REPRODUCTION SERVICE

Department of Army:
Army Materiel Command Headquarters, Alexandria, Virginia (SH)

SEWING

Department of Army:
Redstone Arsenal, Alabama (Provide specified end items produced through use of customized, heavy-duty sewing service) (SH)

SPONGE RUBBER MATTRESSES REHABILITATION

General Services Administration:
Requirements for GSA Region 3 (SH)

TAPE CLEANING

Department of Air Force:
Wright-Patterson Air Force Base, Ohio (SH)

[FR Doc. 87-28208 Filed 12-9-87; 8:45 am]
BILLING CODE 6820-33-M

federal register

Thursday
December 10, 1987

Part IV

Environmental Protection Agency

40 CFR Parts 144, 260, 264, and 270
Hazardous Waste Miscellaneous Units; Standard; Applicable to Owners and Operators; Final Rule

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Parts 144, 260, 264, and 270

[FRL. 3220-1]

Hazardous Waste Miscellaneous Units; Standard; Applicable to Owners and Operators

AGENCY: Environmental Protection Agency.

ACTION: Final rule.

SUMMARY: The Resource Conservation and Recovery Act (RCRA) authorizes the Environmental Protection Agency (EPA) to issue standards applicable to owners and operators of hazardous waste management facilities. Over the past several years, the Agency has promulgated standards for specific types of treatment, storage, and disposal units, including containers, tanks, surface impoundments, waste piles, land treatment units, landfills, incinerators, underground injection wells, and research, development, and demonstration facilities. However, because some hazardous waste management technologies are not covered by the existing permitting standards, owners and operators of facilities utilizing them cannot obtain the RCRA permits necessary to operate them.

To fill this gap, the Agency is today promulgating a new set of standards under Subpart X of Part 264. The standards are applicable to owners and operators of new and existing hazardous waste management units not covered under the existing regulations. This will enable the Agency, and the States that adopt equivalent authorities, to issue permits to miscellaneous waste management units.

DATE: This final rule is effective January 11, 1988.

ADDRESSES: The official record for this rulemaking under docket No. F-87-SPXF-FFFFF is located at the U.S. Environmental Protection Agency, 401 M Street SW., Washington, DC 20460. It is available for viewing from 9:00 a.m. to 4:00 p.m., Monday through Friday, excluding holidays. The public should make an appointment to review docket material by calling (202) 475-9327. The public may copy a maximum of 50 pages of material from any one regulatory docket at no cost. Additional copies cost $0.20 per page.

FOR FURTHER INFORMATION CONTACT: For general information, contact the RCRA/Superfund Hotline at (800) 424-9346 (toll free) or (202) 382-3000 in Washington, DC. For information on the technical aspects of this rule, contact Kent Anderson, Land Disposal Branch, Waste Management Division, Office of Solid Waste (WH-565E), U.S. Environmental Protection Agency, 401 M Street SW., Washington, DC 20460, telephone (202) 382-4654.

Preamble Outline

I. Authority

These regulations are issued under authority of sections 1006, 2002(a), and 3001 through 3013 of the Solid Waste Disposal Act (SWDA), as amended by the Resource Conservation and Recovery Act of 1976 (RCRA), as amended, 42 U.S.C. 6901 *et seq.*

II. Background

A. Development of the Hazardous Waste Regulatory Program

The Environmental Protection Agency is required by section 3004 of RCRA to establish standards for owners and operators of hazardous waste facilities in order to protect human health and the environment. These standards establish the duties of and provide the basis for issuing permits to the owners and operators of hazardous waste treatment, storage, and disposal (TSD) facilities under section 3005 of RCRA. Therefore, these standards serve not only to regulate the operations of these TSD facilities, but also to provide a basis for evaluating the issuance of these permits.

The Agency has promulgated these regulations in stages. On May 19, 1980 (45 FR 33221), the Agency issued regulations establishing administrative requirements for certain types of hazardous waste management, general provisions for facility owners and operators, permitting procedures for hazardous waste management facilities, and procedures for State program

authorization. On January 12, 1981 (46 FR 2802), the Agency issued regulations establishing technical standards and permitting requirements for certain storage and treatment facilities. On January 23, 1981 (46 FR 7678), and June 24, 1982 (47 FR 27516), the Agency issued technical standards for hazardous waste incinerators. On April 7, 1982 (47 FR 15032), and April 16, 1982 (47 FR 16544), the Agency issued regulations for demonstrating financial responsibility. On July 26, 1982 (47 FR 32274), the Agency promulgated technical and permitting standards for new and existing TSD facilities on land, including surface impoundments, waste piles, land treatment units, and landfills.

On July 15, 1985 (50 FR 28702), the Agency amended its hazardous waste management rules to codify several statutory changes required by the Hazardous and Solid Waste Amendments of 1984 (HSWA). These changes included revisions to the technical requirements for land TSD facilities, revisions to the permitting requirements for all TSD facilities, and limitations on the placement of hazardous waste in salt-dome formations, salt bed formations, underground mines, and caves. In addition, these amendments included new rules that allow for the permitting of certain research, development, and demonstration facilities.

These standards are presented in Table 1.

TABLE 1.—FEDERAL RULES PERTAINING TO THE MANAGEMENT OF HAZARDOUS WASTE

RCRA Code	Description
40 CFR Part 260	Basic regulatory definitions of what is covered under these standards.
40 CFR Part 261	Definition of a hazardous waste.
40 CFR Part 262	Requirements for hazardous waste generators.
40 CFR Part 263	Requirements for hazardous waste transporters.
40 CFR Part 264	Establishes the permitting standards in the form of specific conditions for facility operation, design, performance, and location.
40 CFR Part 265	Establishes operational standards for existing facilities (on or before November 19, 1980) with "interim standards" until the site has obtained a final permit or it loses its interim status because of the provisions outlined under HSWA.
40 CFR Part 266	Establishes standards applicable to generators and transporters of materials used in a manner that constitutes disposal. This also includes standards for disposal of specific hazardous wastes where hazardous materials are used/recycled for recovery of heat, precious metals, and reclaimed batteries.
40 CFR Part 268	Sets treatment standards and schedules for prohibition of wastes for land disposal (including surface units, injection wells, salt domes, salt beds, underground mines or caves, or concrete vaults or bunkers).
40 CFR Part 269	Establishes permitting standards for control and monitoring of air emissions at TSDs.
40 CFR Part 270	Outlines definitions and basic requirements for RCRA permits.
40 CFR Part 271	Sets out the guidelines for final approval of State hazardous waste programs that will be used instead of the Agency's program.
40 CFR Part 124	Establishes the permit process to be followed under several Agency programs.

B. Summary of the Need for Subpart X

Although the Agency has issued regulations for the major hazardous waste management technologies and practices, gaps still remain. To close the gaps in the RCRA regulations and to cover unregulated hazardous waste management units, on November 7, 1986, the Agency proposed the Subpart X rule. Subpart X covers miscellaneous units and essentially completes the coverage of hazardous waste management units.

Currently, promulgated regulations in 40 CFR Parts 264 and 265 are the primary regulations for many types of hazardous waste management units as defined in § 260.10. These include containers, tanks, surface impoundments, waste piles, land treatment units, landfills, and incinerators. Research, development, and demonstration facilities and underground injection wells are regulated under Part 270 and the Underground Injection Control Program of the Safe Drinking Water Act (40 CFR Part 146), respectively.

The Agency is aware, however, that certain existing and future hazardous waste management practices and technologies do not or may not fit the description of any of the units covered by the existing regulations. If they do not fit these descriptions, then they cannot be fully permitted and can only operate as interim status facilities. This is not desirable because it prevents the construction of new units or expansion of existing units. For example, thermal treatment of hazardous waste in units other than incinerators, boilers, or industrial furnaces may not be fully permitted because such units are not at present covered by Part 264 or Part 266. This means that existing units with interim permit status under Part 265 may not receive a full Part 264 RCRA permit. In addition, Part 264 permitting standards provide better environmental protection than the interim standards.

The Agency has received a number of requests that standards be issued to allow the construction of new hazardous waste management units not previously covered by Part 264. Furthermore, some types of new units that cannot now be constructed may reduce risks to human health and the environment from the management of hazardous waste. Therefore, the Agency regards the Subpart X rule as a means of allowing flexibility for technological development and innovation.

C. General Approach and Scope of Subpart X

This regulation covers miscellaneous units not regulated under the standards for specific types of treatment, storage, and disposal units in Part 264 Subparts I through O or Part 146 or Part 270. Because these standards cover both existing and future treatment, storage, and disposal technologies, today's approach is to promulgate a new set of general standards that will cover diverse technologies and units. The Agency may develop specific technology standards in the future, if the need arises.

The Agency is regulating under today's rule most of those units that are not covered by a subpart under Part 264 or Part 146. For example, units that do not fit the definition of any of the units covered by the standards of Part 264 or Part 146 would be regulated as miscellaneous units. In addition, unless otherwise excluded, if a new type of unit

were developed that did not fit the definition of tank, container, surface impoundment, waste pile, land treatment unit, landfill, incinerator, boiler, industrial furnace, or underground injection well, it would be regulated under Subpart X. An example of a miscellaneous unit would be a thermal treatment unit such as a wet-air oxidation device that is not an incinerator or a tank. Another example would be a long-term retrievable storage unit that is not a tank, waste pile, landfill, or other Part 264 unit, or an underground injection well. An example of a unit that will not be regulated under Subpart X, as explained in III.B.2., is open burning of nonexplosive wastes.

Subpart X will not supersede or replace any specific restrictions on activities contained in another subpart or provide a vehicle for escaping from those restrictions. For example, 40 CFR 264.175 stipulates that container storage areas must have a secondary containment system to drain and remove leakage. This requirement may not be evaded by seeking a permit under Subpart X.

Likewise, miscellaneous units permitted under Subpart X that are also defined by RCRA as "land disposal" units (see final rule at 51 FR 40572) may not avoid the Part 268 restrictions on land disposal of untreated or improperly treated hazardous waste. For example, although the use of an underground mine, cave, or formation for the placement of hazardous waste may, under some circumstances, be considered a miscellaneous unit, such a unit would also be subject to the Part 268 land disposal restrictions, since it is defined as "land disposal" by RCRA. Therefore, any hazardous waste subject to land disposal restrictions that is placed into a miscellaneous "land disposal" unit must be treated prior to land disposal in compliance with a treatment standard promulgated under Part 268, unless the owner or operator demonstrates, to a reasonable degree of certainty, that there will be no migration of hazardous constituents from the unit for as long as the waste remains hazardous.

