However, this particular rulemaking for OTC topical otic drug products is not expected to pose such an impact on small businesses. Therefore, the agency certifies that this final rule will not have a significant economic impact on a substantial number of small entities.

List of Subjects in 21 CFR Part 344

OTC drugs, Topical otic drug products.

Therefore, under the Federal Food, Drug, and Cosmetic Act and the Administrative Procedure Act, Subchapter D of Chapter I of Title 21 of the Code of Federal Regulations is amended by adding new Part 344, to read as follows:

PART 344—TOPICAL OTIC DRUG PRODUCTS FOR OVER-THE-COUNTER HUMAN USE

Subpart A—General Provisions

Sec.

344.1 Scope.

344.3 Definitions.

Subpart B—Active Ingredients

344.10 Topical otic active ingredient.

Subpart C—Labeling

344.50 Labeling of topical otic drug products.

Authority: Secs. 201(p), 502, 505, 701, 52 Stat. 1041–1042 as amended, 1050–1053 as amended, 1055–1056 as amended by 70 Stat. 919 and 72 Stat. 948 (21 U.S.C. 321(p), 352, 355, 371); 5 U.S.C. 553; 21 CFR 5.11.

Subpart A—General Provisions

§ 344.1 Scope.

(a) An over-the-counter topical otic drug product in a form suitable for topical administration is generally recognized as safe and effective and is not misbranded if it meets each of the conditions in this part in addition to each of the general conditions established in § 330.1.

(b) References in this part to regulatory sections of the Code of Federal Regulations are to Chapter I of Title 21 unless otherwise noted.

§ 344.3 Definitions.

As used in this part:

(a) *Anhydrous glycerin.* An ingredient that may be prepared by heating glycerin U.S.P. at 150° C for 2 hours to drive off the moisture content.

(b) *Earwax removal aid.* A drug used in the external ear canal that aids in the removal of excessive earwax.

Subpart B—Active Ingredients

§ 344.10 Topical otic active ingredient.

The active ingredient of the product consists of carbamide peroxide 6.5 percent formulated in an anhydrous glycerin vehicle.

Subpart C—Labeling

§ 344.50 Labeling of topical otic drug products.

(a) *Statement of identity.* The labeling of the product contains the established name of the drug, if any, and identifies the product as an "earwax removal aid."

(b) *Indication.* The labeling of the product states, under the heading "Indication," the following: "For occasional use as an aid to" (which may be followed by: "soften, loosen. and") "remove excessive earwax." Other truthful and nonmisleading statements, describing only the indications for use that have been established and listed above, may also be used, as provided in § 330.1(c)(2), subject to the provisions of section 502 of the act relating to misbranding and the prohibition in section 301(d) of the act against the introduction or delivery for introduction into interstate commerce of unapproved new drugs in violation of section 505(a) of the act.

(c) *Warnings.* The labeling of the product contains the following warnings under the heading "Warnings":

(1) "Do not use if you have ear drainage or discharge, ear pain, irritation, or rash in the ear or are dizzy; consult a doctor."

(2) "Do not use if you have an injury or perforation (hole) of the ear drum or after ear surgery unless directed by a doctor."

(3) "Do not use for more than 4 days; if excessive earwax remains after use of this product, consult a doctor."

(4) "Avoid contact with the eyes."

(d) *Directions.* The labeling of the product contains the following statement under the heading "Directions": FOR USE IN THE EAR ONLY. Adults and children over 12 years of age: tilt head sideways and place 5 to 10 drops into ear. Tip of applicator should not enter ear canal. Keep drops in ear for several minutes by keeping head tilted or placing cotton in the ear. Use twice daily for up to 4 days if needed, or as directed by a doctor. Any wax remaining after treatment may be removed by gently flushing the ear with warm water, using a soft rubber bulb ear syringe. Children under 12 years of age: consult a doctor.

(e) *Optional wording.* The word "physician" may be substituted for the word "doctor" in any of the labeling statements in this section.

Dated: May 3, 1986.

Frank E. Young,

Commissioner of Food and Drugs.

[FR Doc. 86-17854 Filed 8-7-86; 8:45 am]

BILLING CODE 4160-01-M

federal register

Friday
August 8, 1986

Part III

Environmental Protection Agency

40 CFR Parts 260, 261, 262, 263, and 271
Hazardous Waste Management System;
Exports of Hazardous Waste; Final Rule

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Parts 260, 261, 262, 263, and 271

[SW-FRL-3038-3]

Hazardous Waste Management System; Exports of Hazardous Waste

AGENCY: Environmental Protection Agency.

ACTION: Final rule.

SUMMARY: On March 13, 1986, the U.S. Environmental Protection Agency (EPA) proposed regulations under the Resource Conservation and Recovery Act (RCRA), as amended by the Hazardous and Solid Waste Amendments of 1984 (HSWA), that would apply to exports of hazardous waste (51 FR 10146). EPA is today promulgating the final regulations on this subject. Consistent with HSWA, the regulations prohibit the export of hazardous waste unless certain requirements are met. These requirements include advance written notification to EPA of the plan to export hazardous waste, prior written consent to such plan by the receiving country, attachment of a copy of the receiving country's written consent to the manifest accompanying each waste shipment, and conformance of the shipment to such consent. In addition to provisions concerning the preceding requirements, today's rule includes provisions governing special manifest requirements, exception reporting, annual reporting, recordkeeping, transporter responsibilities, confidentiality, and State authorization.

DATES: Effective Date: November 8, 1986. Exports are prohibited on or after the effective date except in compliance with these regulations. Accordingly, unless consent by the receiving country has been obtained by that date, an export cannot take place. EPA will begin accepting notifications in accordance with these regulations immediately in order to allow time to obtain consent from a receiving country by the effective date of these regulations. Exporters are, therefore, encouraged to submit notifications expeditiously in order to allow time to obtain consent by November 8, 1986, for exports to occur on or soon after that date.

ADDRESSES: The OSW docket is located at: EPA RCRA Docket (Sub-basement), 401 M Street, SW., Washington, DC 20460.

The docket is open from 9:30 to 3:30 Monday through Friday, except for Federal holidays. The public must make an appointment to review docket materials. Call Mia Zmud at 475–9327 or Kate Blow at 382–4675 for appointments. The public may copy a maximum of 50 pages of material from any one regulatory docket at no cost. Additional copies cost $.20/page.

FOR FURTHER INFORMATION CONTACT: Carolyn K. Barley, (202) 382–2217, Office of Solid Waste, Room S–257 (WH–563), 401 M Street, SW., Washington, DC 20460 or the toll-free RCRA Hotline: (800) 424–9346 (in Washington, DC, call (202) 382–3000).

SUPPLEMENTARY INFORMATION:

Preamble Outline

I. Authority

These regulations are being promulgated under the authority of sections 2002(a), 3002, 3003, 3006, 3007, 3008 and 3017 of the Solid Waste Disposal Act, as amended by the Resource Conservation and Recovery Act, as amended, 42 U.S.C. 6912(a), 6922, 6923, 6926, 6927, and 6937.

II. Background and Summary of Final Rule

A. Existing Export Regulations

On February 26, 1980, EPA promulgated regulations under the Resource Conservation and Recovery Act of 1976 (RCRA) governing exports of hazardous waste. 45 FR 12732, 12743–12744 (codified at 40 CFR Parts 262 and 263). These regulations place certain requirements on generators and transporters regarding exports of hazardous waste in light of the special circumstances involved in international shipments. Since RCRA did not expressly address exports of hazardous waste, these provisions were promulgated primarily under RCRA sections 3002 (Standards Applicable to Generators of Hazardous Waste) and 3003 (Standards Applicable to Transporters of Hazardous Waste) and are limited in scope. A detailed description of EPA's existing export regulations can be found in the Supplemental Information accompanying the proposed rule for Exports of Hazardous Waste. 51 FR 8744 (March 13, 1986).

B. The Hazardous and Solid Waste Amendments of 1984

On November 8, 1984, the President signed into law a set of comprehensive amendments to RCRA, entitled the Hazardous and Solid Waste Amendments of 1984 (HSWA). These comprehensive amendments have far-reaching ramifications for EPA's hazardous waste regulatory program. Among other things, they add a new Section 3017 to RCRA specifically addressing hazardous waste exports.

Generally, subsection (a) of section 3017 provides that, beginning 24 months after enactment of HSWA, the export of hazardous waste is prohibited unless the person exporting such waste: (1) Has provided notification to the Administrator; (2) the government of the receiving country has consented to accept the waste; (3) a copy of the receiving country's written consent is attached to the manifest which accompanies the waste shipment and; (4) the shipment conforms to the terms

of such consent. In lieu of meeting the above requirements, a person may export hazardous waste if the United States and the government of the receiving country have entered into an international agreement establishing notice, export, and enforcement procedures for the transportation, treatment, storage, and disposal of hazardous waste and the shipment conforms to the terms of such agreement.

Subsection (c) of section 3017 sets forth the requirement to notify the administrator before the shipment leaves the United States and specifies the information to be included in such notification. Subsections (d) and (e) establish procedures for obtaining the receiving country's consent to accept the waste. Subsection (f) addresses the effect of an international agreement on the requirements of Section 3017. Subsection (b) requires the Administrator to promulgate regulations necessary to implement section 3017. Subsection (h) provides that section 3017 does not preclude the Administrator from establishing other standards for the export of hazardous waste under sections 3002 and 3003 of RCRA. Congress also amended section 3008 of RCRA to provide criminal penalties for knowingly exporting hazardous waste without the consent of the receiving country or in violation of an existing international agreement between the United States and the receiving country.

Section 3017 of HSWA contains one additional requirement with which exporters were required to comply immediately upon enactment of HSWA: Subsection (g) requires any person exporting hazardous waste to file with the Administrator, no later than March 1 of each year, a report summarizing the types, quantities, frequency, and ultimate destination of all hazardous waste exported during the previous year. EPA codified this particular statutory requirement in its export regulations on July 15, 1985. 50 FR 28702, 28746.

C. March 13, 1986 Proposed Rule

On March 13, 1986, EPA proposed to amend its hazardous waste export regulations to implement section 3017 and thereby improve its current program governing exports. 51 FR 8744. These specific amendments were plced in a revised Subpart E of 40 CFR Part 262. Because Subpart E currently includes special requirements governing imports of hazardous waste and the disposition of waste pesticides by farmers, these provisions were proposed to be moved to new Subparts F and G respectively with no substantive changes. Amendments were also proposed to 40 CFR Parts 260 regarding confidentiality, Part 263 pertaining to transporters of hazardous waste, and Part 271 with respect to State authorization.

Readers should refer to the proposed rule for a discussion of the content, alternatives considered, and rationale for the positions taken in the proposal.

D. Summary of the Final Rule

Today's final rule on the export of hazardous waste adopts most of the provisions of the proposed rule with certain modifications. In summary, today's rule prohibits exports of hazardous waste unless: (1) Notification of the intent to export is provided to the Administrator; (2) prior written consent is obtained from the receiving country; (3) a copy of the prior written consent is attached to the manifest; and (4) the shipment conforms to the terms of the written consent.

Changes arising out of comments on the proposed rule concern primarily: (1) The definition of exporter; (2) the definitions of receiving and transit countries; (3) collection of a copy of the manifest by U.S. Customs at the U.S. point of departure; (4) hazardous wastes for which notification and consent is required; (5) the period of time covered by a notification; (6) the effective date of the regulations; and (7) special requirements for exports by rail.

In addition to today's final rule on the export of hazardous waste, readers should be aware that pursuant to section 6(e) of the Toxic Substances Control Act, EPA has banned the export of polychlorinated biphenyls (PCBs) of 50 PPM or greater in the absence of an exemption. See 40 CFR 761.10. Today's rule on the export of hazardous waste does not affect this prohibition.

III. Responses to Comments and Analysis of Issues

This section of the preamble addresses the major comments received by EPA on the proposed rule and describes the Agency's position on the major issues raised in the proposal and during the comment period. A separate background document responds to each comment received on the proposal which is not responded to in this preamble as part of the record for this rulemaking. Provisions retained as proposed and not discussed in this preamble are retained for the reasons set forth in the preamble to the proposed rule.

A. Applicability and General Requirements [§§ 262.50, 262.52]

Section 262.50 describes the applicability of Subpart E. Since EPA is changing the definition of exporter [discussed in Section III.B.2. below], this section provides that Subpart E requirements are applicable not only to persons required to initiate the manifest which specifies a treatment, storage, or disposal facility (TSDF) in the receiving country as the designated facility but also to any intermediaries arranging for the export (i.e., export brokers). A reference to the requirements applicable to transporters transporting waste for export has also been added to this provision to direct transporters' attention to the applicable requirements of Part 263. As explained in the proposal, the special export requirements apply in addition to any applicable domestic requirements which apply independently (e.g., Part 262 requirements applicable to generators) except to the extent Subpart E specifically provides otherwise.

As in the proposal, this section also provides that the export requirements apply to all exports of hazardous waste unless an international agreement is entered into between the United States and the importing country which sets forth different requirements. As the United States has yet to enter into any such agreements, § 262.58 is reserved to address any agreements the United States may enter into in the future.

Section 262.53 summarizes the requirements applicable to exports. Some minor language changes have been made to this section to again reference transporter requirements of Part 263 and to reflect the delineation of responsibilities between transporters and other "exporters" of hazardous waste as discussed in Section III.B.2 below.

B. Definitions [§ 262.51]

1. Definition of "Receiving Country"

In the March 13, 1986 proposed rule, EPA defined "receiving country" as the foreign country of "ultimate destination" of a hazardous waste. It was EPA's intent to distinguish "receiving country" from "transit country" which was defined as any foreign country through which a hazardous waste passes en route to a receiving country. Prior consent was proposed to be required only from "receiving countries" not "transit countries." The Agency proposed, however, to exercise its discretion under Section 3017(h) to provide notification to transit countries.

EPA specifically requested comments concerning its proposed definition of receiving country, recognizing the importance of the term as used in section 3017. Various alternatives available for defining this term were noted in the proposal such as defining "receiving country" as: (1) All countries through which the waste passes; (2) the first country the waste enters; or, (3) the final destination of the waste. A number of comments were received on this issue, many of which were in agreement with the Agency's definition. However, some commenters recommended expanding the definition of "receiving country" to include any foreign country the waste passes through en route to its ultimate destination, i.e., "transit country."

The primary concern of these commenters was that, under the language of EPA's definition of receiving country, long-term storage or treatment could occur in a "transit country" without its consent so long as the waste would subsequently be sent elsewhere. Moreover, EPA would have no authority to prohibit long-term storage or treatment in a transit country where the transit country objected to the shipment. The scenario was presented where an exporter intended to ship a waste first to country "A" for treatment, then to country "B" for multi-year storage while the "ultimate" disposal facility in country "C" was prepared to receive and dispose of the waste. Under this scenario, even if countries "A" and "B" objected to the shipment, EPA would have no authority to prohibit the shipment to those countries. Concern was expressed that this would encourage unscrupulous exporters to evade consent requirements with sham long-term treatment and storage. In addition, the dangers involved in storing and/or treating the waste were suggested to be of equal concern as those involved in the ultimate disposal of the waste.

EPA is also concerned about long-term storage and/or treatment of U.S. waste in a foreign country. In fact, EPA's proposal explained that its intent was to require consent from the "ultimate destination" of the waste in contrast to countries where mere *transportation through* or *temporary* storage *incidental to transportation* was to occur.

The proposal, however, envisioned that although there may be several transit countries involved, there would be only one "ultimate destination" of the waste. The scenarios presented by commenters have brought to EPA's attention that not only was EPA's proposed regulatory language ambiguous but that there may be, in rare circumstances, more than one country in which something more than mere transportation and/or temporary storage incidental thereto could occur. In order to ensure that prior consent is obtained from countries, in which treatment and/or long-term storage is to occur, the final rule defines "receiving country" as the foreign country to which a hazardous waste is sent for the purpose of treatment, storage or disposal (except for temporary storage incidental to transportation). The final rule also redefines "transit country" as any foreign country, other than a receiving country, through which a hazardous waste is transported. These definitions reflect the intent of the proposal to exempt from the prior consent requirement mere transportation through or temporary storatge incidental to transportation with the added recognition that, in rare circumstances, there may be more than one "receiving country."

In redefining the term "receiving country," EPA recognizes that there may be limits to an exporter's knowledge of further shipment of U.S. generated hazardous wastes from a treatment, storage or disposal facility (TSDF) in one foreign country to another. Thus, EPA interprets the term "receiving country" to include only those countries to which an exporters knows or can reasonably ascertain that the waste will be sent for treatment, storage or disposal. EPA cannot hold exporters responsible for independent decisions by foreign TSDFs to further export a hazardous waste.

The primary exporter is responsible for properly designating a country as a transit country. If any uncertainty arises regarding whether certain "storage" occurring in a foreign country is "storage incidental to transportation," primary exporters should refer, for guidance, to the preamble to the rule clarifying when a transporter handling shipments of hazardous waste domestically is required to obtain a storage permit. See 45 FR 86966 (December 31, 1980). Thus, in determining whether a country is a receiving country or a transit country, the factors to be considered are the nature of the handling of the waste in such country and the length of time the waste remains in such country. EPA is not at this time, however, placing a time limit on the length of time considered "temporary storage incidental to transportation." One of the commenters suggesting a broader definition of receiving country also recognized the need for an exception for temporary storage incidental to transportation. That commenter recommended a 10-day limit consistent with domestic requirements. *See* 45 FR 86966 (December 31, 1980). EPA, however, does not feel it appropriate to impose a specific time limitation on storage incidental to transportation where exports are concerned. The time limitation in the rule referenced above was reached based upon the general nature of the transportation domestically. International transportation, on the other hand, may vary among foreign countries. EPA does not have, at this time, information which would allow it to devise a generally applicable time limitation for storage incidental to transportation internationally. To ensure the proper implementation of today's regulation, EPA will selectively review notifications to ensure that countries designated by exporters as transit countries are not, in fact, receiving countries. If EPA determines that a country is improperly designated as a transit country, it will require that country's prior consent to the waste shipment.

In EPA's view, the final definitions of receiving and transit countries and the decision to require notification of transit countries and both notification of and prior consent from receiving countries is consistent with the statute and best implements Congressional intent in enacting section 3017. Congress did not define the term "receiving country" in section 3017. The statutory language uses the term "receiving country" in the singular form which arguably indicates that Congress contemplated only one receiving country. On the other hand, however, use of the singular version may simply reflect the assumption that exports commonly would involve only one receiving country. The statutory language also provides for notification of the *treatment, storage or disposal* facility abroad to which the waste will be sent. This language arguably indicates that Congress contemplated notification of any country in which "treatment," storage" or "disposal" occurs. However, this notification requirement is qualified by the term "ultimate" treatment, storage or disposal facility. This arguably indicates that "receiving country" encompasses only the final destination of the waste with the phrase "treatment, storage or disposal facility" being used simply as the common phrase for identifying the hazardous waste facility which is the "ultimate" destination. To complicate matters further, however, "ultimate" storage is a contradiction in terms since EPA has defined "storage" as the holding of hazardous waste for a

temporary period *at the end of which the hazardous waste is treated, disposed of or stored elsewhere.* Thus, technically, storage could never be "ultimate," yet Congress used the term "storage" and must have intended it to have some content. An argument could be made that "ultimate" means the TSDF in a *single* foreign country when the waste is temporarily stored in such country and then moved to another facility in that same country for disposal. In this vein, the phrase "treatment, storage or disposal facility" would arguably evidence intent that notification and prior consent be obtained from any country in which treatment, storage or disposal occurs. Unfortunately, the legislative history of section 3017 does not shed any light on Congress' intent regarding the content of "receiving country."

In view of the ambiguity of this term, EPA believes that it is best defined as the country in which treatment, storage or disposal occurs but not a country in which mere transportation (including temporary storage incidental to transportation occurs. Neither the statutory language nor legislative history evidences a clear intent to require both notification and prior consent for mere transportation through a foreign country which would include, consistent with domestic transportation, temporary storage incidental to transportation.

In EPA's view, Congress was concerned with informing a foreign country *and obtaining the prior consent* from a country which is actually ending up with the waste whether through disposal, treatment or long-term storage. In other words, Congressional concern was with countries truly accepting the waste and taking significant action to deal with the waste. Generally, the considerations and ramifications for these countries will be different from and greater than those of countries in which only transportation occurs. Moreover, treatment and long-term storage in a foreign country can be a means to avoid domestic regulation of hazardous waste disposition and can pose problems similar to the actual disposal of hazardous wastes. For example, a surface impoundment engaged in "long term storage" of a waste is likely to present risks similar to an impoundment engaged in "disposal" of a waste, assuming the unit is designed, operated and located in a similar manner. Consent from foreign countries in which treatment or storage (other than incidental to transportation) occurs also is necessary to protect against attempts to avoid consent requirements by labeling particular activities as long-term storage or treatment.

EPA believes that concerns associated solely with transportation through a country are addressed through notification alone which will provide a country with information to enable it to respond to accidents which may occur during transportation. Response is also assisted, and protection afforded for such activities, through the container, labeling and placarding requirements imposed on the transportation of hazardous waste both domestically and by other countries. The notification of transit countries also allows such country to take action to prohibit the entry of such waste into its borders. The treatment of transit countries in the final rule also furthers Congressional intent to impose a minimum of additional regulatory burdens on U.S. generators and administrative burdens on EPA while establishing a more comprehensive and responsible export policy. See 130 Cong. Rec. S9152 (daily ed. July 25, 1984); 129 Cong. Rec. H8163 (daily ed. October 6, 1983). Finally, EPA's definitions of receiving and transit countries and its decision to require prior consent of receiving countries and notification for transit countries is consistent with a new draft decision recently issued by the Organization for Economic Cooperation and Development (OECD) concerning the transboundary movement of hazardous wastes. (Draft Council Decision and Recommendation on Exports of Hazardous Waste from the OECD Area, March, 1986.)

2. Definition of Exporter

a. *Appropriate Liabilities and Responsibilities.* In the proposed rule, EPA defined "exporter" to be the person who is required to prepare the manifest in accordance with 40 CFR Part 262, Subpart B for a shipment of hazardous waste that specifies a TSDF in the receiving country as the facility to which the waste will be sent. Thus, for example, the exporter could be the generator in one case (*see* 40 CFR 260.10, 262.20), the owner or operator of a treatment, storage or disposal facility who initiates a shipment of hazardous waste in another (*see* 40 CFR 264.71(c), 265.71(c)), or a transporter who mixes hazardous waste of different DOT shipping descriptions in yet another (*see* 40 CFR 263.10(c)(2)). The proposal also discussed an alternative definition of exporter—any person who intends to export a hazardous waste. Under this definition, all parties involved in the export (i.e., the generator or person required to assume generator responsibilities, transporter, and any export broker) would be required to comply with all of the export requirements and could be held liable for any failure to do so. Under such a definition, however, only one party would be expected to assume and perform particular duties (such as providing notification) on behalf of all the parties. The proposal noted that this alternative was similar to the treatment afforded generators where several persons meet the definition of generator (*see* 45 FR 72024 (Oct. 30, 1980)).

EPA rejected this alternative primarily because: (1) It is difficult to define the point at which intent to export occurs and the manifest constitutes clear evidence of such intent (e.g., a question arises as to whether an initial generator who sends its waste to a domestic recycling facility and that facility subsequently exports the waste for further recycling "intends" to export); (2) where several parties meet the definition of "exporter," confusion might occur regarding which party should provide notification on behalf of all the parties potentially causing delay and/or duplicative notification; (3) parties such as transporters should not be subject to liability for responsibilities more appropriately placed on generators or persons required to assume generator responsibilities; and, (4) the party preparing the manifest generally appeared to be in the best position to supply EPA with the information required in the notification, receive the EPA Acknowledgment of Consent for attachment to the manifest, and ensure that the shipment conformed with the terms of the receiving country's consent.

While some commenters supported EPA's proposed definition of exporter, others suggested that full potential liability for export notification and other violations should be placed on all parties engaged in the export. One commenter suggested that EPA could avoid duplicative notification by requiring transporters and brokers to submit a copy of the relevant notification and other documents with an appropriate certification, thereby creating an incentive for such persons to verify the information obtained from the person preparing the manifest. One commenter was especially concerned that, under the proposed rule, waste transporters and brokers who often actually arrange for the domestic transport, international transit, and ultimate treatment, storage, and disposal of the waste would be largely exempt from enforcement.

The Agency agrees, at least in part, with the concerns expressed by these

commenters. Although the Agency suggested in the preamble that the preparer of the manifest designating a foreign TSDF would remain liable for any violations of the duties imposed upon him when performed by a broker on his behalf, the Agency agrees with the commenter that brokers arranging for the export should also be held directly responsible for accurate notification and compliance with the consent of the receiving country. These persons are acting on behalf of the party required to initiate the manifest and often may be similarly situated. For example, a broker would be knowledgeable of most information required in a notification since he would be arranging for the export. Therefore, the Agency has added to the definition of exporter "any intermediary arranging for the export."

The term "intermediary" means "broker." An intermediary/broker is a party who arranges for an export by acting as a middleman between the party originating the manifest and another party involved in the export such as the transporter or foreign waste management facility. An intermediary/broker can be licensed or unlicensed, an agent or an indepentent contractor. The term "intermediary" excludes transporters, provided the transporter's role is limited to transporting the waste. The term would, however, include transporters if the transporter were also taking on intermediary responsibilities such as arranging for the management of the waste with the foreign TSDF.

With regard to the responsibilities and liabilities of transporters transporting waste for export, EPA is not, for the most part, making the changes suggested by these commenters. The proposed rule included two significant amendments to § 263.20. One prohibited a transporter from accepting a waste from an exporter unless an EPA Acknowledgment of Consent was attached to the manifest. The other required transporters to ensure that the EPA Acknowledgement of Consent accompanied the hazardous waste en route. In addition, existing regulations require transporters to send a copy of the manifest back to the generator (§ 263.20(g)) and to deliver the entire quantity of hazardous waste to the place outside the United States designated by the generator (§ 263.21(a)(4)). These duties parallel the duties placed on transporters of domestic waste shipments. EPA does not believe that transporters of hazardous waste for export should be held responsible for other elements of the notification and consent, such as ensuring that the waste meets the description contained in the notification or that the quantity of waste consented to by the receiving country has not been exceeded. EPA does not believe it necessary or practical to require transporters to verify that the waste matches the description contained in the notification. This could be construed to necessitate periodic sampling and waste analysis by transporters who are generally not qualified to undertake these actions. In addition, it is possible that the originator of the manifest may employ a number of transporters to transport waste covered by a single notification. It does not seem equitable or practical to require each transporter to ensure that the total quantity consented to by the receiving country has not been exceeded.

Of course, if the transporter knows or is willfully blind to the fact that the waste does not conform with the terms of the consent, he may nonetheless be subject to criminal enforcement action under section 3008(d). In view of the availability of criminal sanctions for such actions, EPA is adding to the requirements applicable to transporters, the requirement that a transporter may not accept a waste for export where he knows the shipment does not conform to the Acknowledgement of Consent. Thus, whereas a transporter has no affirmative duty to ensure conformance of the shipment with the consent, if he is aware that the shipment is not in conformity, he has the duty to refuse to transport the waste.

To clarify its criminal enforcement authority under section 3008(d)(6) against a transporter who knowingly exports hazardous waste without the consent of the receiving country, the Agency is making another change to the definition of exporter. In so doing, EPA wishes to preclude any misunderstanding about the reach of seciton 3008(d) which might otherwise have been caused by the definiton of "exporter" for Subpart E purposes. Therefore, in order to make clear its criminal enforcement authority under section 3008(d) while clearly delineating the limited administrative responsibilities of transporters, the final rule uses the term "primary exporter" to refer to the person defined as an "exporter" in the proposed rule, and, as discussed previously, any intermediary arranging for the export. This change makes clear that these persons are not the only parties which are "exporters" subject to certain responsibilities under section 3017 and criminal enforcement action under Section 308. Transporters transporting hazardous waste for export are also a type of "exporter."

The responsibilities of the primary exporter are contained in Part 262, Subpart E. Although under this revised definition, there may be more than one party acting as the primary exporter, e.g., "the person required to initiate the manifest . . . and any intermediary arranging for the export,' the Agency expects one party to submit the notification, keep the required records, and submit the required annual report, etc. on behalf of all the parties. These parties should decide amongst themselves which party should perform these functions on behalf of the other parties meeting the definition of "primary exporter." This is similar to the situation where several parties meet the definition of generator. See 45 FR 72024, 72026 (October 30, 1980). Enforcement actions can, however, be taken against all primary exporters where equitable and in the public interest.

The responsibilities of transporters are identified in 40 CFR Part 263. These responsibilities include the two amendments to § 263.20 included in the proposed rule (with a minor adjustment for rail transportation discussed at Section G below), the existing requirements of §§ 263.20(g), 263.21 and 263.22(d), and the new requirements that a transporter may not accept hazardous waste for export if he knows the shipment does not conform with the Acknowledgment of Consent and he must deliver a copy of the manifest to the U.S. Customs official at the point the waste leaves the United States (discussed at Section E below). In EPA's view, Section 3017 accords it the discretion to determine who constitutes the "person who exports" or "person who intends to export" and to delineate the responsibilities of each person involved consistent with the intent of section 3017.

At the suggestion of commenters, EPA is also making one other change to the definition of exporter. Rather than define "primary exporter" as the person required to "prepare" a manifest, the final rule defines "primary exporter" as the person required to "originate" a manifest designating a foreign TSDF. The purpose of this revision is to make clear that it was and remains EPA's intent that liability is not solely on the individual who physically completes the manifest but rather on the person responsible for originating the manifest. It should be noted that "person" is broadly defined in § 260.10 to include, among others, individuals, corporations, and partnerships. An entity such as a corporation may comprise many individuals. Thus, many individuals can, in appropriate circumstances, be held

liable for non-compliance with the requirements applicable to a primary exporter. For example, the corporate president, vice-president, facility manager, and environmental officer may all be subject to criminal enforcement action under section 3008(d)(6) where such persons decide to export hazardous waste without the consent of the receiving country. EPA emphasizes that the definition of primary exporter does not limit EPA's authority to enforce criminally under section 3008(d)(6) against such parties. *Cf. United States v. Johnson & Towers, Inc.*, 741 F. 2d 662, 667 (3rd Cir. 1984) *cert. denied*, 105 S. Ct. 1171 (1985) (holding that definition of "person" for purposes of knowing unpermitted disposal of hazardous waste under section 3008(d)(2) is not limited to the "owners or operators" regulated under RCRA administrative requirements but rather extends as well to individual employees of the entity disposing of the waste).

b. Applicability of the Export Requirements to Certain Hazardous Wastes. Under EPA's proposed definition of "exporter," the regulations governing exports would be applicable to exports of hazardous waste initiated by persons required to prepare a manifest under 40 CFR Part 262, Subpart B or an equivalent provision in an authorized State program. Thus, exports of any hazardous wastes that are exempt from the manifest requirements of Part 262, Subpart B would not be subject to any of the export requirements. Accordingly, such hazardous wastes as samples, residues in empty containers, wastes generated in product transportation vehicles, certain wastes when recycled, and wastes generated by small quantity generators of less than 100 kg/mo would be excluded from the export requirements. *See*, e.g., 40 CFR 261.4(c) and (d), 261.5, 261.6, and 261.7. In the preamble to the proposed rule, EPA questioned whether Congress intended to regulate for export wastes not regulated domestically and requested comment on whether EPA should expand the wastes subject to section 3017.