D. Comments Received on the Proposed Rule

The 43 sets of public comments received on the November 7, 1986, proposal generally favored the implementation of Subpart X. The Agency considered all the public comments and categorized them into three general areas to provide a collective response:

- Specificity of Subpart X standards,
- Definition of "miscellaneous unit," and
- Redefinition of "landfill."

General responses to the first two categories appear below. In addition, the Agency discusses certain comments more specifically in later sections of the preamble.

Comments applicable to the redefinition of "landfill" are discussed in Section IV.B of the preamble. "Background Document: Subpart X Comments and Responses" contains all of the public comments that were received in accordance with the request for comments in the proposal and the Agency's response to these comments. This document is available in the Subpart X docket.

1. Specificity of Subpart X Standards

The Subpart X standards specify that health and environmental safety must be a primary concern during the management of hazardous wastes in miscellaneous units. The standards also require that existing regulations become an integral part of today's Subpart X standards for "miscellaneous" units. The Agency's intention of incorporating existing regulations with general Subpart X standards was the approach generally welcomed by the commenters

The Agency has concluded that it is best to develop generic standards, not technology-specific standards, because the generic standards can cover a set of diverse technologies effectively. Most commenters have confirmed the need for such an approach. If the Agency developed technology-based standards, the Subpart X rule would not differ from the existing requirements in Parts 264 and 265. For most of the miscellaneous units, insufficient information is available to develop technology-based standards at this time. Even for those units for which there may be sufficient information available to develop technology-based standards, to do so would result in a major delay in permitting these units while standards were developed, proposed, and finalized. Therefore, the Agency chose to develop generic standards after considering the advantages and disadvantages of other approaches, including design and operating standards, technical and environmental performance standards, containment standards, and facility-specific risk assessment. Subpart X provides the Agency with flexibility in regulating miscellaneous units by providing generic permitting standards under Subpart X.

The Subpart X rule allows the hazardous waste management industry flexibility in developing new technologies or modifying existing technologies. Public comments suggest that certain units, such as open burning/open detonation (OB/OD), physical/chemical/biological treatment units (e.g., pyrolysis, stripping, and in-situ biodegradation), and land-based hazardous waste disposal units (e.g., salt beds, salt domes, and underground mines or caverns), may require technology-specific standards. Some of these technologies are unique methods for managing specific types of hazardous wastes for which no alternative technology exists, and none of the existing permitting standards may be applicable However, the Agency believes that the generic permitting standards under Subpart X would be just as applicable to open burning/open detonation, physical/chemical/biological treatment units, and land-based hazardous waste disposal units as any other Subpart X unit. Moreover, under Subpart X, the Agency has the flexibility to develop technology-specific standards for these units on a permit-by-permit basis when considering the technology-specific data submitted by the applicant to develop the permit conditions based on the environmental performance standards and to issue a permit.

A significant number of comments were received discussing different hazardous waste management technologies that the commenters considered should be eligible candidates for Subpart X permits. For a few technologies, extensive descriptions were submitted as part of the comment. For example, separate descriptions were submitted for each of these technologies: wet air oxidation, aboveground engineered vaults, enclosed buildings, in-situ biodegradation, in-situ vitrification, and open burning/open detonation of explosive wastes. The information obtained from these comments will be useful when the technology becomes widely used. At that time, the Agency will consider developing guidance or specific standards for those units included as miscellaneous units. As an example, the Agency is developing permit guidance for open burning/open detonation of explosive wastes.

A few commenters objected to the unlimited authority that Subpart X gives a permit writer when permitting a wide range of miscellaneous units. They saw this authority as a possible hindrance to the effective permitting of specific units.

The Agency agrees that there may be some cases in which permit writers must exercise some discretion. However, the Agency is developing permit guidance for certain types of units that will

provide assistance in the permitting process. While this guidance will not be binding on the Agency, and there still may be some permit variations between similar units, we believe that permit guidance will reduce any such variations by providing direction to permit writers and permit applicants, with regard to specific Subpart X technologies. For example, the Agency is developing specific Subpart X permit guidance for OB/OD and geologic repositories other than injection wells This guidance will explain how to mitigate emissions or releases from these units and thus minimize long-term health and environmental hazards. As more experience is gained, the Agency may develop guidances on other Subpart X units. In addition, the Agency will use the support of EPA's Permit Assistance Teams (PAT) staff to promote nationwide consistency in the issuance of Subpart X permits. The PAT staff can also help the individual permit writer understand unfamiliar technologies.

Some commenters requested clarification on when ground water and/or surface water must be monitored at miscellaneous units. The Agency requires that when applying for a permit, the applicant must assess the potential for release or migration of hazardous constituent(s) to each of the media. Based upon this assessment, a determination will be made as to the type and frequency of monitoring that will be necessary at any specific unit or site.

2. Definition of "Miscellaneous Unit"

"Miscellaneous unit" is defined in the proposed Subpart X rule as a hazardous waste management unit that is used to treat, store, or dispose of hazardous wastes but that does not fit the current RCRA definition of container, tank, surface impoundment, pile, land treatment unit, landfill, incinerator, boiler, industrial furnace, or underground injection well

Most of the commenters suggested that the Agency should provide a list of technologies or units that can be categorized as Subpart X units. They believed this would avoid confusion over which units should be permitted under Subpart X. If such an all-inclusive list were published with today's rule, however, it would become quickly outdated because new technologies are being developed frequently. In response to commenters' requests, the Agency has provided examples of units in Section III, B.1 and 2, that are covered and not covered under today's rule. Since Subpart X is a catchall category, the list provided here is not all-inclusive and comprehensive.

Commenters also indicated that a definitive listing of all applicable units would circumvent the need for requiring two types of permits (e.g., a tank-like unit would not need both a tank permit and a Subpart X permit). They claimed that obtaining two permits is very costly and time consuming and often duplicates efforts. The Agency does not intend to require two permits for any miscellaneous unit. Under the regulatory approach selected today, a Subpart X permit would be issued for the miscellaneous unit, which may include certain requirements that are specific to other types of units. For example, for a miscellaneous unit resembling a tank, a Subpart X permit would be issued that would include certain of the Subpart J tank standard requirements.

3. Redefinition of "Landfill"

Comments applicable to the redefinition of "landfill" are discussed in Section IV.B of the preamble.

III. The Agency's Approach

A. Alternative Approaches Considered

In preparing the proposed Subpart X rule, the Agency considered a number of regulatory approaches. The Agency selected a combination approach since no singular approach was best suited to protect human health and the environment while still providing flexibility in addressing the diversity of waste management units included in Subpart X. Under this approach, appropriate elements of design and operating standards, technical performance standards, containment standards, facility-specific risk assessment, and environmental performance standards will be applied to miscellaneous units on a case-by-case basis. This approach will result in less delay by providing permitting standards for those miscellaneous units for which sufficient data are not available to develop more specific standards. The alternative approaches considered were design and operating standards, technical performance standards, containment standards, facility-specific risk assessment, environmental performance standards, and a combination of these approaches.

1. Design and Operating Standards

Design and operating standards would require the installation of specific equipment or the use of particular processes. These standards would be process- and unit-specific.

The majority of commenters favored these standards, since many were interested in obtaining specific requirements for their units. The Agency determined that preparing these standards would be resource-intensive because it would need to collect extensive data on each specific type of unit. In addition to collecting the data, the Agency would need to develop a proposed rule and promulgate a final rule which would also greatly delay the permitting of miscellaneous units. Therefore, this approach would be a detriment to the development of innovative technology, since owners or operators would need to wait for EPA to promulgate new rules before applying for a permit.

Under today's approach, all miscellaneous units will be permitted under the general standards of Subpart X. Nevertheless, in the future, the Agency may develop specific design and operating standards for the various types of units, when there is a better understanding of the technology, process efficiency, and process safety needs.

One commenter who disagreed with the Agency, believed that the design and operating standards (or technical performance standards) for Subpart X units would be easy to implement. In contrast, another commenter agreed with the Agency's decision *not* to propose specific design and operating standards for miscellaneous units, because it would be impossible to regulate a new technology by predetermined design and operating standards that may or may not be appropriate for the individual unit in question. In addition, he further claimed that these predetermined standards could be more or less stringent than necessary to protect human health and the environment.

The majority of the commenters were concerned about the lack of specific design and operating standards for OB/OD facilities. They feared that omitting specific standards may lead to extensive delays and considerable expense in the permitting process. They were concerned that they may not be able to address completely the permit reviewers' requirements and may have difficulty obtaining a permit.

After reviewing the comments, the Agency believes that the promulgation of unit-specific design and operating standards is not necessary at this time. The generic standards, in conjunction with the permit guidance under development for OB/OD units, should provide sufficient information to develop permits without excessive delays. Moreover, the Agency is uncertain whether it possesses sufficient information to promulgate specific design and operating standards for OB/

OD units. Even if it had such information, the process of developing, proposing, and promulgating unit-specific standards for these units would cause major delays in issuing permits for these units. At some later date, the Agency may decide to develop specific design and operating standards for these units.

2. Technical Performance Standards

This regulatory approach would establish specific engineering objectives and allow the permit applicant to develop a design or set of practices to achieve these objectives.

One commenter indicated that it is difficult to define technical performance standards, since the technologies and associated "engineering objectives" will be continually refined. Another commenter suggested "establishing performance standards whereby a treatment operator would be required to demonstrate a degree of minimal acceptable variability in a treated product with respect to constituents of concern." A third commenter stated that the Agency should determine performance capabilities and establish specific levels of performance for thermal treatment devices (e.g., pyrolysis, calcination, wet-air oxidation, and microwave destruction). The Agency agrees with the first commenter mentioned above and has decided not to use this approach, because the specificity of the engineering objectives contained in technical performance standards could make permitting extremely difficult for miscellaneous units involving innovative technologies.