(1) *Comments Suggesting that EPA Narrow the Applicability of Section 3017.* Several commenters focused on recycled waste and suggested that all hazardous waste exported for use, reuse, reclamation or other recycling be exempt from the export requirements even when subject to the manifest requirement. Various reasons for this position were put forth including: (1) Additional administrative costs created by the regulations of hazardous waste exported for recycling could damage or destroy the economic viability of such recycling and result in environmentally less preferable management; (2) due to the volatility of prices paid for recycled metals in international trade, the delay caused by waiting for the receiving country's consent could have a significant adverse economic impact; (3) recyclers have an economic incentive to be certain that their wastes are in fact recycled; therefore, more secure handling of wastes intended for recycling is assured; and (4) the stigma involved in treating hazardous wastes intended for recycling as "hazardous waste" might cause the receiving country to refuse consent. These commenters further argued that there is no indication of Congressional intent to include hazardous wastes for recycling under section 3017; in their view, the phrase "treatment, storage or disposal" as used in section 3017 does not include recycling. Lastly, these commenters cite other sections of RCRA and its legislative history as an indication of Congressional intent to foster all types of recycling of hazardous waste.

EPA does not agree that all hazardous wastes exported for use, reuse, reclamation or other recycling should be exempt from the export requirements. EPA's authority to regulate materials for recycling under Subtitle C has been fully discussed in other rule-makings and need not be repeated in detail here. *See* 48 FR 14472 (April 4, 1983); 50 FR 614 (January 4, 1985). Hazardous waste recycling and ancillary activities are within the statutory meanings of the terms "treatment, storage and disposal." In view of the absence of statutory language limiting the reach of these terms for purposes of section 3017, EPA does not believe Congress intended to exempt hazardous wastes for recycling which EPA fully regulates domestically. Similarly, the argument that hazardous wastes that are recycled do not require regulations because they are inherently valuable and do not generally pose significant risks also has been refuted elsewhere. *See*, e.g., 48 FR at 14473 *et seq;* 50 FR at 617–18. Moreover, although EPA is sympathetic to any impacts the requirement of consent may have with respect to some wastes when exported for recycling, where EPA has made the determination that a hazardous waste recycling activity poses sufficient risk domestically to be subjected to full regulation, there is no justification sufficient to override the need of a foreign country receiving such wastes to be accorded notification and the opportunity to accept or reject such waste. Full regulation domestically is clear evidence that this is the type of waste for which foreign countries would also wish to receive notice and have the means by which to reject such waste and police activities involving such wastes. Narrowing the applicability of section 3017 as these commenters suggested might also encourage sham recycling activities. The potential for this is increased in the context of exports since the foreign facility is outside EPA's jurisdiction, thus making enforcement by EPA more difficult. Accordingly, the final rule continues to apply to all wastes for recycling, which are required to be manifested.

To accommodate commenters' concerns regarding stigmatization of exported recycled hazardous wastes by labeling these materials "hazardous wastes," EPA recommends that exporters include information in their notifications indicating that the waste involved is a "recyclable material" (see 40 CFR 261.6(a)(1)). EPA can then pass this information on to the foreign countries involved. EPA also is doubtful that the possibility of stigmatization or the economic impacts some commenters fear will prove significant. As a result of international discussion and agreement, many countries have become knowledgeable regarding the issue of transboundary movements of hazardous waste. For example, joint decisions and recommendations have been generated under the auspices of the Organization for Economic Cooperation and Development and by the Commission of European Communities. Accordingly, in many cases where recycling of a valuable material is involved, it is likely that the countries involved will demonstrate a sufficient degree of sophistication to respond appropriately and expeditiously to notifications concerning such activities. Moreover, in view of the means EPA intends to use to transmit information, delay on the United States' part and any consequent economic impacts which might result therefrom are unlikely.

The Agency wishes to point out that a relatively narrow set of hazardous secondary materials are not defined as solid wastes and, therefore, are not hazardous wastes when recycled in a particular manner (e.g., listed commercial chemical products that are to be reclaimed (50 FR 614, 619, *codified at* 40 CFR 261.2)). Thus, these materials would not be subject to the export requirements.[1] Exporters of such

[1] These same listed commercial chemical products would, however, be a hazardous waste when, for example "used in a manner constituting disposal." *Id.*

materials, nevertheless, should keep in mind that they have the burden of proof to show that such materials are to be recycled in a manner bringing them outside the scope of "solid waste." *See* 50 FR at 642 and 40 CFR 261.2(f). Exporters "must keep whatever records or other means of substantiating their claims that they are not managing a solid waste because of the way the material is to be recycled." 50 FR at 642–643. This might include, for example, a description of the foreign recycling facility, evidence that the recycling facility is licensed or otherwise qualified by the foreign jurisdiction, and/or a copy of the contract indicating the terms of the transaction. *See* also *United States v. Hayes International Corp.*, 786 F.2d 1499, (11th Cir. 1986) (in a prosecution under Section 3008(d)(1) of RCRA for the knowing transportation of waste to an unpermitted facility, the court rejected defendant's claim that it believed the hazardous waste at issue was being recycled, where evidence indicated the lack of a good faith belief).

EPA is aware of evidence that certain materials that have been exported ostensibly for recycling were actually examples of sham recycling. Improper disposal was intended and in fact occurred. For example, a 41-count indictment charging conspiracy, mail fraud, and utilization of false statements was returned on April 17, 1986, by a federal grand jury sitting in the Southern District of California against four officers and owners of two corporations that were allegedly, among other things, claiming to be recycling waste when in fact they knew it was being illegally disposed of in Mexico.

Any notification, consent or annual report based on false representations is invalid. Thus, persons exporting hazardous waste are subject to civil and criminal enforcement actions. These actions are based upon the fact that the exporter did not comply with applicable notification, consent and/or annual report requirements.

Another extremely small group of hazardous secondary materials, although considered hazardous wastes, are either fully exempt or partially exempt from regulation by EPA domestically. *See* 40 CFR 261.6(a)(2) and (3) (50 FR 614, 665 (January 4, 1985)). Exporters of such secondary materials should keep in mind that the burden of proof is also on the exporter to demonstrate that such waste falls within one of these exemptions. The applicability of the export requirements to these wastes when exported is discussed in detail below in conjunction with other wastes for which manifests are not required domestically.

EPA also wishes to note that if, as a result of promulgating a new hazardous waste characteristic, adding additional wastes to the list of hazardous wastes, or other regulatory changes, additional wastes become subject to manifesting, exporters of such waste must also comply with the requirements promulgated in today's rule.

(2) *Comments Suggesting that EPA Broaden the Applicability of section 3017.* Some commenters supported the Agency's proposal to exempt from the export requirements those wastes that are presently exempted from manifest requirements. One commenter, however, objected to this scheme suggesting that the language of section 3017 (which states that ". . . no person shall export any hazardous waste identified or listed under this subtitle" unless the requirements of section 3017 are met) clearly indicates Congressional intent to subject all hazardous wastes to the export requirements of section 3017. EPA does not agree that Congress intended to require notification and consent for all hazardous wastes in view of the statutory language itself and the established domestic RCRA program.

EPA's regulatory definition of "hazardous waste" is a broad one. It includes all solid wastes which are listed hazardous wastes or which exhibit the characteristic of ignitability, corrosivity, reactivity, or EP toxicity. Generally, hazardous wastes (whether listed or characteristic) are subject to the generally applicable regulations governing their generation, transportation, treatment, storage and disposal. *See* 40 CFR Parts 262, 263, 264 and 265. However, there are a very small number of "hazardous wastes" which EPA, for one reason or another, has totally exempted from domestic regulation. These include, for example, residues under certain specified amounts in empty containers and scrap metal (if it demonstrates a characteristic of hazardous waste) when sent for recycling. 40 CFR 261.7, 261.6(a)(3)(iv). In EPA's view, Congress could not have intended to regulate for export those "hazardous wastes" which EPA does not regulate domestically. It is highly unlikely that Congress would have been more concerned about wastes exported than wastes in its own backyard. For example, as Representative Mikulski, the sponsor of section 3017, stated:

> Our own country will have safeguards from the ill effects of hazardous waste upon passage of [HSWA]. We should take an equally firm stand on the transportation of hazardous waste bound for export to other countries. 129 Cong. Rec. H8163 (daily ed. October 6, 1983) [emphasis added].

An "equally firm" stand on exports would not require regulation of a waste for export not regulated domestically.

Nor does EPA agree that section 3017 is clear on its face regarding its scope of coverage. Although section 3017(a) does include language prohibiting the export of "any hazardous waste" unless certain conditions are met, one of those conditions is the requirement to attach a copy of the receiving country's consent "to the *manifest* accompanying the hazardous waste shipment" [emphasis added]. And, in transmitting notification to a receiving country, section 3017 includes a requirement that EPA, in conjunction with the Department of State, include "a description of the Federal regulations which would apply to the treatment, storage and disposal of the hazardous waste in the United States." These requirements evidence an intent on Congress' part to encompass something less than "all hazardous wastes" since where a waste is not regulated domestically, consent could *not* be attached to the manifest nor would there be any regulations for EPA to describe which govern the domestic treatment, storage or disposal of such wastes. Thus, EPA does not believe that Congress mandated notifying a foreign country of a "hazard" the United States itself does not believe of sufficient concern to regulate domestically.

The question of the reach of section 3017 also arises with respect to certain hazardous wastes which are regulated minimally domestically, although excluded from the generally applicable requirements placed on the generation, transportation, treatment, storage and disposal of hazardous wastes. These include, for example, samples for testing and wastes generated by small quantity generators generating less than 100 kg/mo of hazardous waste. *See* 40 CFR 261.4(d); 261.5 FR at 10174 (March 24, 1986).[2]

EPA does not believe that application of the export requirements was intended for those wastes excluded from the generally applicable manifesting requirement even though some de minimus requirements are imposed domestically. In EPA's view, the function served by the manifest domestically is similar to the function served by the notification and consent internationally. The manifest notifies persons receiving the waste or handling the waste of the nature of the materials

[2] The final rule as it applies to small quantity generators is also discussed at Section H of this preamble.

being dealt with and as such affords such persons the opportunity to reject the waste or, if accepted, provides sufficient information to ensure proper handling of the waste. The manifest also serves as a tracking mechanism which allows policing of hazardous waste management and allows action to be taken against persons improperly handling the waste. Similarly, the notification requirement for exports notifies the foreign country receiving the waste of the nature of the materials and as such affords the receiving country the opportunity to reject the waste or if accepted, allows it to have information sufficient to enable it to deal with the waste. The consent requirement allows the foreign country to take action to prohibit unsafe or inadequate handling of a waste by withholding consent.

In EPA's view, therefore, the lack of imposition of the manifest requirement domestically indicates that such wastes do not reach a level of concern to necessitate notice or a mechanism by which action can be taken to police or enforce against improper handling of these wastes. Accordingly, it is unnecessary to impose an equivalent mechanism on exports of these wastes. It also is doubtful that Congress intended to regulate a waste for export more stringently than domestically. Since no tracking mechanism is available domestically for EPA to know whether such a waste ultimately was exported or actually remained in this country, no similar mechanism is necessary for foreign countries. Moreover, in many cases it is unlikely that, in view of the reasons for excluding such wastes from the manifest requirement, these are the types of wastes for which Congress intended notification and consent. For example, in view of the de minimus amounts and practical safeguards involved in dealing with samples, it is unlikely that a significant environmental problem could result or that a foreign country would be significantly concerned about such wastes. *See* 46 FR at 47426 (September 25, 1981).

Accordingly, EPA is not expanding the scope of section 3017 beyond those wastes for which manifesting is required domestically, with one exception. That exception is spent industrial ethyl alcohol when exported for reclamation. This particular hazardous waste presents a special situation. This waste was exempted from regulation by EPA domestically in view of the fact that the Bureau of Alcohol, Tobacco and Firearms already imposes notice and tracking requirements similar to those imposed generally by EPA on hazardous wastes domestically. EPA regulation, therefore, was considered redundant. *See* 50 FR at 649 (January 4, 1985). Since notice and tracking requirements are placed on these wastes domestically in lieu of EPA's requirements, EPA believes that this is the type of waste for which notification and consent should apply for exports. Thus, the final regulation includes an amendment to 40 CFR 261.6 regarding spent industrial ethyl alcohol when exported for recycling. That provision requires that, in the absence of an applicable international agreement specifying different requirements, the person initiating the export of such material and any intermediary arranging for the shipment must: (1) Provide notification to EPA; (2) export only with the consent of the receiving country and in conformance with such consent; (3) provide a copy of the EPA Acknowledgment of Consent to the shipment to the transporter transporting the material for export; (4) submit an annual report; and, (5) retain certain records. The "person initiating the shipment" is intended to mean the person who would have been required to prepare the manifest but for the exemption in existing 40 CFR 261.6(a)(3)(i). In addition, the final rule requires transporters carrying such materials to refuse to accept such shipment if he knows that it is inconsistent with the Acknowledgment of Consent, ensure that the EPA Acknowledgment of Consent accompanies the waste and that the waste is delivered to the facility designated by the person initiating the shipment. These requirements meet the statutory minimum of section 3017 plus a recordkeeping requirement for enforcement purposes. All other requirements applicable to other exports will not apply to exports of industrial ethyl alcohol exported for recycling since they are essentially tied to the EPA manifesting system or are inapplicable domestically.

(3) *Other Issues Related to the Applicability of section 3017.* One foreign government commented that the definition of exporter should apply to persons required to prepare a manifest both for waste subject to EPA's regulations as well as waste considered hazardous by the transit and receiving countries. Although EPA supports such an approach in principal, it believes that if a foreign receiving country wishes to expand the universe of waste for which it receives notification, this can best be accomplished through an international agreement between the country and the United States. Moreover, it is questionable whether section 3017 provides authority for EPA to regulate any materials for export that are not "hazardous wastes" identified or listed under RCRA.

Several commenters requested clarification of the applicability of the definition of exporter to certain specific situations. One commenter presented the situation where multiple generators send their waste to a domestic facility for recycling and the recycler later exports still bottoms and other byproducts of the recycling process for use as fuel. In this scenario, the recycler would be the party who originates the manifest designating a foreign TSDF, and thus would be the primary exporter. The initial generators would have designated the domestic facility on their manifests and therefore would not meet the definition of primary exporter. Of course, if the initial generator knew that its waste was being exported by the recycler without the consent of the receiving country, and yet continued to ship waste to that recycler or agreed to participate in the scheme, the initial generator might well be subject to criminal charges for aiding and abetting the recycler and/or conspiring with the recycler to violate section 3008.

Another commenter requested clarification on the aplicability of the export requirements when hazardous waste is generated in Alaska and transported through Canada to a facility in the continental United States. This commenter noted that, apparently, EPA did not intend to require notification of Canada under such circumstances since the term "transit country" was proposed to be defined as the country through which a hazardous waste passes "en route to a receiving country." The phrase "en route to a receiving country" was used in the proposal simply to denote short-term storage that may occur "en route." EPA did not intend this language to exempt such shipments from the notification requirement applicable to transit countries. To make this clear, the phrase "en route to a receiving country" has been deleted in the final rule. This action is consistent with an OECD decision to which the United States is a signatory. Decision and Recommendation of the Council on Transboundary Movement of Hazardous Waste, February 1, 1984.

Two commenters urged the Agency to broaden the exemption for certain samples from the export requirements. These commenters requested that EPA broaden the sample exemption to cover hazardous waste samples exported for the purpose of determining: (1) Whether the foreign facility will accept the waste

stream; (2) the treatment, storage, or disposal measures the foreign facility would use; and (3) the price the foreign facility would charge for the treatment, storage, or disposal of the waste. Existing §261.4(d) conditionally exempts from Subtitle C requirements, any sample of solid waste that is collected "for the sole purpose of testing to determine its characteristic or composition." Because such samples are not subject to the manifest requirements of Part 262, Subpart B, they are exempt from the export requirements. The Agency believes that this comment has merit, not only in the context of exports but also for the management of samples domestically. However, the Agency believes that creating such an exemption would require further analysis for both exports and domestic shipments, and if deemed appropriate, proposal for public comment. The Agency questions what the appropriate conditions for such an exemption would be. For example, the Agency would want to consider whether a quantity limitation or some type of limit on the types of waste covered by the exemption would be desirable. Accordingly, the Agency will consider these suggestions for possible further regulatory action and is not expanding the scope of the § 261.4(d) sample exemption at this time. Unless and until future regulatory action is taken, exports of hazardous waste samples outside the scope of § 261.4(d) must comply with the export requirements. Alternatively, foreign waste management facilities could contract with laboratories in the United States to do any necessary analysis.

3. *Other Definitions.* In its proposed rule, EPA proposed definitions for two additional terms—"EPA Acknowledgment of Consent" and "Consignee." The definition of "EPA Acknowledgment of Consent" has not been changed from the proposed rule. A full discussion of comments and EPA's plans regarding the EPA Acknowledgment of Consent is set forth in Section III. D. of this preamble.

Two comments were received on the proposed definition of "Consignee.' in the proposal, "Consignee" was defined as the ultimate treatment, storage, or disposal facility to which the hazardous waste will be sent in the receiving country. One commenter suggested adding "recycling" to the list of facility types, since the proposal intended to cover wastes exported for recycling. EPA does not believe that this change is necessary because, as discussed above, the term "treatment" clearly covers recycling (see, e.g., 40 CFR 260.10).

The second commenter objected to the use of the word "ultimate" in the definition of "Consignee," suggesting that in the case of hazardous wastes that are exported for recycling, storage or treatment, the initial TSDF that receives the waste may transfer certain portions of the waste to a second TSDF. According to this commenter, exporters frequently have no knowledge of or control over such secondary transfers and may be unable to identify, especially prospectively, such secondary TSDF's. EPA acknowledges that further management of an exported waste may occur after it is sent to a foreign TSDF which is beyond the control or knowledge of the exporter. A foreign TSDF may on its own initiative decide to send waste to another TSDF. EPA did not intend to require an exporter to specify actions which occur in a foreign country unknown to him or beyond the scope of his control. EPA used the adjective "ultimate," consistent with the statutory language of Section 3017, to distinguish between the facility to which the waste is being sent for treatment, storage or disposal in a receiving country and a facility *in that same country* at which a shipment may be stored incidental to transportation (e.g., at transfer facilities, loading docks). For example, if a waste is being exported to London, England via Portsmouth, England and the waste is held temporarily in Portsmouth awaiting transportation to London, the consignee would be the facility in London.[3]

The type of storage incidental to transportation which EPA intended to distinguish from the "ultimate" destination of the waste is similar to that type of storage discussed in the preamble to the rule clarifying when a transporter handling shipments of hazardous waste is required to obtain a storage facility permit.

See 45 FR 86966 [Dec. 31, 1980]. However, for purposes of determining who is the consignee, as between a temporary storage facility at which the waste may be stored incidental to transportation and the ultimate destination of the waste, no time limit on the length of such storage is being proposed as is the case in the rule referenced above. EPA believes it would be extremely difficult, if not impossible due to unforeseen events occurring in transit abroad, for an exporter to know prospectively whether a shipment might be stored, for example, for more than ten days at a storage facility in the course of transportation and would thus become the consignee. Accordingly, the consignee is the facility of ultimate destination of the waste in a receiving country and not a temporary storage facility where a waste may be stored for a short period of time incidental to transportation.

Thus, EPA interprets the term "ultimate TSDF" to mean the final destination of the waste in a receiving country known to the exporter. In view of its interpretation of this term, EPA finds it unnecessary to change the language of the proposed rule.

C. Notifications of Intent to Export [§ 262.53]

EPA received a number of comments on the subject of notification. These comments focused on four issues related to the notification: (1) The 60-day advance time suggested for submission of the notification; (2) separate notification for each shipment; (3) the period covered by the notification; and (4) renotification.

Subsection (c) of section 3017 requires that any person who intends to export a hazardous waste shall, before such waste is scheduled to leave the United States, provide notification to the Administrator. The purpose of this notification is to provide sufficient information so that a receiving country can make an informed decision on whether to accept the waste and, if so, to manage it in an environmentally sound manner. The notification is also intended to ensure that environmental, public health, and U.S. foreign policy interests are safeguarded and to assist EPA in determining the amounts and ultimate destination of exports of U.S. generated hazardous waste so as to enable EPA and Congress to gauge whether the right to export is being abused.

The regulatory notification requirements are intended to implement the broad statutory requirements for notification set forth in section 3017(c) and ensure that sufficient information is obtained to satisfy Congressional intent.

1. Sixty-Day Advance Time

Section 262.53(a) of the proposed rule suggested that the exporter submit notification to the Agency 60 days before the waste was scheduled to leave the United States. This 60-day advance time represented EPA's best estimate of the amount of time it would take to notify a receiving country, obtain consent, and transmit such consent to the exporter. EPA noted in the proposal that the statute itself sets forth the time

[3] In view of the changes in the definition of receiving country, it should be noted that there may be more than one consignee in those rare circumstances where there is more than one receiving country.

frame (30 days) within which a complete notification must be transmitted to the receiving country after receipt by EPA and the time frame (30 days) within which the consent or objection must be transmitted to the exporter after receipt by the Secretary of State. Since EPA believed the information could be transmitted in less time than statutorily required (see discussion in Section III.D), this 60-day advance time allowed approximately thirty days for the receiving country to provide its consent or objection to the Department of State.

EPA received several comments on the 60-day advance time. Most of the commenters focused their responses primarily on the 30-day period for a receiving country to transmit its consent or objection to the Department of State. One commenter stated that 30 days was an adequate period for dissenting governments to protest shipments. The commenter added that a longer period would cause unnecessary and costly delays in disposing of wastes. Another commenter proposed that a receiving country should be deemed to have given its consent if it fails to respond to EPA's notice within 30 days.

Other commenters expressed a concern that a 60-day advance notice was inadequate and that a 90-day advance notice would be necessary. One commenter in favor of a 90-day advance time stated that the 60-day notice would cause delays in exporting waste. Another commenter expressed the view that a 60-day advance time was too long. This commenter maintained that 30 days would be sufficient and proposed a "fast track" system to expedite EPA transmission.

After reviewing the comments, EPA has decided to retain the 60-day advance time as the recommended submittal time. This period should provide time for EPA, the Department of State, and the receiving country to process the notification and transmit the receiving country's consent or objection to the exporter. In fact, the amount of time estimated for EPA and the Department of State to transmit information already reflects a "fast track" system to expedite transmission. Therefore, EPA does not believe, at this time, that it would be appropriate to shorten the suggested time frame. Of course, exporters may submit notifications at a later date since the 60-day advance time is solely a recommended minimum advance time. Exporters should keep in mind, however, that this could increase the risks of a delay in receipt of consent and consequent delay in shipment.

EPA disagrees with the commenter's recommendation that failure by a receiving country to respond to a notification should be considered consent. EPA cannot require a foreign country to respond within a specific number of days. Moreover, EPA does not have the authority to assume consent if there is no response within a specific time period because the statute prohibits exports in the absence of written consent. With respect to those exporters who believe the 60-day advance time is too short, EPA notes that exporters may always submit notifications further in advance if they so desire.

EPA reminds exporters that the 60-day advance time is only EPA's best estimate of the time transmission of information will take. A receiving country may take longer to respond than estimated. Accordingly, regardless of the time when a notice is submitted (even if submitted 60 days or more in advance), the shipment cannot take place until consent has been obtained. Exporters therefore, are encouraged to submit notifications at the earliest possible date.

2. Separate Notification for Each Shipment

The proposed rule provided that a single notification could cover more than one shipment; a separate piece of paper providing notification for each shipment would not be necessary. This was considered consistent with legislative intent since the statute itself specifies that a notification include information on the "frequency of shipment." Since the statute was not clear on this point, however, the Agency specifically requested comments regarding whether separate notification should be required for each shipment.

The vast majority of commenters stated that separate notification was unnecessary. Several commenters noted that such notification would be burdensome to the Agency as well as to industry. Another commenter found separate notifications for each shipment to be contrary to Congressional intent since the statute requires that the "frequency of shipment" be specified in the notification. Only one commenter supported separate notification for each shipment. This commenter, however, stressed that such notification would be the ideal. EPA agrees with the majority of commenters that Congress did not intend notification for each shipment, and that such notification would create unnecessary burdens on industry, the Agency, and foreign countries. As a result, separate notification for each shipment is not required in the final rule.

3. Notification Period (24 Months vs. 12 Months) [§ 262.53]

In its proposal, EPA indicated that a notification could cover a period of up to 24 months. The Agency also requested comment on the alternative of allowing notifications to cover only a 12-month period. Comments received on this issue were divided.

Except for one comment, those in favor of a 24-month period did not provide EPA with a reason why they favored this time period over the 12-month period. The commenter who did provide an explanation suggested that a two-year period would provide the receiving country with time to become familiar with the characteristics of the hazardous waste and to determine whether the facilities were able to properly dispose of the hazardous waste.

Other comments supported the change to a 12-month notification period. Several commenters suggested that because of the difficulties in forecasting export activities over a 24-month period, numerous renotifications would be required, resulting in no net reduction of the burden on exporters. A commenter in support of the 12-month period said that it would improve the accuracy of the estimated number and quantity of shipments identified in a notification. One commenter was concerned that foreign countries would be reluctant to consent to exports for a period as long as 24 months, resulting in the need for protracted negotiations with the receiving country. Another commenter explained that the 12-month time period would allow the receiving country to have greater control over the shipments across the border.

EPA finds the comments in favor of a 12-month notification persuasive and agrees that the better view is to allow notifications to cover a maximum of 12 months rather than 24. In addition, EPA notes that since governments within some countries tend to change rapidly and records may be lost or misplaced or policy changes may occur, the more frequent annual notice would provide more current information to foreign governments than would a 24 month notice. Finally, the amount and detail of information on the effects of hazardous waste on human health and the environment is always increasing, and annual reviews of consent would allow reassessment of any new data.

One commenter asserted that, in view of its regular standard exportation practices, annual or biennial "renotification" for unchanged practices should not be required where a single

notification provides a complete and accurate picture of the waste exportation practices that will occur. Recognizing that practices which deviate from the notification could be enforceable violations of RCRA, this commenter felt that a notification should be allowed to cover any period of time so long as the initial notification fully and accurately reflects the notifier's practices. EPA does not believe that submittal of the notification on an annual basis presents a burden to exporters since such a requirement would only entail duplication of the original notification. Moreover, prudent planning by the exporter should prevent any interruption in exports which might result as a consequence of awaiting new consent. Further, annual notification provides receiving countries with a formal mechanism to review information relative to incoming shipments in light of any new developments which may occur within that country within the previous 12-month period.

4. Renotification [§ 262.53]

Paragraph (c) of proposed § 262.53 required renotification and new consent from the receiving country for changes in the conditions specified in the original notification. Two commenters suggested that renotification should not be required for small variations in shipping procedures and routes.

EPA believes there is some merit to these comments. In fact, the proposal represented an attempt to build into the notification requirements the flexibility to allow for minor changes without renotification and consent. For example, it was proposed that notification include the "estimated" number of shipments of the hazardous waste. Upon re-examination of the issue of notification, however, EPA has decided that some minor regulatory changes would be appropriate. Whereas EPA believes that renotification is necessary where material conditions in the original notification change (since this may affect the original consent granted by the receiving country), it does not believe that certain minor deviations from the original notification warrant renotification and additional consent. In EPA's view, certain notification information is more for informational purposes than integral to a decision to accept or reject a waste. Accordingly, EPA believes that it is doubtful that such deviations would be of sufficient concern to a foreign country for it to wish to reconsider its consent. Moreover, renotification for minor deviations in certain information would put unnecessary burdens on foreign countries, EPA and exporters. And, in view of the need for at least a two-month advance notification, exporters may not at that date have highly detailed information on an export.

In determining what types of changes should trigger the need for renotification and consent, EPA considered which items are most likely to be highly variable and more importantly, which items would be likely to affect the receiving country's consent. For example, EPA believes that any increase over the estimated quantity of waste to be exported should require renotification and consent. However, EPA has concluded that decreases in the quantity exported would not be likely to affect the receiving country's consent and, therefore, is not requiring renotification for such changes. EPA also is requiring renotification and consent for any changes in the waste description, consignee, ports of entry to and departure from a foreign country, the manner in which the waste will be treated, stored or disposed of in the receiving country, the name of any transit countries, the handling of the waste in transit countries, important factors for a receiving country in determining whether to accept or reject a hazardous waste or for a transit country to take appropriate action. Although renotification will be required for changes in the ports of entry to and departure from transit countries, the names of any transit countries, the appropriate length of time the waste will remain in transit countries, and the nature of the handling of the waste in such countries, consent of the receiving country will not be required for these changes since they are unlikely to affect the receiving country's original consent. However, when the Agency receives notification for these types of changes, it will provide notice of them to any affected transit country.

Renotification will not be required when there is a change in the mode of transportation to be utilized. An exporter may not know sufficiently in advance the highly specific details on how the waste is to be transported. Moreover, the mode of transportation may change en route. For example, transportation which was originally planned to take place by truck may be changed at the last minute to railroad due to unexpected events. EPA also will not require renotifications when there is a change in the type of container in which the waste will be transported. The exporter must already meet the specific container requirements of the Department of Transportation, as well as any such requirements of all transit and receiving countries. Moreover, exporters must be allowed to repackage containers damaged en route. Renotification will also not be required for changes in the exporter's telephone number since such a change should not affect the receiving country's consent.