In response to the second commenter, the Agency agrees that certain technical performance standards could be developed to protect human health and the environment, however, a single set of these standards in all likelihood may not be suitable for all of the diverse types of miscellaneous units. Second, other than for possibly one or two technologies, the development of all technology-inclusive technical performance standards is not feasible because of (a) the lack of adequate data for setting standards and (b) the continued development of new technologies. In response to both the second and third commenters, for those units for which there possibly is sufficient information available to develop technical performance standards, these units could be excluded from the Subpart X rule. However, to do so would result in several years' delay in permitting these units while the standards are being developed, proposed, and finalized. However, in the future, specific standards may be developed for certain types of units when adequate data become available.

One commenter proposed setting waste-specific standards rather than technical performance standards. The Agency rejected this suggestion, since waste-specific standards would create the same problems as discussed for the technical standards for innovative technologies. Moreover, insufficient data are available to develop waste-specific standards. As more information becomes available, however, the Agency may consider developing such standards.

3. Containment Standards

Another approach the Agency considered was the development of performance standards requiring containment of hazardous waste within certain boundaries. While such an approach may prevent environmental contamination under some hydrogeological conditions, the Agency is concerned that it may only delay contamination in others. In addition, absolute containment in all media may not always be necessary to protect human health and the environment.

The Agency did not receive any support for this approach or any suggestions as to how this approach could be used for miscellaneous units. On a case-by-case basis, however, some permits issued under today's rule may be based on containment (for example, the containment features achieved by the design and operating standards for landfill units), such as liners and barriers or a combination of containment features and geological siting considerations.

4. Facility-Specific Risk Assessment

The Agency's evolving policy is to assess more explicitly the risks involved in its permitting and regulatory decisions. Under a facility-specific risk assessment regulatory approach, the permit applicant would be required to perform fate and transport analyses and human health and environmental risk assessments based on the RCRA goal of protecting human health and the environment. However, since the costs of risk analyses could be extremely high for miscellaneous units, and since the data available for estimating risks from Subpart X units are limited, this approach was not considered feasible as a sole regulatory approach.

Three commenters responded to this approach. They thought that facility-specific risk assessment would be expensive, time-consuming, inconclusive, and difficult to implement. In addition, they stated that there may not be enough data available to make valid risk assessments. One commenter suggested that a comprehensive risk analysis should be required only when specific standards for other permitted operations or processes (e.g., wastewater discharges, air emissions) are unavailable.

The Agency agrees that using risk assessment as the sole approach is not appropriate for many of the same reasons identified by the commenters.

Today's approach assesses the risks from various releases and the potential emissions of hazardous constituents in a general way. Based on the assessment data submitted with a permit application, specific design and operating standards to mitigate the site-specific risks could be identified and incorporated during the permitting process.

5. Environmental Performance Standards

Environmental performance standards seek to set either the numerical health and environmental standards or the nonnumerical performance requirements necessary to protect human health and the environment. These standards may take the form of numerical exposure specifications (such as the allowable concentration of a chemical at the points of human exposure), pollutant concentrations permitted to be released to the environment, or general objectives or goals to serve as a guide for protecting human health and the environment.

The Agency views environmental performance standards as the most important feature of today's rule for new and existing miscellaneous waste management units. For example, existing environmental performance standards for air and water may be utilized, as appropriate, in permitting a facility. Section 3005 of RCRA requires that standards applicable to owners and operators of treatment, storage, and disposal facilities be those "necessary to protect human health and the environment."

If this approach was selected as the sole approach, however, then it might be difficult for permit applicants of certain types of miscellaneous units to consistently demonstrate compliance with these standards. For example, with the open burning/open detonation technology, emissions monitoring is not feasible. Thus, it would be difficult to demonstrate compliance with an established performance standard. For the same reason, enforcement of these standards for certain units might be difficult. In addition, this approach was not selected as the sole approach

because the existing performance standards for air and water do not address all constituents of concern under RCRA Subtitle C.

One commenter questioned the need for special performance evaluations under Subpart X. This commenter noted that air emissions and effluent standards are now required for more conventional technologies that could be applied to most Subpart X thermal, chemical, and biological treatment units, with the exception of open burning/open detonation of explosive wastes. In addition, the commenter asserted that treatment standards for the land disposal restrictions will apply to Subpart X units and, therefore, should reduce requirements for special operating and environmental standards.

The Agency disagrees with these comments. EPA foresees the need for special performance evaluations because the existing air and water standards, when applied to certain Subpart X units, may provide inadequate protection to human health and the environment since they do not address all constituents of concern under RCRA Subtitle C. As stated earlier, the existing applicable standards and any additional requirements specific to a given unit will minimize the health and environmental risks. Environmental performance standards as a part of today's approach allow flexibility in meeting goals for the protection of human health and the environment. The flexibility offered by this approach is needed in Subpart X because of the variability of miscellaneous units.

6. Combination of Approaches

This approach combines the appropriate elements of all five previously discussed alternatives, and applies them on a case-by-case basis. Several commenters supported this approach as providing flexibility for innovative technologies. One commenter, however, stated that the units included in Subpart X were so diverse that one general rule may be difficult to apply. But the Agency believes that the diversity of existing units and the need to include potential future technologies necessitate a general rule that can be applied on a case-by-case basis.

B. Selected Appoach for Subpart X Standards

After evaluating the various alternatives, the Agency selected the proposed combination approach without modification for today's rule for miscellaneous units. This approach is based on appropriate elements of all five alternatives discussed above and will be applied to miscellaneous units on a case-by-case basis. Under this approach, miscellaneous units will be required to be located, designed, constructed, operated, maintained, and closed in a manner that will prevent any release that may have adverse effects on human health or the environment due to migration of waste constituents into the ground water or subsurface environment; surface water, wetlands, or soil surface; or air.

The Agency has decided to use Subpart X standards to regulate all units that are not currently included elsewhere under RCRA. These include, but are not limited to, (a) placement of hazardous waste in geologic repositories other than injection wells; (b) placement of hazardous wastes in deactivated missile silos, other than injection wells or tanks; (c) thermal treatment units other than incinerators, boilers, or industrial furnaces; (d) units open burning and open detonating explosive wastes; and (e) certain chemical/physical/biological treatment units. The units that are excluded from Subpart X include: (a) units currently regulated under other portions of Part 264; (b) units open burning nonexplosive hazardous wastes; (c) units excluded from permitting under Parts 264 and 270; (d) certain mobile units; (f) enclosed buildings for treatment, storage, or disposal; (e) underground injection wells (40 CFR 146); and (9) RD&D units covered under 270-65.

Units covered under today's rule will comply with standards that provide performance objectives for protection of human health and the environment. The performance objectives require permit applicants to evaluate the potential environmental impacts of the unit or facility and to demonstrate that any releases from the unit will not adversely affect human health or the environment.

For technologies where (1) a particular hazardous waste management system resembles another type of unit for which EPA has promulgated standards and (2) the permit applicant has identified the differences between the potential effects on human health and the environment posed by the two units, the use of site-specific design, operating, monitoring, and containment procedures modified to account for the differences must be developed and, therefore, will be required parts of the facility permit. Generally, these standards will be drawn from existing regulatory requirements and guidance documents, as well as permit guidance being developed for specific types of miscellaneous units. For units that do not resemble another type of unit, the applicant must still address the unit's effect on all media, and, where appropriate, specific requirements applicable to other types of units will be added to the facility permit.

In the permitting process, selected features of design and operation, technical performance, containment, and environmental performance standards, as well as the risk-based assessment, will be specified, so that the overall objective of protecting human health and the environment is achieved. Determination of the appropriate requirements will be made on a case-by-case basis and the rationale for their applicability will be provided in each permit. In certain cases, the design and operation of a Subpart X unit may resemble that of a specific type of unit now regulated under RCRA (e.g., a landfill). To the extent that they are similar, the appropriate requirements under the existing unit-specific subparts will be applied. For example, for some units, liners may be specified.

The regulatory approach finalized today by the Agency offers several advantages. First, it allows the Agency to address a full range of environmental issues raised by any waste management situation without waiting to establish specific design and operating conditions or other standards. By identifying several sets of environmental performance standards in today's rule, the Agency allows development of waste- and site-specific permits responsive to various ground-water, surface water, and air quality concerns, as well as complex natural processes in the surface and subsurface environments that may arise at each site. The Agency will also apply the authority of section 3005(c)(3) "omnibus" to other Part 264 hazardous waste management units as necessary to protect human health and the environment.

Second, for those Subpart X units requiring compliance with the standards developed for a specific medium, appropriate portions of the existing standards will be incorporated into the permit as required by today's rule. For example, in regulating air emissions from pyrolysis units, the Agency will incorporate the applicable portions of existing standards (e.g., incineration standards for meeting the air quality standards).

The Agency has concluded that it is not possible to set design and operating standards for all of the potential Subpart X units, since a variety of units will be covered by today's rule. One set of standards either will not be stringent enough or will be excessively stringent

when applied to these diversified technologies. Subpart X will cover a number of technologies for which little or no information is available; hence, the Agency's decision not to set technology-based standards. However, the site and unit-specific information submitted during the permitting process for individual units will allow the permit-issuing authority to tailor each permit to the particular risks and circumstances based on the nature of the technology, the types of wastes, the site location, and the regional meteorological, climatic, and hydrogeological characteristics. For example, in the case of innovative technologies, data collected under a RD&D permit may be submitted when risk assessment data are not available.

A comprehensive evaluation as required by today s rule will provide assurance that the permitted miscellaneous unit poses a minimal environmental threat. However, situations may arise when the Agency must deny a permit or defer a decision until additional data become available. Under certain circumstances, to obtain the additional data, a research, development, and demonstration permit might be appropriate. In cases where the permit application must be denied, the Agency will follow the procedures for the Notice of Deficiency (NOD) under 40 CFR 124.3.

The major disadvantage of the proposed approach is that the bulk of the design, construction, operation, monitoring, and closure specifications will be developed and specified through the permit process. As discussed above, the Agency will review and adopt or modify relevant requirements from Subparts I through O of Part 264, as appropriate. As more permitting or research experience and knowledge are gained, the Agency may develop guidances for specific types of facilities to aid the permit applicant and writer (e.g., the Agency is preparing guidance on open burning and open detonation of explosive wastes and on emplacement of wastes in certain massive geologic formations such as salt domes). In addition, the Agency will provide assistance to a permit applicant or writer.

1. Examples of Units Covered Under Subpart X

Because the Agency intends Subpart X to cover "miscellaneous" units, including future technologies, a definitive list of the units that will be covered under the subpart cannot be provided. However, the Agency agrees that it will be helpful to identify several types of units that may receive permits issued under Subpart X.

a. *Placement of Hazardous Waste in Geologic Repositories.* Placement of containerized hazardous waste or bulk non-liquid hazardous waste in geologic repositories such as underground salt formations, mines, or caves, either for the purpose of disposal or long-term retrievable storage, is included under Subpart X. Clarification of units that are regulated under the RCRA permit-by-rule for injection wells with Underground Injection Control permits is included in III B.2.(e) of the preamble.

Restrictions on land disposal of hazardous waste imposed by sections 3004(d) through (m) of RCRA apply to these units. These standards dictate that restricted hazardous wastes cannot be disposed of on land beyond specified dates, unless they are treated in compliance with Agency-established treatment standards or unless EPA grants a variance that demonstrates that there will be no migration out of the unit for as long as the wastes remain hazardous.

b. *Placement of Hazardous Waste in Deactivated Missile Silos.* Treatment, storage, and disposal of hazardous waste in deactivated missile silos that are not underground injection wells or are not covered under Part 264 standards will be covered under Subpart X. However, to the extent that the deactivated missile silo meets the regulatory definition of an injection well or tank it would be regulated under 40 CFR Part 146 or Part 264, respectively. Clarification as to units that are regulated under the RCRA permit by-rule for injection wells with Underground Injection Control permits is included in III B.2.(e) of the preamble.

c. *Thermal Treatment Units Other Than Incinerators.* A number of different types of thermal treatment units, including combustion and noncombustion types, are in operation today and have potential application to hazardous waste treatment. Combustion and noncombustion units such as molten salt pyrolysis, calcination, wet-air oxidation, and microwave destruction, which are not covered under Part 264 Subpart O regulations will be covered under Subpart X. Many of these units have not yet operated on a commercial scale, but owners of some of these units are expected to seek RCRA hazardous waste facility permits for commercial operation in the future.

d. *Open Burning/Open Detonation of Explosive Wastes.* These units (as defined in § 265.382) are neither typical thermal treatment units nor incinerators. The Agency promulgated interim status standards applicable to open burning and open detonation units in Subpart P of Part 265 (§ 265.382 on May 19, 1980 (45 *FR* 33251)). These standards require (1) that units be operated in a manner that does not threaten human health and the environment and (2) that a minimum safe distance from other properties be maintained when waste explosives are disposed of by open burning or open detonation. Permitting of hazardous waste management units for open burning or open detonation of waste explosives is covered in the Subpart X rule. When upgrading existing units or permitting new units, the applicable portions of Part 265 Subpart P standards (e.g., minimum safe distances) will be incorporated during issuance of Subpart X permits. Because OB/OD is a treatment process, it is not subject to the land disposal restrictions imposed by sections 3004 (d) through (m) of RCRA.

e. *Certain Chemical, Physical, and Biological Treatment Units.* Hazardous waste management units that treat hazardous waste by chemical, physical, or biological methods in units other than tanks, surface impoundments, and land treatment units during interim status are covered under Subpart Q of Part 265 The Subpart X regulations of Part 264 and the applicable portion of Subpart Q of Part 265 will be considered in permitting these units. Under the land disposal restrictions, no *in-situ* hazardous waste treatment on land will be permitted (without the *prior* use of a best demonstrated available technology (BDAT) for treatment). Therefore, none of the *in-situ* treatment methods will be Subpart X units/technologies.

2. Examples of Units Not Covered or Units for Which Subpart X Permits Will Not Be Issued

a. *Treatment, Storage, and Disposal in Units Currently Regulated Under Part 264.* Under today's rule, treatment, storage, or disposal in units now regulated under Part 264 may be permitted only under the applicable subparts of Part 264. For example, placement of hazardous waste in a tank or surface impoundment for treatment is covered under Subpart J or Subpart K, respectively, and disposal of hazardous waste in a tank is covered under Subpart N, and must be permitted using those standards.

b. *Open Burning of Nonexplosive Hazardous Waste.* Although by its terms Subpart X applies to all units not covered under Part 264, including open burning and open detonation of nonexplosive hazardous waste, the Agency has concluded that open burning of such non-explosive waste cannot be

conducted in a manner that is protective of human health and the environment. The Agency made this finding in 1980 in promulgating the general ban on open burning of nonexplosive hazardous waste (40 CFR 265.382) and has no new information to suggest this conclusion should be revised. The Agency, therefore, intends to deny any permit applications it receives under Subpart X for such activities.

c. *Units Excluded From Permitting Under Parts 264 and 270.* Certain units are specifically excluded from permitting under the Part 264 and Part 270 standards. For example, publicly owned treatment works and ocean disposal activities are not permitted under Part 264 standards, since they are covered by permits-by-rule (see 40 CFR 264.1 (c) and (e)). Another example is operation of a wastewater treatment unit (40 CFR 264.1(g)(6)). These units continue to be excluded from Part 264 standards and would not be subject to Subpart X.

d. *Mobile Units.* Mobile waste management units are becoming available and may be used for treatment of hazardous wastes as part of a general waste treatment strategy or on a short-term basis to destroy specific wastes for remedial site cleanup, spill control, and other types of emergency responses. These units are presently regulated under 40 CFR 264 and 270, and certain changes to the permit requirements have been proposed and are currently being evaluated by the Agency. These units may also be involved in research, development, and demonstration activities and, as such, may be covered by a research, development, and demonstration permit.

Mobile units using technologies that are covered under other subparts of Part 264, such as incineration or treatment in containers, are excluded from Subpart X. However, those units included in Section IIIB.1., which are mobile, are covered under today's rule.

e. *Placement of Hazardous Waste Underground That Is Currently Regulated Under Part 146.* RCRA Subpart X permitting will not apply where EPA has an existing permit program which addresses the particular hazardous waste management practice. It is thus necessary to outline those waste management practices currently covered by the underground injection control (UIC) program. Hazardous waste injection is regulated under the authorities and mandates of both the Safe Drinking Water Act (SDWA) and RCRA. Wells must have authorization under both acts to operate. Authorization-by-rule under 40 CFR 144.21 or a UIC permit under 40 CFR 144 Subpart D provides the SDWA authorization for hazardous waste wells. Interim status under 40 CFR 265.430 or a RCRA permit-by-rule under 40 CFR 270.60(b) provides the RCRA authorization. This permit system is in place for the injection in bulk form of liquids, slurries, and sludges. Technical standards for these practices are in 40 CFR Part 146.

These current technical standards, however, do not fully address some potential disposal or storage practices that may fall under EPA's regulatory definition of well injection. EPA defines "well injection" in 40 CFR 144.3 and 146.3 as the "subsurface emplacement of fluids through a bored, drilled or driven well; or through a dug well, where the depth is greater than the largest surface dimension." EPA defines "fluids" in 40 CFR 144.3 and 146.3 as "material or substance which flows or moves whether in a semisolid, liquid, sludge, gas or any other form or state."

A broad reading of these definitions might suggest that granular hazardous waste poured into a salt dome, for example, would be within the scope of the UIC program. The very recent opinion in *NRDC v. EPA*, Cons. Cases No. 85–1915 and 86–1096 (1st Cir., July 17, 1987) contains language suggesting extremely broad interpretations of the scope of the UIC program. This opinion remands regulations for the disposal of high level radioactive waste, spent nuclear fuel, and transuranic wastes at 40 CFR Part 191 which were promulgated under the mandates of the Nuclear Waste Policy Act of 1982 (NWPA) and the authority of the Atomic Energy Act of 1954. Some of the legal analysis, however, concerns interpretations of "well injection" and "fluids" under the SDWA. The opinion suggests that containers or solids lowered down a shaft would be "well injection" of "fluids" if contaminants in this material might ultimately "flow" or move into the accessible environment (Slip-Opinion at page 29). The court was particularly concerned that EPA had not evaluated the relationship of the SDWA and NWPA.

We are currently evaluating the legal analysis in this opinion and will address the specific issues of these definitions at a later date. However, EPA believes that it can address the issue of RCRA Subpart X and UIC permitting at this time for the range of long-term retrievable storage and disposal practices. Part 146 technical standards do not currently address practices other than the injection of noncontainerized liquids, slurries, and sludges. Other management practices, such as the placement of containerized wastes or solids, would require standards on a case-by-case basis. EPA intends the environmental objective for these latter practices to be the same, such as will meet the requirements of the SDWA and RCRA, whether a particular practice is termed to be "underground injection" or not. Specifically, in the context of this regulation, the Agency intends to apply the mandate of the SDWA to prevent the endangerment of underground sources of drinking water, as is consistent with RCRA's mandate to protect human health and the environment.

This final rule provides that the Director apply standards for these miscellaneous management practices through the RCRA Subpart X permit. RCRA permit procedures provide at least as much public participation as the UIC permit procedures and are thus, a fully appropriate vehicle to impose standards whether solely under the authority of RCRA or under the combined authority of RCRA and the SDWA (See 40 CFR Part 124). The final rule, therefore, contains amendments to 40 CFR Part 144.31 which requires that a Subpart X permit will constitute a UIC permit for hazardous waste well injection for which current Part 146 technical standards are not generally appropriate. In promulgating this amendment to § 144.31, we are not specifying that these miscellaneous management practices constitute underground injection, but rather, to the extent any of these practices may be determined to be underground injection § 144.21 will authorize a facility under the SDWA if the unit has a RCRA Subpart X permit.

The above permitting scheme does not, in and of itself, remove the restrictions on the placement of noncontainerized or bulk liquid hazardous waste in any salt dome formation, salt bed formation, underground mine, or cave under section 3004(b)(1). That provision requires the Administrator to find, after notice and opportunity for hearings on the record in the affected areas, that such placement is protective of human health and the environment to remove the prohibition. "Fluids" under the UIC program are "liquids" under § 3004(b) when they do not pass the Paint Filter Liquids Test contained in Method 9095 of the "Test Method for Evaluating Solid Wastes, Physical/Chemical Methods" [EPA Publication No. SW–8461].

f. *Enclosed Buildings Used for Treatment, Storage, or Disposal.* The Agency is considering under separate action the appropriate mechanism to permit activities in enclosed buildings.