The changes noted above are consistent with Section 3017 since the statutory language itself in several respects builds in flexibility in the notification requirements in an effort to achieve the same result as these more specific regulatory provisions. In addition, in the absence of these changes, exporters are likely, for example, to simply list all possible ways a waste may be transported to avoid renotification. Under such circumstances, a foreign country would be receiving no more specific information on these elements. Accordingly, § 262.53(c) has been changed to require renotification for all changes in the original notification except for changes in the exporter's telephone number, mode of transportation, type of container, and decreases in quantity. In addition, the regulatory language has been modified to make clear that consent of the receiving country is not required for changes to the information noted above which is pertinent to transit countries.

EPA is also concerned about the language of proposed § 262.53(a)(2)(ii) which required that the notification contain "the estimated number of shipments of the hazardous waste and the approximate date of each shipment." Commenters stated that the requirement to estimate the number and total quantity is meaningless and explained that waste generation is never preplanned and exact, therefore, information on the amount of waste generated cannot be exact. Other commenters disagreed with the requirement to include the date of shipment, also explaining that waste generation is never preplanned and exact, consequently, information on the shipment dates cannot be exact. Other commenters also disagreed with the requirement to include the date of shipment, explaining that it is not always feasible to know even 60 days in advance of a shipment the exact date when waste will be transported. The commenters suggested that EPA require the expected frequency of shipment rather than the exact date.

Although the notification requirement as proposed only required the *approximate* dates and estimated number of shipments, EPA notes that no guidance was provided on how much deviation from the approximate date and estimated number of shipments was

allowable without the need for renotification. To avoid the uncertainty inherent in the proposed language, and in view of the comments received expressing concern with this requirement, EPA has chosen to adopt, in the final rule, the statutory language requiring notification of "the estimated frequency or rate at which such waste is to be exported and the period of time over which such waste is to be exported." EPA believes this change clearly meets Congressional intent for notification while providing important flexibility to exporters.

Except for the changes regarding notification discussed above, EPA is retaining § 262.53 as proposed for the reasons set forth in the preamble to the proposal.

D. Procedures for the Transmission of Notification, Consent or Objection

Subsections (d) and (e) of section 3017 require the Department of State to transmit notification of the intended export to the government of the receiving country within thirty days of receipt by EPA of a complete notification from the primary exporter. EPA must then notify the primary exporter of the receiving country's consent or objection to the intended export within thirty days of receipt of a response by the Department of State. Because the exchange of information among EPA, the Department of State, receiving countries and transit countries is administrative in nature and imposes no requirements on the public, EPA did not propose specific procedures to implement these statutory requirements.

As discussed in the proposal, EPA and the Department of State plan to telegraphically transmit the notification as well as the receiving country's response. Notifications would be sent from EPA to the Department of State for transmission to the U.S. Embassy in the receiving country. The U.S. Embassy would forward the information to appropriate authorities in the receiving country in translation, if necessary, with a request for an expeditious written response. Upon receipt of this written response, it would be translated by the U.S. Embassy in the receiving country, if necessary, and cabled to the Department of State for transmission to EPA. Where the terms of the receiving country's consent are understandable only by reference to the export notification (e.g., the receiving country simply references a notification and gives consent without reiterating terms described in the notification), the cable will also include relevant portions of such notification. Where the receiving country fully consented to the export or consented with specified modifications, this cable would constitute the EPA Acknowledgment of Consent and would be sent to the primary exporter for attachment to the manifest. Where the foreign country reject the shipment, EPA would so notify the primary exporter in writing. Meanwhile, the original written communication from the receiving country would be sent to the Department of State in Washington in the diplomatic pouch mail. This document would then be forwarded to EPA for retention. A copy would also be forwarded to the exporter.

As required by section 3017, in notifying receiving countries of intended shipments, the government of the receiving country would also be advised that United States' law prohibits the export of hazardous waste unless the receiving country consents to accept the waste. The notification would include a request to provide the Department of State with a response to the notification which either consents to the full terms of the notification, consents to the notification with specified modifications, or rejects receipt of the hazardous waste. Also in accordance with statutory requirements, a description of the Federal regulations which would apply to the treatment, storage, and disposal of hazardous waste in the United States would be provided to the receiving country.

While most commenters favored EPA's suggested procedure of using the cable as the EPA Acknowledgment of Consent, several commenters maintained that an exact duplicate or mechanical reproduction of the actual written consent must be used in lieu of a cable. These commenters suggested that EPA's proposal was contrary to the plain language of the statute and voiced concern over the possibility of human error in transcribing information into a cable or in translating such information.

In EPA's view, transcription of a receiving country's consent into a cable and attachment of such cable to the manifest meets the statutory requirement that a "copy" of the receiving country's written consent be attached to the manifest accompanying the waste shipment. The term "copy" is not limited to a "photo" copy or other mechanical reproduction but can include typed or handwritten "copies." Moreover, EPA believes that "copy" is broad enough to encompass a translation of a receiving country's consent. EPA also believes that the statute accords EPA the discretion to implement the export requirements in a workable and practical fashion. In EPA's view, this necessitates use of telegraphic communications.

U.S. Embassy personnel will be well qualified to translate the receiving country's response and, as indicated in the proposal, EPA will work closely with the Department of State to ensure that cables prepared by the U.S. Embassy include an exact reiteration or translation of the receiving country's consent. EPA remains concerned that mailing actual reproductions of documents will cause unnecessary delays that can be avoided by the use of cables. Without the use of cables, it would be necessary to increase, and possibly significantly increase, the advance time for submission of notifications. This would require exporters to project their export plans even further into the future when submitting their notifications, risking an increase in the number of renotifications necessary and consequent burdens on EPA, exporters, foreign countries and the Department of State. In addition, were EPA to require that the actual consent document be mailed, transmission would be dependent on a postal system over which neither EPA nor the Department of State would have control. It would be unfair to leave exporters dependent upon postal systems which, in some countries, are of questionable reliabilty. Nor does EPA believe it would be appropriate to use the Department of State's diplomatic pouch mail. The Department of State has indicated that while diplomatic pouch mail is generally received within two weeks, in some instances it can take from three to six weeks and, therefore, transmission could exceed the 30-day time frame provided by the statute for transmission of consent to the exporter upon receipt by the Secretary of State.[4]

One commenter suggested that, although a facsimile of the written consent should be provided the exporter, a Department of State translation might also be helpful. However, this commenter believed that exporters should, nonetheless, be held to compliance with the foreign language

[4] One commenter suggested that the statutory time frame problem could be resolved by defining receipt by the Secretary of State as receipt by the Department of State in Washington. Generally, the U.S. Embassy in a foreign country is the representative of the Secretary of State and, therefore, the better view is that receipt by the Embassy is receipt by the Secretary of State. Even were this suggestion adopted, however, the problem would remain that notifications would need to be submitted further in advance thereby risking a consequent increase in burdens on all parties involved due to the increased likelihood that renotification would be necessary for changes in the shipment.

version. EPA notes in response to this comment that it would not take enforcement action against an exporter who relied in good faith on an Embassy translation. Moreover, it would be unfair to require reliance on the foreign language version under such circumstances. Any difficulties arising out of an erroneous translation by the United States is a matter best dealt with by the governments of the countries involved and is a matter of foreign relations appropriately left to the Department of State. Furthermore, were exporters held to the foreign language version, exporters might feel the need to obtain their own translations which could result in various versions of the consent. This could cause needless complications. With use of the Department of State translation, exporters and EPA will be relying on the same translation. Accordingly, EPA is retaining its definition of Acknowledgment of Consent and the procedures for transmission of the notification and consent as proposed except in one respect. To assist in expediting transmission, the final rule adds a requirement that exporters mark the envelope containing the notification "Attention: Notification to Export."

With regard to transit countries, transmission of notification will proceed similar to that for receiving countries. EPA will notify primary exporters of any response of a transit country. As noted earlier, EPA strongly urges exporters to reroute wastes objected to by transit countries since transit countries may take action to prohibit entry.

E. Special Manifest Requirements [§ 262.54]

This section sets forth special manifest requirements pertaining to exports of hazardous waste in light of the special circumstances relative to such shipments. The final rule adopts the provisions as proposed for the reasons set forth in the preamble to the proposed rule except in one significant respect.

During the development of the proposed rule, EPA considered requiring the transporter to deliver a copy of the manifest to a U.S. Customs official at the point the waste leaves the United States. Customs officials would periodically forward the copies it collected to EPA. Such a requirement would serve as a means to assist EPA in enforcing section 3017. The Agency decided not to propose this requirement because it had no evidence that exporters were violating current notification requirements. In addition, the Agency was of the opinion that copies of manifests retained by generators could be obtained (e.g., for comparison with notification and consent documents) if concerns arose about violations of section 3017.

The Agency received comments both opposing this requirement as well as strongly urging the Agency to reconsider its decision on this subject. After evaluating the comments received on this issue, obtaining further information on violations of existing notification requirements, and reconsidering the advantages and disadvantages of the collection of manifest copies, EPA has determined that submission of the manifest at the border should be required. Thus, § 262.54(i) of today's rule requires the primary exporter to provide the transporter with an additional copy of the manifest and § 263.20(g)(4) requires the transporter to deliver a copy of the manifest to the Customs official at the point the waste leaves the United States. This is a new tracking device intended to assist EPA in working with the U.S. Customs Service to establish an effective program to monitor and spot-check exports of hazardous waste. This requirement will allow the Agency to monitor closely the generator's compliance with the EPA Acknowledgment of Consent, coordinate enforcement actions with foreign countries, establish trends and patterns for enforcement and program development, and respond to Congressional inquiries. It also provides clear evidence of an important element of proof in enforcement actions (i.e., that an export did or did not occur) and serves as a deterrent to illegal activities. Moreover, this requirement will allow EPA to respond promptly to hazardous waste incidents in foreign countries. Routine submission of these documents to EPA is important in light of foreign policy concerns involved in exporting hazardous wastes. The diplomatic ramifications of improper shipments of United States' wastes could have a significant impact on the United States as a responsible member of the international community.

The Agency believes that the need for an additional copy of the manifest will result in an insignificant increase in the paperwork burden on the regulated community since this requirement does not include preparation of any additional information but only requires an additional copy of existing information.

F. Annual Reports, Recordkeeping, and Exception Reports [§§ 262.55, 262.56, 262.57]

Section 3017(g) of RCRA imposes a new annual reporting requirement for exports of hazardous waste. The annual reports should be sent to the Office of International Activities (A-106), United States Environmental Protection Agency, Washington, D.C. 20460. Comments received regarding the proposed rule's annual reporting requirement were largely favorable.

One commenter noted that meeting the annual report requirement for exported wastes would be very easy for exporters who reside in States, such as New York, which already require such reports. Another commenter proposed the creation of an annual report form. Since the number of exporters filing annual reports is expected to be very small, the Agency does not believe that an annual report form is necessary in order to enable it to process annual reports. Nor does the Agency believe that expenditure of the resources necessary to develop and print annual report forms is justified in view of the relatively small number of exports.

One commenter explained that submittal of the annual report would be unrealistic since its members presently do not submit reports and, therefore, do not maintain records on export shipments. This commenter also stated that EPA could easily obtain the material found in the annual report from the biennial report, and that requiring both is unnecessary. EPA notes, in response to this commenter, that section 3017 of RCRA requires annual submissions of information on exports. Therefore, annual reporting is a statutory requirement and information submitted biennially would not meet this requirement. Since commenters did not refute EPA's assertion that most generators retain separate records on domestic shipments and exports, EPA does not believe that the administrative burden on exporters to file annual reports on exports and biennial reports on domestic waste management is excessive. Also, as discussed in the proposal, EPA believes that this approach is administratively less burdensome on the Agency.

A second commenter questioned whether information found in the annual reports could be more readily obtained from computerized notice records. Because the annual report is a statutory requirement, regarding what actually occurred, the notice records cannot be used as a substitute. The annual reporting information will tend to be more specific than the notification information. For example, it will provide information of the actual quantity exported if under the amount estimated in the prior notification.

Accordingly, EPA has retained the annual reporting requirement as

proposed except in one respect. One commenter stated that, by exempting generators who file annual reports from reporting exports on the biennial report form, EPA cannot exempt exporters from the new HSWA waste minimization requirements of section 3002(a)(6) (C) and (D). EPA does not believe that exporters will be exempt from such requirements in most cases based upon the assumption that, generally, an exporter will not only export waste but also will ship some wastes off-site for treatment, storage or disposal domestically. Accordingly, the requirements of section 3002(a)(6) (C) and (D) will be met for all wastes by filing the biennial report as required by 40 CFR 262.41. Nevertheless, to cover the annual circumstance where a person exports all his hazardous wastes, the final rule includes a requirement that unless provided pursuant to 40 CFR 261.41, an exporter must include in the annual report submitted in even numbered years: (1) A description of the efforts undertaken during the year to reduce the volume and toxicity of waste generated; and (2) a description of the changes in volume and toxicity of waste actually achieved during the year in comparison to previous years to the extent such information is available for years prior to 1984. Small quantity generators generating less than 1,000 kg/mo are exempt from this requirement consistent with 40 CFR 262.44 (*See* 51 FR 10146, 10176 (March 24, 1986)). Exporters of spent industrial ethyl alcohol for reclamation are also exempt since this requirement does not otherwise apply to such wastes.

With regard to the proposed recordkeeping and exception reporting requirements, EPA received no significant comments on these provisions. Accordingly, EPA is retaining §§ 262.55 and 262.57 as proposed for the reasons set forth in the preamble to the proposed rule.

G. Transporter Responsibilities

The March 13, 1986 proposal amended § 263.20 to prohibit a transporter from accepting waste from an exporter unless, in addition to a manifest, an EPA Acknowledgment of Consent was attached to the manifest. EPA also proposed to amend this section to require transporters to ensure that an EPA Acknowledgment of Consent accompanied the waste en route. No changes were proposed regarding other requirements of Part 263 applicable to transporters transporting waste for export. *See* 40 CFR 263.20(g), 263.21, 263.22(d). As discussed in Section III.B. of this preamble, EPA is retaining these requirements as proposed and is adding the additional requirements that the transporter deliver a copy of the manifest to a U.S. Customs official at the point the waste leaves the United States and that the transporter refuse to accept hazardous waste for export if he knows it does not conform to the Acknowledgment of Consent.

One further change is also being made in the transporter requirements. This pertains to exports by rail. In drafting the proposed rule, EPA recognized that existing domestic regulations for shipments by rail do not require that the manifest travel with the waste shipment nor do they require that intermediate rail transporters sign the manifest. *See* 40 CFR 263.21(d). Instead, a shipping paper is required to accompany the waste and the manifest must be sent to the next non-rail transporter, the TSDF, or, for exports, the last rail transporter designated to handle the waste in the United States. These special requirements were imposed on rail transporters due to the special nature of the railroad industry in recognition that railroads have sophisticated computerized tracking information systems. If the manifest system were applied to the rail system without adjustment, normal operating practices would be so disrupted as to effectively prevent the use of this method of transportation. *See* 45 FR 86970, 86971 (December 31, 1980). In the rail system, shipping papers are left with railcars at interchange points to be picked up by the transferee railroad. Thus, no face-to-face contact occurs and the normal manifest system is unworkable.