While this does not rule out the possibility that these units could be permitted under Subpart X, no decision has been made at this time.

g. *Research, Development, and Demonstration (RD&D) Units Covered Under § 270.65.* The purpose of an RD&D permit is to allow for testing and demonstration of innovative and experimental technologies, including the modification of existing technologies. If a unit meets the requirements of an RD&D permit under § 270.65, then that unit will not be eligible for a Subpart X permit.

IV. Amendments to Part 260: Definitions

After evaluating the public comments and current definitions of Part 260, the Agency has added a new definition for "miscellaneous unit," and has amended the "landfill" definition.

A. Miscellaneous Unit

Today the Agency defines the term "miscellaneous unit" to refer to hazardous waste management units used to treat, store, or dispose of hazardous wastes that do not fit the current definition of container, tank, surface impoundment, pile, land treatment unit, landfill, incinerator, boiler, industrial furnace, underground injection well with appropriate technical standards under 40 CFR Part 146, or unit eligible for an RD&D permit under § 270.65.

None of the commenters suggested specific definitions for "miscellaneous unit." They did, however, address several units or processes that they believe should or should not be included as miscellaneous units. One commenter stated that the definition of "miscellaneous unit" is too broad and that the Subpart X standards along with this definition may further encumber the already overburdened RCRA permitting process. On the other hand, another commenter indicated that the definition of "miscellaneous unit" is adequate, provided the existing expansive definition of "landfill" is appropriately limited.

Two commenters requested clarification. One suggested that enclosed buildings should not be considered waste piles or tanks and, therefore, should be considered miscellaneous units. The other stated that clarification is necessary to avoid possible confusion between open burning/open detonation units and waste piles and other types of units.

An additional commenter suggested that "open burning," as defined in 40 CFR 260.10, does not accurately define the nature of the reaction that occurs at facilities treating explosive wastes. Another commenter proposed that the definition of "open burning" be amended to include "detonation" and "deflagration." A few commenters suggested that the Agency define the types of wastes that can be burned or detonated in open burning/open detonation units.

In general, it appears that some of the commenters believe that a clear definition and understanding of "miscellaneous unit" is essential to meet applicable permitting requirements under Subpart X without undue delays. Second, commenters requested a definitive list of units, processes, or technologies that can be considered "miscellaneous units" under Subpart X in order to minimize any confusion in the permitting process that may result from this regulation.

Through both the definition and the discussion in this preamble, the Agency has made it clear what is meant by a "miscellaneous activity" and what units can be eligible candidates for Subpart X permits. The Agency concluded that by making the definition of "miscellaneous unit" broad, it allows the owner or operator and the regulatory authority to incorporate all types of units not previously covered under Part 264. In the preamble, we have attempted to further clarify the types of units that are covered and not covered under Subpart X by giving various examples under each category. However, an all-inclusive list of units covered by Subpart X is not provided. To do so would require amending the regulation each time a new process is developed. This would greatly delay the permitting of such units.

B. Landfill

Today's rule defines "miscellaneous unit" as a catchall category. Previous to today's change, landfills as defined in 40 CFR 260.10 covered certain units that did not fit within the definition of other land disposal units. Under that provision, "landfill" meant "a disposal facility or part of a facility where hazardous waste is placed in or on land and which is not a land treatment facility, a surface impoundment, or an injection well." Therefore, "landfill" was a catchall category for all disposal facilities that did not meet the definition of a land treatment facility, a surface impoundment, or an injection well. The use of the term "miscellaneous unit" as the catchall category requires redefining "landfill" so as to limit it to a discrete category of specific units covered under Subpart N of Part 264. Therefore, in the Subpart X proposal, the Agency requested comments on how to clarify the landfill definition such that it no longer constituted a catchall category.

After considering all of the comments received on this issue, the Agency has decided to define the term "landfill" similar to the definition in § 260.10 with a few minor modifications. Under today's rule, the Agency has defined the term "landfill" to mean a disposal facility or part of a facility where hazardous waste is placed on or in land and which is not a land treatment facility, a surface impoundment, an injection well, a pile, a salt dome formation, a salt bed formation, a cave, or a mine.

In the proposed rule, the Agency requested comments specific to the redefinition of "landfill". After a careful review of all the comments, the Agency decided not to significantly change the previous "landfill" definition but rather to clarify those units that are classified as "landfill" facilities.

A significant number of comments were received on the proposal to revise the existing "landfill" definition. The majority of these comments addressed the adequacy of the proposed goal to identify more precisely the types of waste management practices included within this category. The Agency has accomplished this goal by listing additional practices that are either included in or excluded from the definition.

A "disposal facility", as defined in § 260.10, means a facility used for intentional placement, where waste will remain after closure. This distinguishes storage and treatment in tanks from disposal facilities. However, it also allows the placement of wastes in tanks and vaults used for disposal provided the unit meets the landfill standards.

The new "landfill" definition provides that piles are not landfills. When "landfill" was defined in 1980, it was clearly the intent of the Agency to exclude piles. By amending our landfill definition to reflect this fact, we are simply clarifying the scope of the definition.

In the 1984 Hazardous and Solid Waste Amendments (HSWA) to the Solid Waste Disposal Act, Congress recognized salt dome formations, salt bed formations, caves, and mines as separate types of hazardous waste facilities or units and in section 3004(b) directed the Agency to develop standards for these units. If these units were already covered by the landfill standards, this would be unnecessary. Similarly, under section 3004(k) of HSWA, the types of units covered by the land ban are separately listed as landfills, salt dome formations, salt bed

formations, underground mines, caves, etc. Clearly, Congress did not intend that these units be covered by the term "landfill."

"Landfill" will cover tanks or vaults used for disposal of hazardous waste. Subpart J of Part 264 only regulates storage and treatment in tanks and the Agency to date has not developed specific standards for disposal of hazardous waste in tanks. However, under limited circumstances, the Subpart J standards do allow treatment or storage tanks that cannot remove all contamination at closure to close and to perform post-closure care in accordance with the closure and post-closure requirements for landfills. Disposal in tanks will be regulated under the Subpart N standards as a landfill because "landfills" and the disposal of hazardous waste in tanks raises similar human health and environmental concerns and because tanks are similarly placed on or in the land. This does not result in a change in the way tanks used for disposal are regulated, since previous to today's rule the landfill category constituted a catchall category for disposal units not regulated elsewhere.

By changing the "landfill" definition, the Agency has not changed the status of those facilities that were previously considered to be "landfills". Rather, the change has clarified the previously described scope of the definition. Consequently, this change has not reduced the scope of facilities covered under either the land ban provisions of section 3004(d) of HSWA or the minimum technology requirements of section 3004(o) of HSWA.

V. Amendments to Part 264: Subpart X Regulation for Miscellaneous Units

The regulations promulgated today under 40 CFR Part 264 apply to miscellaneous waste management units that are used to treat, store, or dispose of hazardous waste. Conforming changes to accommodate the addition of Subpart X are provided for in Part 264, Subparts B, E, F, G, and H. These changes merely serve to make the general requirements of Part 264 applicable to miscellaneous units.

The Agency intends the general facility requirements of Part 264, Subparts A through E, G, and H, to apply to miscellaneous units. In addition, although the Agency made an oversight in the proposed rule, under today's final rule the corrective action requirements of section 3004(u) that were codified at 40 CFR 264.101 automatically apply to miscellaneous units. The Subpart F ground-water protection requirements will apply somewhat differently to miscellaneous units compared to the conventional types of units. For miscellaneous units, Subpart F requirements under § 264.101 for corrective action will always apply. However, the requirements under § 264.91 through 264.100 for monitoring and response action programs apply only to those units that have a potential for contamination of ground water. These standards will apply on a case-by-case basis through the new § 264.602, which is explained below.

It should be noted that the term "Director" has been substituted for "Regional Administrator." "Director" means the Regional Administrator or the State Director in an authorized State, as the context requires. This change conforms to the terminology selected for use in other recent amendments to the hazardous waste management regulations.

The promulgated standards for miscellaneous units are discussed below, section by section.

A. Section 264.600—Applicability

This section limits the applicability of the regulations of Subpart X to owners and operators of miscellaneous hazardous waste management units. By using the term "miscellaneous," this section incorporates the definition of "miscellaneous unit" from § 260.10.

B. Section 264.601—Environmental Performance Standards

The most important features of the regulations for new and existing miscellaneous waste management units are the environmental performance standards set forth in § 264.601. Section 3004 of RCRA requires that standards applicable to owners and operators of treatment, storage, and disposal facilities be those "necessary to protect human health and the environment." In § 264.601, the Agency has translated this overall goal into a set of objectives that provide a guide for owners and operators of miscellaneous units and for permit writers. Those objectives are to protect ground water, surface water (including wetlands), air quality, and soil, which are the principal pathways for migration of hazardous constituents to receptors. While each of these objectives must be addressed in the permit, a permit may not need to specify conditions that protect each of these environmental media.

Most of the commenters suggested that the environmental performance standards, if made unit-specific, would aid in protecting human health and the environment from releases of contaminants. Other commenters objected to the requirement for detailed ground-water, surface water, and air quality assessments, especially for facilities using technologies where it is unlikely that the waste or its constituents would come in contact with water, soil, or air media. As stated in the preceding paragraph, an assessment must be conducted for each medium, however, if the assessment shows that there will be no impact on a given medium; the permit need not specify conditions to protect that medium.

Another commenter said that these standards are geared to toxic wastes. The commenter further indicated that, in the case of explosive wastes, there will be a poor fit between these regulatory requirements and a particular unit. The commenter stated that ground-water migration is unlikely during open burning of explosive wastes. The performance standards require that an assessment be conducted for each of the media. If the assessment shows that, in this case, ground water will not be impacted, then the permit need not specify conditions to protect the ground water.