In keeping with the existing system for railroads, EPA's proposed export provisions required the Acknowledgment of Consent to be attached to the shipping paper in lieu of the manifest. In commenting on the proposal, the Association of American Railroads, brought to EPA's attention that the rail industry is now moving toward a system where there will be no exchange of papers between rail carriers. Each rail carrier will have its own shipping paper issued through a computerized system and therefore not even an exchange of a shipping paper will occur by leaving the shipping paper with the rail car. Instead, each rail carrier operator would carry its own shipping paper for the shipment. In the rail industry's view, the proposed export requirements represented a step backward since the requirement that the Acknowledgment of Consent be attached to the shipping paper would require that papers be passed from rail carrier to rail carrier and the new "paperless" exchange would be unworkable. This commenter, therefore, suggested that the Acknowledgment of Consent be attached to the manifest which is forwarded ahead to the last rail transporter to carry waste in the U.S.

EPA did not intend to prevent or discourage the use of rail transportation through the export requirements. Nor does EPA believe that this was Congress' intent. In fact, EPA's intent in the proposal was to accommodate the special circumstances of the rail industry while ensuring that the purpose and intent of section 3017 was met. However, while EPA understands that attachment to a shipping paper under the new rail system may not be workable, it is difficult to understand why a copy of the Acknowledgment of Consent cannot be left in the rail car with the shipment. This would not require any face-to-face contact since the document would simply travel with the rail car as it is passed from one railroad to another. Accordingly, the final rule provides that the Acknowledgment of Consent simply accompany the waste shipment for shipments by rail and need not be attached to the shipping paper. Consistent with section 3017, this will allow the consent to accompany the waste shipment.[5] EPA invites further comment on this issue and will consider further modification to this requirement once the new "paperless" rail system is implemented if it can be shown that this requirement essentially prohibits exports by rail.

H. Small Quantity Generators

As previously discussed in Section III.B.4 of this preamble, EPA proposed to define an exporter as the person required to prepare the manifest pursuant to 40 CFR Part 262, Subpart B for a shipment of hazardous waste that specifies a treatment, storage, or disposal facility in the receiving country to which the waste will be sent. Under the rules existing at the time of the March 13, 1986 proposal, generators of less than 1000 kg/mo of hazardous waste in a calendar month (i.e., small quantity generators) were not subject to Subpart B of Part 262 (or any other Part 262–266 or 270 regulations),[6] provided

[5] The proposed rule also allowed the Acknowledgment of Consent to be attached to the shipping paper for exports by water (bulk shipment) in view of the domestic scheme for this type of transportation. The final rule does not change the proposal with regard to these exports since there were no comments suggesting that this would be a significant problem.

[6] Generators of between 100–1000 kg/mo were required by Section 3001(d)(3) of HSWA to manifest any waste shipped off-site with a single copy of the Uniform Hazardous Waste Manifest beginning July 1985.

the small quantity generator complied with § 262.11 (hazardous waste determination) and ensured delivery of his waste to an on-site facility or off-site facility either of which met one of five criteria:

1. Permitted under Part 270;
2. In interim status under Parts 270 and 265;
3. Authorized to manage hazardous waste by a State with a hazardous waste management program approved under Part 271;
4. Permitted, licensed, or registered by a State to manage municipal or industrial solid waste; or
5. A facility which beneficially uses, reuses, or legitimately recycles or reclaims its waste or treats its waste prior to beneficial use, reuse, or legitimate recycling or reclamation.

As the preamble to the proposal noted, it appeared that, technically, a small quantity generator who exported his waste would be subject to then-existing export requirements since he would be unable to comply with any of the above requirements. The proposed rule did not propose to change this result. Therefore, under the proposed rule, small quantity generators who exported their wastes would have been subject to full Part 262 requirements, including the proposed export requirements, while small quantity generators who shipped to any of the five kinds of domestic facilities identified above would continue to be exempt from the Part 262 requirements. The proposal indicated that EPA would be considering whether this was the appropriate treatment of small quantity generators in the final rule. In so doing, EPA would specifically consider any changes which ultimately might be made in the small quantity generator provisions being considered in a separate rulemaking (50 FR 31278 (August 1, 1985)). In addition, EPA would consider whether there should be more concern for a waste exported than dealt with domestically.

Since the March 13, 1986 proposal on exports, EPA has published its final rules for generators of less than 1000 kg/mo at 51 FR 10146 (March 24, 1986). In general, that rulemaking subjects generators of 100–1000 kg/mo to most of the hazardous waste management regulations, including the Part 262 multiple copy manifest requirements and retains the current exemption for generators of less than 100 kg/mo from the Part 262 manifesting and other regulatory requirements.

In determining the final export requirements appropriate for generators of less than 100 kg/mo of hazardous waste, EPA has decided to exempt these generators from the export requirements to be consistent with the Agency's domestic policy with respect to these generators. As discussed at Section III.B.2. above, in EPA's view, only those wastes for which manifests are required domestically are the types of wastes that are properly the subject of section 3017. Moreover, as EPA stated in the March 24, 1986 final rule, it had no data to indicate that additional regulation of generators of less than 100 kg/mo of hazardous waste would provide any significant additional level of environmental protection. Generators of less than 100 kg/mo of hazardous waste account for only 0.07 percent of the total quantity of hazardous waste generated nationally. A review of damage cases also indicated that very few incidents involved quantities below 100 kg. Finally, it does not appear that the effect of the then-existing regulatory language which subjected exports by these generators to Part 262 requirements was intentional.

Accordingly, the final rule modifies § 261.5 to make clear that these generators are exempt from Part 262 requirements for exports as well as for domestic shipments. Any concerns that a foreign country may have about receiving such wastes can be resolved through a bilateral agreement by including the requirement that generators of less than 100 kg/mo provide notification for exports of hazardous wastes.

Generators of 100–1000 kg/mo will be subject to the export rules since under the March 24, 1986 final rule, they are now subject to manifesting requirements.

I. State Authority

1. Effect on State Authorization

Consistent with existing procedures, the proposal provided that States could not assume the authority to receive notifications of intent to export. In addition, States would not be authorized to transmit such information to foreign countries through the Department of State or to transmit Acknowledgments of Consent to the exporter. In EPA's view, foreign policy interests and exporters' interests in expeditious processing were better served by EPA's retaining these functions. This would provide the Department of State with a single point of contact in administering the export program and will better allow for uniformity and expeditious transmission of information between the United States and foreign countries. With the exception of these functions, EPA proposed that States include requirements equivalent to those promulgated today.

EPA specifically requested comments on this approach. As no comments were received objecting to the notification process set forth in the proposed rule, EPA has retained the language of the proposed rule in this respect. However, the final rule includes changes to proposal § 271.11 to require State programs to include a requirement that, for exports, a transporter may not accept a waste for export if he knows it does not conform to the Acknowledgment of Consent and must deliver a copy of the manifest to the U.S. Customs official at the point the waste leaves the United States. These changes simply reflect the addition of these requirements to the Federal requirements discussed above.

2. Universe of "Hazardous Waste" in Authorized States

In the preamble to the proposed rule, EPA explained that where a State has obtained authorization, "hazardous waste" for purposes of the export requirements would be the authorized State's universe of hazardous wastes plus wastes EPA identifies or lists pursuant to HSWA. EPA requested comments on the alternative of basing implementation on the Federal universe of hazardous wastes.

Comments received on this issue were divided. One commenter stated that the approach proposed could result in inconsistencies among States which would be confusing to foreign countries. In addition, such an approach could create unfair burdens on persons exporting from certain States. This commenter also stated that EPA's concern that exporters would have to become familiar with both Federal and State universes of hazardous waste if only the Federal universe was regulated was unfounded.

This commenter further stated that since any authorized State's universe of hazardous wastes must include at least the entire Federal universe, exporters would have little difficulty familiarizing themselves with the Federal universe. In addition, this commenter noted that the use of the Federal universe would be simpler for persons who export from more than one State, obviating the need for detailed knowledge of the universe of hazardous wastes in every State where such persons engage in the export business.

Commenters supporting EPA's approach argued that all wastes considered hazardous at the point of origination should be subject to the

export requirements to assure proper management and disposition.

After reviewing the comments received on the proposed approach and the implications of such an approach, EPA has determined that basing implementation on the authorized State universe plus those wastes identified or listed by EPA pursuant to HSWA remains the better approach. The "authorized State universe" of hazardous wastes consists of: (1) Those wastes in the Federal universe for which the State was authorized at the time it first received final authorization and (2) any wastes subsequently identified or listed by EPA for which the State has received authorization (by filing a request for approval of a program revision). The authorized State universe does not include wastes which are identified or listed by the State as hazardous wastes under State law but are not identified or listed as such by EPA. *See* 40 CFR 271.1(i)(2).

This approach is consistent with EPA's usual interpretation of the phrase "hazardous wastes identified or listed under this subtitle." The only period of time when any inconsistency among States might occur is during the period allowed States to update their programs to add a non-HSWA waste newly listed or identified by EPA. See 40 CFR 271.21 (Amendments to this section were proposed on January 1986 at 51 FR 496–504.) Only during this period might a particular waste from State A be subject to the export requirements (because State A's program revision is approved early) while the same waste from State B would not be subject to the export requirements (because State B's program revision is approved later than State A's). EPA does not believe that the potential for this inconsistency merits deviating from its usual interpretation of the phrase "identified or listed under this subtitle." Moreover, were export requirements applicable to the Federal universe, more wastes would be subject to the export requirements than are regulated on a national level domestically. This would be inconsistent with the intent to treat wastes for export similar to wastes dealt with domestically. Similarly, a material newly listed by EPA and stored in a State during the time period allowed a State to revise its program to add such waste, would not be subject to regulation while stored but would be subject to regulation once the export of such waste was initiated. Thus, materials exported would become subject to regulation ahead of the time States are required to regulate the waste domestically. This would make little sense.

To what extent commenters may be suggesting that EPA also regulate wastes listed by a State beyond those regulated Federally, EPA also rejects this approach as inconsistent with its usual interpretation of "identified or listed" under this Subtitle. In addition, EPA would not have the authority to enforce violations with respect to such wastes which would make little sense with respect to a program primarily Federally implemented. Thus, under this final rule, hazardous wastes identified or listed by the State as part of its authorized program which are broader in scope (not in the Federal universe) will not be subject to the export regulations.

J. Confidentiality

EPA proposed to amend § 260.2 to provide that information for which a claim of confidentiality is made will be disclosed by EPA only to the extent and by means of the procedures set forth in 40 CFR Part 2, Subpart B, except that information contained in a notification of intent to export a hazardous waste will be provided to appropriate authorities in receiving countries and the Department of State, regardless of such a claim. Information would otherwise be disclosed to the public and transit countries in accordance with 40 CFR Part 2. The final rule adopts this provision as proposed.

As the preamble to the proposal explained, this approach to the confidentiality of section 3017 notices was based upon EPA's interpretation of RCRA. There is an apparent conflict on the face of the statute between section 3007(b) and section 3017. Section 3007(b) could be read as prohibiting all disclosure of any confidential business information contained in a notice of intent to export. However, this reading would contradict section 3017.

Because the statute must be interpreted to give the fullest possible effect on both section 3007(b) and section 3017, EPA interprets section 3017 to require provision of the notification information to a receiving country through the Department of State even if the information in the notice is confidential, but to prohibit disclosure by EPA of such confidential business information to other persons. The purpose of the notification is to allow receiving countries to make an informed decision as to whether to accept the waste and, if accepted, how to deal with that waste. Moreover, section 3017 prohibits the export of hazardous waste in the absence of consent by the receiving country. Thus, unless such information can be divulged to the Department of State and receiving countries, informed consent could not be obtained and the export would be prohibited.

If a claim of confidentiality is asserted as to any notification information, EPA will exercise its discretion to determine whether it is the type of information that is important for a transit country to know. For example, it would be important for a transit country to know the type and amounts of waste but probably not important for it to know the port of entry to a receiving country. If the information claimed confidential is deemed to be information of which a transit country should know, the time frame set forth in section 3017(d) for submission of a "complete" notification to a receiving country will not begin to run until a determination by EPA of the validity of any such claim has been made. Only upon EPA's completion of the processing of the confidentiality claim will the notification information be provided to receiving countries and any nonconfidential information provided to transit countries. Since an export cannot take place in the absence of the consent of the receiving country, exporters should be aware that claims of confidentiality could, therefore, significantly delay shipment.

EPA received comments on this subject which stated that the availability of export information should not be abridged. EPA does not believe that the final rule in any way abridges the availability of export information contrary to Congressional intent. In fact, as EPA noted in the proposal, it does not believe that notification information generally is entitled to treatment as confidential business information. It has been EPA's experience that existing notifications, which consist of identification of the exporter, waste and consignee, have not been claimed by exporters to be confidential.

Another commenter questioned why EPA could not provide confidential information to a transit country. As discussed above, EPA believes that the only correct reading of sections 3007(b) and 3017 precludes disclosure of confidential information to parties other than receiving countries and the Department of State. However, EPA notes that a transit country that is not satisfied with the information it receives from the notification may take action to prohibit the waste from entering the country.

IV. Enforcement

A. EPA

Noncompliance with RCRA section 3017 or regulations promulgated thereunder is subject to civil and criminal enforcement action under section 3008. As the legislative history of section 3017 states:

> The requirements of this section should be vigorously enforced using all the tools of Section 3008. To accomplish this, the Agency should work with the U.S. Customs Service to establish an effective program to monitor and spotcheck international shipments of hazardous waste to assure compliance with the requirements of the section. Violations should then be vigorously pursued. S. Rep. No. 98-284, 98th Cong., 1st sess. 48.

Most important, HSWA includes an amendment to section 3008(d) of RCRA authorizing criminal penalties against any person who exports a hazardous waste without the consent of the receiving country or in nonconformance with an international agreement between the U.S. and a receiving country. Section 3008(d)(6) establishes incarceration of up to two years and/or a fine of $50,000 per day for knowingly exporting a hazardous waste without consent or in violation of a bilateral agreement. Penalties and prison terms may be doubled for second offenses. EPA intends to prosecute violators to the fullest extent.

Subsection (d)(6) of section 3008 subjects to criminal sanctions "any person who knowingly exports" hazardous waste to a foreign country without that sovereign's consent. The receiving country's consent is premised on the correctness of the data on the export notification. "Consent" based upon the false representation of the exporter is invalid.

The following examples of knowing exportation are meant to illustrate (but do not limit) cases in which the Agency would find that the receiving country's consent has not been given and criminal enforcement might be pursued:

1. Exportation of hazardous waste without notification (or without renotification as required under 40 CFR 262.53(c));
2. Exportation of hazardous waste after notification but without consent (or after renotification but without consent based on the renotification); or
3. Exportation of hazardous waste with "consent" based on false representation(s) in the notification.

In the enforcement of these regulations, EPA may also use section 3008(d)(3) of RCRA (which prohibits the knowing omission of material information or the making of a false statement or representation in any application, label, manifest, record, report, permit or other document filed, maintained, or used for compliance with Subtitle C (e.g., the notification of intent of export)). These two violations are each punishable by up to two years imprisonment and/or a fine of $50,000. (Potential fines and prison terms are doubled for second offenses.)

B. U.S. Customs Service

The new HSWA provision on the export of hazardous waste raises issues concerning cooperation between EPA and the U.S. Customs Service on enforcement matters. As noted above, Congress intended that EPA "should work with the U.S. Customs Service to establish an effective program to monitor and spotcheck international shipments of hazardous waste to assure compliance with the requirements of [section 3017]." To further this legislative intent, EPA has consulted with and is continuing to consult with the U.S. Customs Service in order to develop an effective program to monitor and spotcheck hazardous waste exports.