The Agency, however, does not feel that it is appropriate to promulgate specific environmental performance standards at this time. Given that miscellaneous units will be regulated by issuing individual permits that are unit- and site-specific, human health and the environment can be protected without being overly stringent in some cases and/or too lenient in others. It is expected that the unit-specific environmental performance standards defined in Subparts I through O will provide baseline, acceptable protection and, at the same time, will allow flexibility in issuing case-by-case variation during the permitting under the Subpart X regulation. In addition, the Agency is developing unit-specific guidance for certain units and may, in the future, provide additional technology-specific guidance, if necessary.

The Agency does not view § 264.601 as a set of specifications that will directly apply to all owners and operators of miscellaneous units. Rather, § 264.601 provides a general set of objectives that will guide the permit applicant (owner or operator), the Agency, and the public in evaluating the acceptability of each unit and the adequacy of the unit design and operation to mitigate risk. The permit applicant is expected to propose the specifications for location, design, construction, operation, monitoring, maintenance, closure, and, where appropriate, post-closure care based on

supporting data and information on the specific unit.

Detailed analysis of each factor in § 264.601 may not be necessary in a permit application, depending on its relevance to the type of unit under consideration and the associated health and environmental risks. For example, certain completely enclosed biological, physical, or chemical treatment units may not require permit conditions imposing monitoring requirements for air or ground water. On the other hand, specific thermal treatment units covered under this subpart may require extensive air monitoring. All of the factors identified in § 264.601, however, should be considered and their relevance should be addressed in the application.

Based on the information about the environmental impacts, specific conditions beyond those suggested by the applicant may be included by the Agency in the permit. Once issued, the permit governs where a unit is to be located and how it is to be designed, constructed, operated, monitored, maintained, and closed.

Few comments were received on each environmental medium—e.g., ground-water migration, surface water and soils, and air. The majority of commenters elaborated on their concerns related to the hazard assessment and the need for controls under the broad category of environmental performance standards. The commenters indicated that they favored development of Subpart X permitting standards because they provide flexibility for developing unit- and/or site-specific assessments of contamination of specific media in the permitting process.

The Agency below discusses what factors should be considered by applicants and permit writers in assessing the potential for adverse effects on each medium. These factors include the type of waste managed, the types of technologies, the types and quantities of emissions or releases, and the extent of migration or dispersion of the waste in various media. The permit applicant must submit information on these assessments, which must be included in the permit in order to be considered as a complete permit application. These assessments must be in sufficient detail to support the applicant's position in demonstrating minimal impact and/or minimizing adverse impacts on each medium.

1. Ground-Water and Subsurface Migration

Section 264.601(a) lists several factors to be considered to prevent any release that may have adverse effects on human health or the environment due to migration of waste constituents in the ground water or subsurface environment. These factors must be addressed to prevent ground-water contamination and the subsurface migration of hazardous waste from miscellaneous units (e.g., geologic repositories and hazardous waste management units that are placed in or on land).

The first factor includes the volume, concentration, and physical and chemical characteristics of the waste placed in the unit. The volume and concentration determine the maximum amount and concentration of waste that may enter the ground water. Physical and chemical characteristics determine (1) the toxicity of the waste; (2) the ability of the waste to be contained, immobilized, degraded, or attenuated or to migrate in various soils and materials; and (3) the probability of undesirable reactions taking place among wastes or between wastes and liners or other containment structures.

The second, third, and fourth factors are the hydrogeologic characteristics of the site and surrounding land, the existing ground-water quality, and the quantity and direction of ground-water flow, respectively. Because these three factors affect the movement of waste constituents in the subsurface environment, they are crucial in assessing the impact on human health and the environment. The hydrogeologic characteristics of the site determine the effect of human activities in the area on the ground water. The third factor focuses on the existing ground-water quality and sources of contamination other than the miscellaneous unit. This factor is relevant for predicting future ground-water uses and the incremental risk of the new unit. The fourth factor assesses the rate and direction of migration and the potential contamination of the site.

The fifth factor is the proximity to and withdrawal rates of current and potential ground-water users. While ground water as a source of drinking water is a primary concern, agricultural and industrial uses of ground water should also be considered. Clearly, water that is contaminated by hazardous waste leachate may present health risks. Information on State ground-water planning and regulatory efforts should also be considered. Also, any changes in ground-water withdrawal rates or patterns can alter the rate of ground-water movement, which influences the rate and direction of migration of contaminants to exposure points. This information is not only necessary to identify potential impacts to the ground water, but it also can be used in determining monitoring well locations, where necessary.

The sixth factor focuses on land-use patterns. Land-use patterns can change hydrogeologic characteristics and they in turn can alter the rate and direction of potential migration to and distribution of wastes in ground water. This information will be used to identify potential impacts to the ground water.

The seventh factor is movement of waste constituents in the subsurface. This includes migration of waste in gaseous or vapor forms. Subsurface migration of wastes is a type of environmental degradation apart from contamination of ground water. The Love Canal incident provides a classic example of unsaturated zone migration. There, waste constituents migrated from a landfill into the basements of nearby homes. The residents were directly exposed through physical contact with waste and inhalation of volatile contaminants. The potential adverse effects of subsurface migration of waste constituents must be considered in addition to any direct effects on surface water and ground water. The same factors that influence ground-water protection are significant when considering subsurface migration.

Both the saturated and unsaturated zones must be considered in evaluating the potential for subsurface migration. This requires knowledge of the characteristics of the waste in the unit and the hydrogeology of the surrounding area. The patterns of land use in the area, including proximity to residential buildings, are particularly important here.

Also considered in factor seven is the migration of wastes to the soil root zone of food-chain crops and other vegetation. Phytotoxicity may occur as a result, as in the case of heavy metals at high concentrations. Even more important, roots may absorb certain hazardous constituents, which the plant may uptake and pass into the human food chain.

The eighth and ninth factors are the potential adverse impacts that exposure to waste constituents can have on human health and on animal health, plants, and physical structures, respectively. This potential depends on many factors, including the concentration, quantity, toxicity, and transport of the waste constituents.

One commenter agreed that the factors listed in § 264.601 for ground water were necessary to evaluate the adequacy of protection provided by a particular unit. Another commenter

suggested that the rule is unclear on how the need for ground-water monitoring will be evaluated. One other commenter questioned why all units must provide data on hydrogeologic characteristics, land-use patterns, ground-water quality, associated human health effects, and animal and crop exposure assessments. This commenter further suggested that data requirements be tailored to the specific type of unit. Another commenter pointed out that it is not necessary to perform a detailed ground-water and surface water assessment for a facility managing or treating a waste that never comes in contact with the surface of the ground. For example, some open detonation facilities have a synthetically lined detonation range.

In response to the above concerns, the Agency does not necessarily require that all miscellaneous units provide a detailed assessment for each of the nine factors. The standard in § 270.23(b) requires that the factors be considered and evaluated, and assessment data must be presented in the permit application. If the permit applicant's preliminary assessment of these factors indicates that the facility will not impact the factor, and the preliminary assessment of that factor is convincing to the Director, then a detailed assessment is not needed. However, a detailed assessment and associated permit conditions must be developed for those factors found by the preliminary assessment to have the potential for ground-water contamination and migration. The preliminary and detailed assessment procedures are not envisioned as a two-tiered permit process. The preliminary assessment is a tool used by an applicant to avoid the need to conduct a detailed assessment, if the preliminary assessment shows that a detailed assessment is not necessary. The adequacy and findings of the assessments will be considered by the Director as part of the permit review process.

2. Surface Water (Including Wetlands) and Surface Soils

Improper disposal of hazardous wastes can have immediate, far-reaching, and long-term effects on human health or the environment due to migration of waste constituents in surface water or wetlands or on surface soils. Units for which factors related to surface water, wetlands, and surface soils may require particular emphasis are those that are situated on land and are used in an open or semi-enclosed manner. It is, therefore, essential to ensure that these structures are designed and constructed to prevent surface water, wetlands, and surface soil contamination.

Many of the same factors that influence ground-water protection and minimize risk from subsurface migration of waste constituents are significant for the protection of surface water, wetlands, and surface soils. Therefore, the sections listed in § 264.601(b) are similar to those in § 264.601(a).

The first factor to be evaluated is the volume of the waste in the unit and the waste's physical and chemical characteristics. This factor determines the potential for contamination of surface water, wetlands, and surface soils.

The effectiveness of containment structures should be considered in the second factor because surface waters, wetlands, and surface soils may be contaminated by ground-water migration and by overland flow of waste constituents. Precipitation, run-on, and runoff controls and subsurface structures should be considered, including liners, dikes, diversion ditches, and cut-off walls.

The third, fourth, fifth, and sixth factors require considerations of the hydrogeology and climate of the area. These factors evaluate the area's topography, rainfall patterns, characteristics of ground-water flow, and the proximity of a unit to surface waters. These factors determine the distribution and degree of surface water, wetlands, and surface soil contamination.

The seventh, eighth, and ninth factors evaluate patterns of surface water and land use, existing surface water, wetlands, and surface soil quality, other sources of contamination, and water quality standards. This information is needed to provide insight into the likelihood of health or environmental impacts. Water quality standards provide numerical and narrative criteria tied to particular uses of water bodies. These criteria should guide the Agency, permit applicants, and the public in evaluating the acceptability of managing waste in a particular unit.

In the tenth and eleventh factors, the impacts of waste constituents entering surface waters on human health and on animals, plants, and physical structures must also be analyzed.

One commenter suggested that surface soil for the active portion of open burning/open detonation facilities, as well as soil samples from the primary downwind areas, be monitored and that the monitoring schedule be based on the volume of waste destroyed. The Agency has concluded that establishment of monitoring schedules is more appropriately defined in the permitting process than in the standards. However, because open burning/open detonation of explosive waste is carried out in pits, trenches, or on the ground surface, or in areas exposed to precipitation, the Agency agrees that it is vital that the factors in this section be adequately addressed so that run-on and runoff are controlled and residual wastes are effectively contained within a well-defined open burning/open detonation area.

3. Air

Some waste management units may present a significant potential for adverse effects on air quality. Section 264.601(c) requires the prevention of any release that may have adverse effects on human health or the environment due to migration of waste constituents in the air, and lists various factors that may be considered in protecting air quality.

The first factor considers the volume and characteristics of the waste in the unit and its potential to react or evaporate to form gaseous, aerosol, or particulate products that enter the atmosphere.