The United States Customs Service has independent authority to stop, inspect, search, seize, and detain suspected illegal exports of hazardous waste under the Export Administration Act, 50 U.S.C. App. 2411, as amended by the Export Administration Amendments Act of 1985, Pub. L. No. 99-64, 99 Stat. 120 (1985), case law, and U.S. Customs Service regulations (e.g., 19 CFR Part 162). Exporters who violate the Export Administration Act or U.S. Customs Service regulations may also be subject to enforcement actions under those authorities.

C. Other Agencies

Exporters of hazardous waste also may be required to comply with pertinent export control laws and regulations issued by other agencies. For example, regulations promulgated by the Bureau of the Census of the Department of Commerce require exporters to file Shipper's Export Declarations for shipments valued over $1,000. 15 CFR Part 30. It may very well be possible that hazardous waste exported for purposes of recycling would have a value of $1,000. On January 1, 1986, the Bureau of Census created a new statistical reporting number for hazardous waste within the "Schedule B—Statistical Classification of Domestic and Foreign Commodities Exported from the United States." This number (818.8000) must be used in preparing shipper Export Declarations as required by 13 U.S.C. 301, and 15 CFR 30.7.

Failure to file a Shipper's Export Delcaration is subject to civil penalties as authorized by 13 U.S.C. 305. It is also unlawful to knowingly make false or misleading representations in such documents. This constitutes a violation of the Export Administration Act. To knowingly and willfully make false or misleading statements relating to information on the Shipper's Export Declaration is a criminal offense subject to penalties as provided for in 18 U.S.C. 1001.

V. Effective Date of the Final Regulations

EPA proposed that any final regulatory provisions issued pursuant to section 3017(c) setting forth export notification requirements shall become effective 30 days after promulgation. It was EPA's position that, although the statute specifies a 180-day effective date, the statute also accorded EPA the discretion to shorten that time period under appropriate circumstances.

Several commenters expressed serious concern with the 30-day effective date, reading EPA's statement on this issue to mean that exports taking place starting 30 days after the date of publication of the final rule would be subject not only to the notification requirement but also the consent requirement. It was not EPA's intent, however, to require both notification and consent for shipments occurring 30 days after promulgation. Rather, EPA intended the date occurring 30 days after promulgation to be the point at which it would begin processing notifications. Consent would not be necessary until the November 8, 1986 statutory deadline.

Accordingly, to effectuate EPA's intent and to provide time for consent to be obtained for shipments occurring on or soon after November 8, 1986, the final rule provides that the regulations are effective November 8, 1986, but that EPA will begin accepting notifications immediately for shipments to occur on or after that date. This should allow time to process notifications in order to obtain consent by the statutory deadline and thereby avoid any hiatus in exports of hazardous waste.

Another commenter asserted that EPA has no authority to shorten the 180-day effective date. However, as explained in the preamble to the proposal, EPA interprets the statute to afford it the discretion to shorten this time period. Section 3010(b) provides that regulations promulgated under Subtitle C shall have an effective date six months after the date of promulgation. That section also allows the Administrator to provide for a shorter period prior to the effective date under specified conditions. Section

3017(b) also sets forth the requirement that regulations be effective six months (180 days) after promulgation. However, it does not mention specifically the Administrator's discretion to allow a shorter time. Thus, the question arises as to whether section 3010(b) or section 3017(b) is controlling. It is EPA's view that section 3010(b) is controlling. Where Congress intended that the Administrator have no discretion to shorten the period prior to the effective date, Congress used specific language to that effect. For example, section 3001(d)(9) (Small Quantity Generator Waste) provides that "the last sentence of § 3010(b) shall not apply to regulations promulgated under this Section." Accordingly, since Congress did not specifically provide otherwise under section 3017, the Administrator retains the authority to shorten this period.

EPA believes a shorter effective date is appropriate with respect to the export rule because the regulated community does not need six months to come into compliance with these rules. These rules are not complex and simply involve the exchange of general information. Moreover, because of the date of promulgation of this final rule, these regulations cannot be effectuated by November 8, 1986,[7] and still allow for a 180 day period prior to the effective date. Yet, EPA believes it is important to have rules in effect to properly implement section 3017 by that date.

Assuming, however, that section 3010(b) is not controlling, EPA believes that its scheme for effectuation of these rules is also authorized by section 3017 itself. Section 3017 specifies several dates by which certain acts should occur: 24 months for full statutory implementation; 12 months for implementation of the notification requirements of subsection (c); 12 months for enactment of regulations to implement the section; and, 180 days before the effective date of the regulations. Exactly how these time frames were intended to work together is unclear. For example, regulations need not be promulgated for 12 months but notification requirements were required to go into effect in 12 months. At the same time, 180 days was specified as the time between promulgation and effectuation of regulations. The various time frames established in section 3017 do not, on their face, logically interrelate, nor is it apparent which time frame would control if any slippage were to occur. In view of the lack of clarity of the statutory language in this respect, it is EPA's position that the time for full implementation of section 3017 must take precedence over the number of days between the promulgation date and effective date of the implementing notes. This scheme comports with Congressional intent that this section go into effect by November 8, 1986, and that regulations be in place by that time. Where EPA is unable to satisfy both of these statutory time frames, the November 8, 1986, deadline for implementing section 3017 is more important than the number of days between promulgation of the rule and its effective date.

[7] Section 3017(a) requires compliance with export requirements 24 months after enactment of HSWA (November 8, 1986).

VI. Economic, Environmental and Regulatory Impacts

A. Impact on Small Quantity Generators

Because of the limited number of generators of between 100–1000 kg/mo EPA expects will export hazardous waste, the impact on small quantity generators should be minimal.

B. Executive Order 12291—Regulatory Impact

Executive Order 12291 (46 FR 13193, February 9, 1981) requires that a regulatory agency determine whether a new regulation will be "major" and if so, that a Regulatory Impact Analysis be conducted.

The Administrator has determined that today's final rule is not a major rule, because it has total estimated costs of less than $100 million per year, and has no significant adverse economic effects.

While EPA recognizes that some companies may experience economic dislocation if there are significant delays in processing notifications and consents, the Agency believes that judicious planning on the part of these companies could eliminate or lessen the impact of such delays, if any. As stated in the preamble to the proposed rule (51 FR 10146, March 13, 1986), EPA will process all notifications and written consents as expeditiously as possible.

C. Paperwork Reduction Act

The information collection requirements in this rule have been approved by the Office of Management and Budget under the Paperwork Reduction Act of 1980, 44 U.S.C. 3501 *et seq.*, and have been assigned OMB control number 2050–0035.

D. Regulatory Flexibility Analysis

Pursuant to the Regulatory Flexibility Act, 5 U.S.C. 601 *et seq.*, a Regulatory Flexibility Analysis must be performed if the regulatory requirements have a significant impact on a substantial number of small entities. No Regulatory Flexibility Analysis is required where the head of an agency certifies that the rule will not have a significant economic impact on a substantial number of small entities.

Since 1980, generators exporting hazardous waste have been required by EPA to notify the Administrator four weeks before the initial shipment of hazardous waste to each country in each calendar year. Based upon an analysis of those notifications received, the Agency has determined that no small entitles have filed notifications of intent to export. EPA does not anticipate that the universe of generators exporting hazardous waste will significantly change in the future. Therefore, this rule is not expected to have a significant economic impact on a substantial number of small entities and does not require a Regulatory Flexibility Analysis. Therefore, pursuant to 5 USC §601(b), I certify that this regulation will not have a significant economic impact on a substantial number of small entities.

List of Subjects

40 CFR Part 260

Administrative practice and procedure, Confidential business information, Hazardous waste, Liquids in landsfills.

40 CFR Part 261

Intergovernmental relations, Hazardous materials, Waste treatment and disposal, Recycling.

40 CFR Part 262

Hazardous material transportation, Hazardous waste, Imports, Exports, Labeling, Packaging and containers, Reporting and recordkeeping requirements, Waste minimization.

40 CFR Part 263

Hazardous material transportation, Waste treatment and disposal.

40 CFR Part 271

Administrative practice and procedure, Confidential business information, Hazardous materials transportation, Hazardous waste, Indian lands, Intergovernmental relations, Penalties, Reporting and recordkeeping

requirements, Water pollution control, Water supply.

Lee M. Thomas,

Administrator.

August 5, 1986.

PART 260—HAZARDOUS WASTE MANAGEMENT SYSTEM: GENERAL

1. The authority citation for Part 260 continues to read as follows:

Authority: Secs. 1006, 2002(a), 3001 through 3007, 3010, 3014, 3015, 3017, 3018, 3019 and 7004, Solid Waste Disposal Act, as amended by the Resource Conservation and Recovery Act of 1976, as amended (42 U.S.C. 6905, 6912(a), 6921 through 6927, 6930, 6934, 6935, 6937, 6938, 6939, and 6974).

2. Section 260.2 is amended by revising paragraph (b) to read as follows:

§ 260.2 Availability of information; confidentiality of information.

* * * * *

(b) Any person who submits information to EPA in accordance with Parts 260 through 266 of this chapter may assert a claim of business confidentiality covering part or all of that information by following the procedures set forth in § 2.203(b) of this chapter. Information covered by such a claim will be disclosed by EPA only to the extent, and by means of the procedures, set forth in Part 2, Subpart B, of this chapter except that information required by § 262.53(a) which is submitted in notification of intent to export a hazardous waste will be provided to the Department of State and the appropriate authorities in a receiving country regardless of any claims of confidentiality. However, if no such claim accompanies the information when it is received by EPA, it may be made available to the public without further notice to the person submitting it.

PART 261—IDENTIFICATION AND LISTING OF HAZARDOUS WASTE

3. The authority citation for Part 261 is revised to read as follows:

Authority: Secs. 1006, 2002[a], 3001, 3002, and 3017 of the Solid Waste Disposal Act as amended by the Resource Conservation and Recovery Act of 1976, as amended (42 U.S.C. 6905, 6912(a), 6921, 6922, and 6937).

4. Section 261.6 is amended by revising paragraphs (a)(3)(i) to read as follows:

§ 261.6 Requirements for recyclable materials.

(a) * * *

(3) * * *

(i) Industrial ethyl alcohol that is reclaimed except that, unless provided otherwise in an international agreement as specified in § 262.58:

(A) A person initiating a shipment for reclamation in a foreign country, and any intermediary arranging for the shipment, must comply with the requirements applicable to a primary exporter in §§ 262.53, 262.56 (a)(1)–(4), (6), and (b), and 262.57, export such materials only upon consent of the receiving country and in conformance with the EPA Acknowledgment of Consent as defined in Subpart E of Part 262, and provide a copy of the EPA Acknowledgment of Consent to the shipment to the transporter transporting the shipment for export;

(B) Transporters transporting a shipment for export may not accept a shipment if he knows the shipment does not conform to the EPA Acknowledgment of Consent, must ensure that a copy of the EPA Acknowledgment of Consent accompanies the shipment and must ensure that it is delivered to the facility designated by the person initiating the shipment.

* * * * *

5. Section 261.5 is amended by revising paragraphs (f)(3) and (g)(3) to read as follows:

§ 261.5 Special requirements for hazardous waste generated by conditionally exempt small quantity generators.

* * * * *

(f) * * *

(3) A conditionally exempt small quantity generator may either treat or dispose of his acute hazardous waste in an on-site facility or ensure delivery to an off-site treatment, storage or disposal facility, either of which, if located in the U.S., is:

* * * * *

(g) * * *

(3) A conditionally exempt small quantity generator may either treat or dispose of his hazardous waste in an on-site facility or ensure delivery to an off-site treatment, storage or disposal facility, either of which, if located in the U.S., is:

* * * * *

PART 262—STANDARDS APPLICABLE TO GENERATORS OF HAZARDOUS WASTE

6. The authority citation for Part 262 continues to read as follows:

Authority: Secs. 1006, 2002(a), 3002, 3003, 3004, 3005, and 3017 of the Solid Waste Disposal Act, as amended by the Resource Conservation and Recovery Act of 1976, as amended (42 U.S.C. 6906, 6912(a), 6922, 6923, 6924, 6925, and 6937).

7. Section 262.41 is amended by revising the introductory text to paragraph (a), (a)(3), (a)(4) and (a)(5), and adding a sentence at the end of paragraph (b) to read as follows:

§ 262.41 Biennial Report.

(a) A generator who ships any hazardous waste off-site to a treatment, storage or disposal facility within the United States must prepare and submit a single copy of a Biennial Report to the Regional Administrator by March 1 of each even numbered year. The Biennial Report must be submitted on EPA Form 8700–13A, must cover generator activities during the previous year, and must include the following information:

* * * * *

(3) The EPA identification number, name, and address for each off-site treatment, storage, or disposal facility in the United States to which waste was shipped during the year;

(4) The name and EPA identification number of each transporter used during the reporting year for shipments to a treatment, storage or disposal facility within the United States;

(5) A description, EPA hazardous waste number (from 40 CFR Part 261, Subpart C or D), DOT hazard class, and quantity of each hazardous waste shipped off-site for shipments to a treatment, storage or disposal facility within the United States. This information must be listed by EPA identification number of each such off-site facility to which waste was shipped.

* * * * *

(b) * * *

Reporting for exports of hazardous waste is not required on the Biennial Report form. A separate annual report requirement is set forth at 40 CFR 262.56.

8. 40 CFR Part 262 is amended by revising Subpart E to read as follows:

Subpart E—Exports of Hazardous Waste

Sec.

Subpart E—Exports of Hazardous Waste

§ 262.50 Applicability.

This subpart establishes requirements applicable to exports of hazardous waste. Except to the extent § 262.58 provides otherwise, a primary exporter

of hazardous waste must comply with the special requirements of this subpart and a transporter transporting hazardous waste for export must comply with applicable requirements of Part 263. Section 262.58 sets forth the requirements of international agreements between the United States and receiving countries which establish different notice, export, and enforcement procedures for the transportation, treatment, storage and disposal of hazardous waste for shipments between the United States and those countries.

§ 262.51 Definitions.

In addition to the definitions set forth at 40 CFR 260.10, the following definitions apply to this subpart:

"Consignee" means the ultimate treatment, storage or disposal facility in a receiving country to which the hazardous waste will be sent.

"EPA Acknowledgment of Consent" means the cable sent to EPA from the U.S. Embassy in a receiving country that acknowledges the written consent of the receiving country to accept the hazardous waste and describes the terms and conditions of the receiving country's consent to the shipment.

"Primary Exporter" means any person who is required to originate the manifest for a shipment of hazardous waste in accordance with 40 CFR Part 262, Subpart B, or equivalent State provision, which specifies a treatment, storage, or disposal facility in a receiving country as the facility to which the hazardous waste will be sent and any intermediary arranging for the export.

"Receiving country" means a foreign country to which a hazardous waste is sent for the purpose of treatment, storage or disposal (except short-term storage incidental to transportation).

"Transit country" means any foreign country, other than a receiving country, through which a hazardous waste is transported.

§ 262.52 General requirements.

Exports of hazardous waste are prohibited except in compliance with the applicable requirements of this Subpart and Part 263. Exports of hazardous waste are prohibited unless:

(a) Notification in accordance with § 262.53 has been provided;

(b) The receiving country has consented to accept the hazardous waste;

(c) A copy of the EPA Acknowledgment of Consent to the shipment accompanies the hazardous waste shipment and, unless exported by rail, is attached to the manifest (or shipping paper for exports by water (bulk shipment)).