The second factor considers the effectiveness of systems and structures to prevent gaseous, aerosol, or particulate emissions.

The third factor considers the operating parameters of the units that make air emissions likely and create a potential for the production of toxic or explosive gases, aerosols, or particulates.

The fourth and fifth factors take into account the atmospheric, meteorologic, and topographic conditions of the site location, the existing air quality, and the sources of contamination near the site.

The sixth and seventh factors assess the potential adverse impacts on human health and on plants, animals, and physical structures. Of special concern is the inhalation of hazardous constituents by humans exposed to air emissions from these units.

Units for which these air standards have particular importance include open burning/open detonation units and thermal treatment units, such as calcination, pyrolysis, and multi-hearth furnaces. In most cases, air emissions from open burning/open detonation cannot be controlled since it is impossible to operate these units under totally enclosed conditions. Because of this, it is essential that open burning/open detonation (OB/OD) permit applicants consider the volumes and characteristics of the waste, as well as the meteorologic and topographic conditions of the site location. However,

one commenter suggested an alternative technology for controlling air emissions from open burning (not detonation) of explosive wastes. This technology effectively reduces emissions by using an air scrubber. It may, therefore, be an attractive option for some facilities that open burn explosive wastes. In addition, units that thermally treat hazardous wastes can release hazardous air emissions. While permits for these thermal treatment units may incorporate most of the incinerator performance standards under Part 264, these standards may not be sufficient or applicable for Subpart X units; therefore, these units must provide the assessment of air quality factors.

One commenter observed that just as a surface facility must consider and guard against accidental contamination of waters or soils, it must also consider the possibility of contaminated air or gas emissions. Therefore, this commenter suggested that the seven factors included in § 264.601(c) be fully considered. In contrast, commenters expressed concern over the use of the word "any" release, viewing it as too restrictive and not warranted for general applicability to all units. Three commenters noted that air emissions resulting from OB/OD cannot be controlled and, therefore, this technology should be exempt from the requirements of § 264.601(c).

By using the word "any," the Agency does not necessarily mean "no" releases. When a potential exists for a release (e.g., during OB/OD, where air emissions are difficult to control), an assessment must be made of all the factors important in protecting air quality.

There was also concern that if the unit is subject to evaluation and to permitting requirements for stationary sources under the Clean Air Act or under State and local air pollution control standards, such standards should be implemented by these authorities, as they are beyond the Agency's authority under RCRA in those jurisdictions. The Agency does not agree that its RCRA authority does not apply to air emissions. Section 3004(n) clearly requires EPA to control air emissions from hazardous waste facilities. EPA will attempt to minimize any duplication of control by incorporating applicable standards from the Clean Air Act into the RCRA permit. A permit may also include additional necessary conditions imposed under RCRA authorities. For example, current standards under the Clean Air Act may not address all types of hazardous air emissions at treatment, storage, and disposal facilities.

One commenter also objected to the use of "hazardous constituent" in § 264.601. He preferred "hazardous constituent of the waste." The Agency did not change the wording "hazardous constituent" because if the unit is only monitored for hazardous constituents of the waste, then hazardous constituents of possible reaction products will go undetected.

Another commenter suggested that since most State air pollution control regulations prohibit open burning but provide an exemption for explosive waste, the RCRA permitting of open burning should be limited to those exemptions or waivers. The Agency agrees with this commenter and has restricted permitting of OB/OD to explosive wastes.

One commenter indicated that a study is being completed to identify and characterize emissions generated at military OB/OD facilities. This commenter suggested that the Agency consider the data, conclusions, and recommendations from this study in determining the type of monitoring requirements for OB/OD disposal activities. The Agency intends to use this information in developing a permit guidance document on OB/OD.

C. Section 264.602—Monitoring, Analysis, Inspection, Response, Reporting, and Corrective Action

Under § 264.602, each miscellaneous waste management unit must have a monitoring program that includes, where appropriate, a ground-water, surface water, soils, and air quality monitoring system. (Alternatives to ambient air monitoring and analysis may include analysis of waste, emissions measurements, and periodic monitoring with portable detectors.) A monitoring program must include procedures for sampling, analysis, and evaluation of data, suitable response procedures, and a regular inspection schedule. This requirement is intended to ensure that the permit specifies all monitoring, inspection, and response activities and the frequency with which these activities are to be conducted. Including these specifications in the permit will require monitoring by the owner or operator to prevent violation of permit requirements and to prevent damage. It will also enable the oversight agency, through inspections and enforcement, to assess whether the unit is in compliance with the permit and, therefore, with the requirements of § 264.601.

Since each miscellaneous unit covered by this section may be distinctive in its design, operation, and location, the Agency is leaving the specifications as well as the extent of the monitoring, inspection, and response program to the evaluation of the permitting official. At a minimum, the monitoring program for a miscellaneous unit should be capable of determining the unit's impacts on ground water in the uppermost aquifer, surface water, air quality, and the extent of surface and subsurface contaminant migration, to ensure compliance with § 264.601.

The program should consider the following: (1) The depth and location of monitoring wells or other sampling devices necessary to obtain representative samples of constituents in various media; (2) the constituents to be monitored and the frequency of monitoring; (3) procedures to maintain the integrity of monitoring devices; (4) sample collection and preservation procedures; (5) analytical methods used for sampling and analysis; (6) applicable procedures for the evaluation of data from the monitoring program; and (7) appropriate response procedures for cases where the monitoring program indicates that the unit is not in compliance with § 264.601.

The monitoring, inspection, and response program under a Subpart X permit will include requirements linking inspections and monitoring of the unit to the appropriate response. The Agency will incorporate the Part 264 Subpart F standards for ground-water monitoring, protection, and corrective action for establishing a ground-water monitoring program at appropriate Subpart X units.

The owner or operator of each miscellaneous waste management unit covered by this section must comply with the biennial reporting requirements specified under § 264.75. These requirements are the same as those in effect for all hazardous waste treatment, storage, and disposal facilities that are specifically regulated under Part 264.

Under RCRA authority contained in sections 3004 (u) and (v), the Agency is developing standards for corrective action at facilities seeking a RCRA permit. EPA has already codified the general obligation to perform corrective action for release from Solid Waste Management Units (SWMUs) at hazardous waste facilities (see 40 CFR 264.101). In the interim, EPA will make a decision on appropriate corrective actions for SWMUs on a case-by-case basis in individual permit proceedings. These standards, scheduled to be proposed in late 1987, will be applicable to hazardous waste management units including Subpart X units to the extent that they can be applied without resulting in highly hazardous situations or adverse cross-media contamination and are technically feasible. Until these

new standards are finalized, the corrective action requirements in § 264.101 apply to Subpart X.

One commenter suggested that the regulations relating to ground-water and surface water monitoring are necessary but should be clarified. The commenter further noted that for some operations (e.g., OB/OD) only some of the factors need to be addressed. Additionally, this commenter suggested that the scope of the requirements should be clarified when a more extensive analysis is indicated. In this commenter's opinion, the requirement in § 270.23(b) is overly broad and the information necessary for detailed assessments often will not be available. Thus, these assessments may be prohibitively expensive if the requirement is broadly interpreted. Another commenter was concerned that the Agency is leaving the specifications, as well as the extent of the monitoring, inspection, and response requirements, to the evaluation of the permitting official.

The Agency agrees to some extent with these commenters. If the Agency provides a comprehensive list of permit requirements, it will be easier for both permit applicants and permit writers in addressing the informational requirements. However, because of the diversity of the types of miscellaneous units, it is impossible to identify specific information requirements for individual units. Where applicable, the Agency prefers that a permit applicant provide (a) detailed plans and engineering reports; (b) hydrologic, geologic, atmospheric, and meteorologic assessments; (c) information on the potential pathways of exposure of humans or environmental receptors and the extent of exposure; and (d) closure and post-closure procedures. In addition, because the nature of each unit can vary a great deal, any steps taken to meet the requirements of the Subpart X environmental performance standards must also be furnished.

One commenter was concerned that the Subpart F standards for ground-water monitoring are not mandated, carte blanche, but are used where appropriate. He noted that in some sections it is clearly stated that miscellaneous units need not comply with Subpart F requirements, and that conversely, in other sections of the rules, the Agency implies that the permit applicant must comply with Subpart F where ground-water monitoring is deemed necessary. This commenter suggested that these inconsistencies should be clarified to require permit applicants to establish a ground-water monitoring program where it is necessary to protect human health and the environment. The Agency agrees and requires compliance with Subpart F ground-water monitoring requirements on a case-by-case determination when necessary to protect human health and the environment.

The monitoring, analysis, inspection, response, and reporting requirements described in this rule are designed to be generic with the establishment of unit-specific requirements during the permitting process. By providing specifics for OB/OD units and geologic repositories in permit guidance to be developed, the Agency will identify unit-specific monitoring and analysis needs.

D. Section 264.603—Post-Closure Care

In addition to complying with the appropriate post-closure standards of Subpart G of Part 264 during the post-closure care period, owners and operators of miscellaneous units permitted under Subpart X that dispose of hazardous wastes must continue to meet the environmental performance standards of § 264.601 that applied in the operating period. This requirement is included to ensure that units used for disposal are maintained properly after closure. It is also applicable to treatment or storage units that cannot completely remove or decontaminate soils or ground water at closure.

Maintaining the unit during this period must be based upon procedures that are specified in a written post-closure plan, as required in § 264.118. Where appropriate, the post-closure plan must include monitoring, response, and maintenance procedures.

In response to post-closure requirements, one commenter recommended that the miscellaneous unit concept also be incorporated into Part 265. He stated that this would allow for the use of innovative technologies during closure of facilities with interim status. He also stated that often materials present at sites regulated under Part 265 must be treated as part of the closure activity and that preparation of a RCRA Part B permit application for new activities at a facility can take up to two years. He argued that some regulatory mechanism should be available for the amendment of a RCRA Part A permit to allow for new activities related to the closure of a site. Unless the miscellaneous unit concept is expanded to Part 265 and an expeditious procedure is developed to amend Part A permits, new technologies for treating hazardous waste will be largely unavailable to facilities closing under interim status.