(d) The hazardous waste shipment conforms to the terms of the receiving country's written consent as reflected in the EPA Acknowledgment of Consent.

(Approved by the Office of Management and Budget under control number 2050–0035)

§ 262.53 Notification of intent to export.

(a) A primary exporter of hazardous waste must notify EPA of an intended export before such waste is scheduled to leave the United States. A complete notification should be submitted sixty (60) days before the initial shipment is intended to be shipped off site. This notification may cover export activities extending over a twelve (12) month or lesser period. The notification must be in writing, signed by the primary exporter, and include the following information:

(1) Name, mailing address, telephone number and EPA ID number of the primary exporter;

(2) By consignee, for each hazardous waste type:

(i) A description of the hazardous waste and the EPA hazardous waste number (from 40 CFR Part 261, Subparts C and D), U.S. DOT proper shipping name, hazard class and ID number (UN/NA) for each hazardous waste as identified in 49 CFR Part 171–177;

(ii) The estimated frequency or rate at which such waste is to be exported and the period of time over which such waste is to be exported.

(iii) The estimated total quantity of the hazardous waste in units as specified in the instructions to the Uniform Hazardous Waste Manifest Form (8700–22);

(iv) All points of entry to and departure from each foreign country through which the hazardous waste will pass;

(v) A description of the means by which each shipment of the hazardous waste will be transported (e.g., mode of transportation vehicle (air, highway, rail, water, etc.), type(s) of container (drums, boxes, tanks, etc.));

(vi) A description of the manner in which the hazardous waste will be treated, stored or disposed of in the receiving country (e.g., land or ocean incineration, other land disposal, ocean dumping, recycling);

(vii) The name and site address of the consignee and any alternate consignee; and

(viii) The name of any transit countries through which the hazardous waste will be sent and a description of the approximate length of time the hazardous waste will remain in such country and the nature of its handling while there;

(b) Notification shall be sent to the Office of International Activities (A–106), EPA, 401 M Street, SW., Washington, DC 20460 with "Attention: Notification to Export" prominently displayed on the front of the envelope.

(c) Except for changes to the telephone number in paragraph (a)(1) of this section, changes to paragraph (a)(2)(v) of this section and decreases in the quantity indicated pursuant to paragraph (a)(2)(iii) of this section when the conditions specified on the original notification change (including any exceedance of the estimate of the quantity of hazardous waste specified in the original notification), the primary exporter must provide EPA with a written renotification of the change. The shipment cannot take place until consent of the receiving country to the changes (except for changes to paragraph (a)(2)(viii) of this section and in the ports of entry to and departure from transit countries pursuant to paragraph (a)(2)(iv) of this section) has been obtained and the primary exporter receives an EPA Acknowledgment of Consent reflecting the receiving country's consent to the changes.

(d) Upon request by EPA, a primary exporter shall furnish to EPA any additional information which a receiving country requests in order to respond to a notification.

(e) In conjunction with the Department of State, EPA will provide a complete notification to the receiving country and any transit countries. A notification is complete when EPA receives a notification which EPA determines satisfies the requirements of paragraph (a) of this section. Where a claim of confidentiality is asserted with respect to any notification information required by paragraph (a) of this section, EPA may find the notification not complete until any such claim is resolved in accordance with 40 CFR 260.2.

(f) Where the receiving country consents to the receipt of the hazardous waste, EPA will forward an EPA Acknowledgment of Consent to the primary exporter for purposes of § 262.54(h). Where the receiving country objects to receipt of the hazardous waste or withdraws a prior consent, EPA will notify the primary exporter in writing. EPA will also notify the primary exporter of any responses from transit countries.

(Approved by the Office of Management and Budget under control number 2050–0035)

§ 262.54 Special manifest requirements.

A primary exporter must comply with the manifest requirements of 40 CFR 262.20–262.23 except that:

(a) In lieu of the name, site address and EPA ID number of the designated permitted facility, the primary exporter must enter the name and site address of the consignee;

(b) In lieu of the name, site address and EPA ID number of a permitted alternate facility, the primary exporter may enter the name and site address of any alternate consignee.

(c) In Special Handling Instructions and Additional Information, the primary exporter must identify the point of departure from the United States;

(d) The following statement must be added to the end of the first sentence of the certification set forth in Item 16 of the Uniform Hazardous Waste Manifest Form: "and conforms to the terms of the attached EPA Acknowledgment of Consent";

(e) In lieu of the requirements of § 262.21, the primary exporter must obtain the manifest form from the primary exporter's State if that State supplies the manifest form and requires its use. If the primary exporter's State does not supply the manifest form, the primary exporter may obtain a manifest form from any source.

(f) The primary exporter must require the consignee to confirm in writing the delivery of the hazardous waste to that facility and to describe any significant discrepancies (as defined in 40 CFR 264.72(a)) between the manifest and the shipment. A copy of the manifest signed by such facility may be used to confirm delivery of the hazardous waste.

(g) In lieu of the requirements of § 262.20(d), where a shipment cannot be delivered for any reason to the designated or alternate consignee, the primary exporter must:

(1) Renotify EPA of a change in the conditions of the original notification to allow shipment to a new consignee in accordance with § 262.53(c) and obtain an EPA Acknowledgment of Consent prior to delivery; or

(2) Instruct the transporter to return the waste to the primary exporter in the United States or designate another facility within the United States; and

(3) Instruct the transporter to revise the manifest in accordance with the primary exporter's instructions.

(h) The primary exporter must attach a copy of the EPA Acknowledgment of Consent to the shipment to the manifest which must accompany the hazardous waste shipment. For exports by rail or water (bulk shipment), the primary exporter must provide the transporter with an EPA Acknowledgment of Consent which must accompany the hazardous waste but which need not be attached to the manifest except that for exports by water (bulk shipment) the primary exporter must attach the copy of the EPA Acknowledgment of Consent to the shipping paper.

(i) The primary exporter shall provide the transporter with an additional copy of the manifest for delivery to the U.S. Customs official at the point the hazardous waste leaves the United States in accordance with § 263.20(g)(4).

(Approved by the Office of Management and Budget under control number 2050–0035)

§ 262.55 Exception reports.

In lieu of the requirements of § 262.42, a primary exporter must file an exception report with the Administrator if:

(a) He has not received a copy of the manifest signed by the transporter stating the date and place of departure from the United States within forty-five (45) days from the date it was accepted by the initial transporter;

(b) Within ninety (90) days from the date the waste was accepted by the initial transporter, the primary exporter has not received written confirmation from the consignee that the hazardous waste was received;

(c) The waste is returned to the United States.

(Approved by the Office of Management and Budget and assigned under control number 2050–0035)

§ 262.56 Annual reports.

(a) Primary exporters of hazardous waste shall file with the Administrator no later than March 1 of each year, a report summarizing the types, quantities, frequency, and ultimate destination of all hazardous waste exported during the previous calendar year. Such reports shall include the following:

(1) The EPA identification number, name, and mailing and site address of the exporter;

(2) The calendar year covered by the report;

(3) The name and site address of each consignee;

(4) By consignee, for each hazardous waste exported, a description of the hazardous waste, the EPA hazardous waste number (from 40 CFR Part 261, Subpart C or D), DOT hazard class, the name and US EPA ID number (where applicable) for each transporter used, the total amount of waste shipped and number of shipments pursuant to each notification;

(5) Except for hazardous waste produced by exporters of greater than 100 kg but less than 1000 kg in a calendar month, unless provided pursuant to § 262.41, in even numbered years:

(i) a description of the efforts undertaken during the year to reduce the volume and toxicity of waste generated; and

(ii) a description of the changes in volume and toxicity of waste actually achieved during the year in comparison to previous years to the extent such information is available for years prior to 1984.

(6) A certification signed by the primary exporter which states:

I certify under penalty of law that I have personally examined and am familiar with the information submitted in this and all attached documents, and that based on my inquiry of those individuals immediately rsponsible for obtaining the information, I believe that the submitted information is true, accurate, and complete. I am aware that there are significant penalties for submitting false information including the possibility of fine and imprisonment.

(b) Reports shall be sent to the following address: Office of International Activities (A–106), Environmental Protection Agency, 401 M Street SW., Washington, DC 20460.

(Approved by the Office of Management and Budget under control number 2050–0035)

§ 262.57 Recordkeeping.

(a) For all exports a primary exporter must:

(1) Keep a copy of each notification of intent to export for a period of at least three years from the date the hazardous waste was accepted by the initial transporter;

(2) Keep a copy of each EPA Acknowledgment of Consent for a period of at least three years from the date the hazardous waste was accepted by the initial transporter;

(3) Keep a copy of each confirmation of delivery of the hazardous waste from the consignee for at least three years from the date the hazardous waste was accepted by the initial transporter; and

(4) Keep a copy of each annual report for a period of at least three years from the due date of the report.

(b) The periods of retention referred to in this section are extended automatically during the course of any unresolved enforcement action regarding the regulated activity or as requested by the Administrator.

(Approved by the Office of Management and Budget under control number 2050–0035)

§ 262.58 International agreements. [(Reserved)]

9. Title 40 CFR Part 262 is amended by adding new Subpart F to read as follows:

Subpart F—Imports of Hazardous Waste

Sec.
262.60 Imports of hazardous waste.

Subpart F—Imports of Hazardous Waste

§ 262.60 Imports of hazardous waste.

(a) Any person who imports hazardous waste from a foreign country into the United States must comply with the requirements of this part and the special requirements of this subpart.

(b) When importing hazardous waste, a person must meet all the requirements of § 262.20(a) for the manifest except that:

(1) In place of the generator's name, address and EPA identification number, the name and address of the foreign generator and the importer's name, address and EPA identification number must be used.

(2) In place of the generator's signature on the certification statement, the U.S. importer or his agent must sign and date the certification and obtain the signature of the initial transporter.

(c) A person who imports hazardous waste must obtain the manifest form from the consignment State if the State supplies the manifest and requires its use. If the consignment State does not supply the manifest form, then the manifest form may be obtained from any source.

10. Title 40 CFR Part 262 is amended by adding a new Subpart G to read as follows:

Subpart G—Farmers

§ 262.70 Farmers.

A farmer disposing of waste pesticides from his own use which are hazardous wastes is not required to comply with the standards in this part or other standards in 40 CFR Part 270, 264 or 265 for those wastes provided he triple rinses each emptied pesticide container in accordance with § 261.7(b)(3) and disposes of the pesticide residues on his own farm in a manner consistent with the disposal instructions on the pesticide label.

Appendix—Uniform Hazardous Waste Manifest and Instructions (EPA Forms 8700–22 and 8700–22A and Their Instructions)

11. The instructions to the Uniform Hazardous Waste Manifest form in the Appendix to Part 262 is amended to add under Item 16 a new paragraph after the first paragraph as follows:

* * * * *

Primary exporters shipping hazardous wastes to a facility located outside of the United States must add to the end of the first sentence of the certification the following words "and conforms to the terms of the EPA Acknowledgment of Consent to the shipment."

* * * * *

PART 263—STANDARDS APPLICABLE TO TRANSPORTERS OF HAZARDOUS WASTE

12. The authority citation for Part 263 is revised to read as follows:

Authority: Secs. 2002(a), 3002, 3003, 3004, 3005 and 3017 of the Solid Waste Disposal Act as amended by the Resource Conservation and Recovery Act of 1976 and as amended by the Quiet Communities Act of 1978 (42 U.S.C. 6912, 6922, 6923, 6924, 6925 and 6937).

13. Section 263.20 is amended by revising paragraphs (a), (c), (e)(2), (f)(2) and (g)(3) and by adding paragraph (g)(4) to read as follows:

§ 263.20 The manifest system.

(a) A transporter may not accept hazardous waste from a generator unless it is accompanied by a manifest signed in accordance with the provisions of 40 CFR 262.20. In the case of exports, a transporter may not accept such waste from a primary exporter or other person (1) if he knows the shipment does not conform to the EPA Acknowledgment of Consent; and (2) unless, in addition to a manifest signed in accordance with the provisions of 40 CFR 262.20, such waste is also accompanied by an EPA Acknowledgment of Consent which, except for shipment by rail, is attached to the manifest (or shipping paper for exports by water (bulk shipment)).

* * * * *

(c) The transporter must ensure that the manifest accompanies the hazardous waste. In the case of exports, the transporter must ensure that a copy of the EPA Acknowledgment of Consent also accompanies the hazardous waste.

* * * * *

(e) * * *

(2) A shipping paper containing all the information required on the manifest (excluding the EPA identification numbers, generator certification, and signatures) and, for exports, an EPA Acknowledgment of Consent accompanies the hazardous waste; and

* * * * *

(f) * * *

(2) Rail transporters must ensure that a shipping paper containing all the information required on the manifest (excluding the EPA identification numbers, generator certification, and signatures) and, for exports an EPA Acknowledgment of Consent accompanies the hazardous waste at all times.

* * * * *

(g) * * *

(3) Return a signed copy of the manifest to the generator; and

(4) Give a copy of the manifest to a U.S. Customs official at the point of departure from the United States.

* * * * *

PART 271—REQUIREMENTS FOR AUTHORIZATION OF STATE HAZARDOUS WASTE PROGRAMS

14. The authority citation for Part 271 continues toread as follows:

Authority: Secs. 1006, 2002(a), and 3006 of the Solid Waste Disposal Act, as amended by the Resource Conservation and Recovery Act of 1976, as amended (42 U.S.C. 6905, 6912(a), and 6926).

§ 271.1 [Amended]

15. Section 271.1 paragraph (j) is amended by adding the following entry to Table 1 in chronological order:

TABLE 1.—REGULATIONS IMPLEMENTING THE HAZARDOUS AND SOLID WASTE AMENDMENTS OF 1984

Date	Title of regulation
* * * * *	
[Insert date of publication].....	Exports of hazardous waste.

16. Section 271.10 is amended by revising paragraph (e) to read as follows except for the note which remains unchanged.

§ 271.10 Requirements for generators of hazardous wastes.

* * * * *

(e) The State program shall provide requirements respecting international shipments which are equivalent to those at 40 CFR Part 262 Subparts E and F, except that:

(1) Advance notification, annual reports and exception reports in accordance with 40 CFR 262.53, 262.55 and 262.56 shall be filed with the Administrator; States may require that copies of the documents referenced also be filed with the State Director; and

(2) The Administrator will notify foreign countries of intended exports in conjunction with the Department of State and primary exporters of foreign countries' responses in accordance with 40 CFR 262.53.

* * * * *

17. Section 271.11 is amended by revising paragraph (c) to read as follows:

§ 271.11 Requirements for transporters of hazardous wastes.

* * * * *

(c) The State must require the transporter to carry the manifest during transport, except in the case of shipments by rail or water specified in 40 CFR 263.20 (e) and (f) and to deliver waste only to the facility designated on the manifest. The State program shall provide requirements for shipments by rail or water equivalent to those under 40 CFR 263.20 (e) and (f). For exports of hazardous waste, the State must require the transporter to refuse to accept hazardous waste for export if he knows the shipment does not conform to the EPA Acknowledgment of Consent, to carry an EPA Acknowledgment of Consent to the shipment, and to provide a copy of the manifest to the U.S. Customs official at the point the waste leaves the United States.

* * * * *

[FR Doc. 86–17999 Filed 8–7–86; 8:45 am]

BILLING CODE 6560–50–M