The Agency recognizes the commenter's concern related to innovative technologies developed under interim status. This commenter is attempting to close a facility using an innovative technology. If the commenter is developing a new technology to treat hazardous waste at the facility being closed, or if he is demonstrating the application of a newly developed technology to treat hazardous waste, then this commenter may be able to use a research, development, and demonstration permit under § 270.65, assuming that he meets all of the requirements of that section. The purpose of RD&D permits is to allow for testing and demonstration of innovative and experimental technologies, including the modification of existing technologies, if the technology is experimental or innovative and there are no permit standards for the activity. Cleanup of facilities may occur, incident to testing and demonstration, under an RD&D permit. If the activity does not qualify for an RD&D permit, then the facility owner or operator must apply for a Subpart X permit.

The commenter stated that guidance on what is meant by removing all "contamination," as well as other "how clean is clean" issues, would be useful in closing Subpart X units. The Agency agrees and is preparing a "clean closure" guidance for release in the fall of 1987 that will provide useful information on one option for closure of land-based units.

Another commenter suggested that Subpart X should address closure of miscellaneous units in a fashion similar to that set forth in subparts relating to tanks, landfills, waste piles, etc. Specifically, § 264.110 should be amended to reference Subpart X. A new section in Subpart X should address closure and post-closure in language similar to the analogous sections in Subparts I through O.

The Agency disagrees with this commenter. Because of the unique characteristics of the miscellaneous units, the specific requirements given in Subparts I through O for closure and post-closure are not necessarily appropriate. Therefore, under § 264.603, these units must continue to comply with the appropriate post-closure standards of Subpart G of Part 264 and the environmental performance standards of § 264.601 during the post-closure care period. However, for a unit that resembles, by definition, one of the units in Subparts I through O, those standards may provide a starting point in developing closure and post-closure requirements for the miscellaneous unit.

In one commenter's opinion, requiring post-closure care if a facility cannot

"remove all contaminated soils or ground water" at closure is unduly restrictive and should be limited to toxic and hazardous constituents remaining at the facility after closure at a level determined to be a threat to human health and the environment. In response to this comment, the Agency, under a separate action, is developing a clean closure guidance. In addition, the Agency in the preamble to the March 19, 1987, Part II, Federal Register sets forth the RCRA standards for "clean closure."

VI. Amendments to Part 270: Permit Requirements

A. General Permit Requirements

Application and review requirements for permitting hazardous waste management facilities under RCRA are contained in Part 270. All owners and operators of units that treat, store, or dispose of hazardous waste in miscellaneous units must obtain permits under Part 270 regulations. Subpart X applicants must comply with the general application requirements, including Part A permit requirements, Part B general application requirements of § 270.10, and Part B specific information requirements. Part 270 regulations specify what information owners and operators of facilities must submit in their permit applications to demonstrate compliance with the Part 264 standards (both the general standards in Subparts A through E, G and H, F when required, and the specific standards in Subpart X). The general information requirements in Part 270 apply to all owners and operators of miscellaneous units.

Most of the comments specific to the permit requirements indicated a need for (1) standardization and acceleration of the permitting process; (2) minimization of the need for individual permits by providing an industry-specific variance, a class permit, or a special permit; and (3) an individual analysis of the applicability of permits and regulations prior to the permitting process. Some commenters were concerned that permit writers will be too autonomous, and that too much specialization will be required to issue Subpart X permits effectively. This could complicate the permitting process by causing both a shortage of qualified permit writers and increased costs to industry, as well as creating an inconsistency in the implementation of the permit standards by the writers.

The Agency has attempted to alleviate to some degree the commenters' concerns over the diverse permit requirements in today's rule by providing a standard, generic permit requirement for miscellaneous units. This standard permit requirement incorporates Part 264's individual compliance standards required under Subparts A through H, as well as the specific standards in Subpart X. In the Agency's opinion, technical support from the Permit Assistance Teams, any technology-specific permit guidance, and the availability of detailed technology descriptions, engineering reports, and information on monitoring, operational features, as well as maintenance, inspection, analysis, and closure procedures contained in the permit application should provide the permit writer with sufficient information to effectively develop permits on the miscellaneous units.

One commenter suggested that the Agency should incorporate standards developed by other agencies, such as the Department of Defense (DOD), Department of Energy (DOE), and the Nuclear Regulatory Commission (NRC). Another commenter requested that a generic permit application form for Subpart X units be developed. Other commenters preferred a specific exemption for *de minimis* quantities of waste processed by certain units operated by the explosives industry. Under RCRA, Small Quantity Generators (SQG)s are provided exemption from the permitting requirement in § 261. However, none of the treatment and disposal standards contained in Part 264 provide exemption from the permitting requirements for managing *de minimis* quantities and the Agency has no authority to, nor does it see any reason to exempt *de minimis* quantities.

The Agency regards these comments as very constructive and has incorporated portions of them in the development of today's rule. For example, in cooperation with the Department of the Army, the Agency is developing a permit guidance for OB/OD. The Agency also intends to review DOE's and NRC's permitting standards developed for the disposal of nuclear wastes in salt domes and deactivated missile silos. In the Agency's opinion, existing Part B permit application forms used for all other subparts of Part 264 are sufficient and provide adequate detail. Hence, no specific permit application form for Subpart X units is warranted. Although the Agency is not providing specific Subpart X permit applications, it is identifying the specific information requirements in the following section.

Another commenter suggested that the Agency should concentrate on establishing an information system capable of informing permit writers of miscellaneous units and providing up-to-date information on what units have been permitted in various States and EPA regions. In his judgment, this would shorten the time spent "reinventing the wheel." The Agency welcomes this suggestion and wants to point out that the Hazardous Waste Data Management System (HWDMS) data base, even though not seen as a perfect information dissemination tool, does serve the purpose of data transfer among the States, EPA regions, and EPA Headquarters.

The HWDMS data base can be accessed through the National Computer Center (NCC), Research Triangle Park, North Carolina, by the Headquarters, Regional, and State EPA officials or their approved contractors. This data base provides hazardous waste generators and management facility-specific information related to Parts A and B permit status. For each type of hazardous waste facility, detailed information is coded. The information includes Standard Industrial Codes (SIC); the facility's name and address; the permit status; the quantities and types of wastes generated and managed; the types of treatment, storage, and disposal methods and their capacities; and financial and ownership status. The data base is updated and revised frequently.

Currently, such a status-reporting mechanism is used by the Agency for tracking research, development, and demonstration (RD&D) permits. Similarly, the Agency may provide the status of various Subpart X permits to Permit Assistance Teams (PAT) staff and permit writers. The intent of the Subpart X units' status reports is to provide current information, such as (a) the types of units for which permit applications are submitted, (b) the unit's permit status, and (c) a brief description of the unit. This will allow various permit writers and PAT staff in different regions to permit similar units consistently and efficiently.

B. Specific Information Requirements for Miscellaneous Units In § 270.23

The specific information requirements for miscellaneous units included in § 270.23 are intended to clarify and define the type of unit that is being permitted. The applicant must describe the unit, its physical characteristics, materials of construction, and dimensions. The bulk of the application is expected to contain detailed plans and engineering reports describing how the unit will be located, designed, constructed, operated, maintained, monitored, inspected, and closed to comply with the requirements of

§§ 264.601 and 264.602. The plan should include a detailed process description.

In developing the application, each of the environmental performance standards must be assessed. Where this assessment indicates that releases to air, surface water, or ground water are possible, the applicant is expected to provide detailed hydrologic, geologic, and meteorologic assessments and maps for the region surrounding the site. Applications for disposal units must contain a description of the plans to comply with the post-closure requirements of § 264.603.

The permit application must contain information (a) on the potential pathways of exposure to humans or environmental receptors of hazardous waste or hazardous constituents and (b) on the potential magnitude and nature of such exposures. In addition, for each treatment unit, any reports on demonstrations of the effectiveness of similar treatment based on laboratory, bench-scale, pilot-scale, or field data gathered under an RD&D permit should be submitted.

If the unit to be permitted involves an innovative or experimental waste treatment process or technology where insufficient data are available to assess its effectiveness, if it is to be demonstrated over a short period of time, and if the technology will be conducted in a unit that meets the RD&D criteria, an RD&D permit may be necessary. For additional information on RD&D permits, refer to § 270.65 and EPA Publication No. EPA/530–SW–86–008, "Guidance Manual for Research, Development, and Demonstration Permits Under 40 CFR Section 270.65." If the demonstration is to be long term (i.e., may eventually be used as a commercial-scale treatment process) or does not meet the RD&D criteria, a permit may be obtained under Subpart X. Under certain circumstances, an RD&D permit may be necessary to gather additional data that may be required to fulfill Subpart X permit-related risk assessment needs. To gather such data the owner/operator can use the RD&D permit as a vehicle to demonstrate the effectiveness of a technology.

If a multi-stage demonstration project is to be permitted under Subpart X, two possible permitting options are available. First, a single permit that covers the entire demonstration could be written. As revisions are needed to a permit to reflect the outcome of individual stages, permit modifications could be requested under 40 CFR 270.41 and 270.42, provided the reason for requesting a modification meets one of the criteria for modification in these subparts. Alternatively, where the outcome of one stage may radically change the subsequent stages, a permit could be obtained for this first stage. At its completion, a permit could be issued for the subsequent stages. Each permit would terminate with the completion of a stage, and a new permit would be issued for the succeeding stage, based upon an evaluation of the results of the concluded stage. The exact permitting strategy to be used would be determined by the permit writer, based upon the type of treatment process and the demonstration.

Under § 270.23, a detailed description of the unit will be required specific to the development of a unit's design, construction, location, operation, maintenance, inspection, and closure so that it meets the requirements of the environmental performance standards.

One commenter was concerned over the information requirements on potential pathways of exposure of humans or environmental receptors to hazardous wastes or constituents. He suggested that knowledge of the potential magnitude and nature of such requirements for every miscellaneous unit to be permitted under Subpart X standards may be unnecessary in certain cases. In his opinion, development of such extensive data for fate and transport studies would be cost-prohibitive and time-consuming. He further suggested that a petition process could be instituted to demonstrate on a case-by-case basis an exemption from such an information requirement.

As mentioned previously, a detailed risk assessment is not necessary. However, at a minimum, the applicant must identify the potential impacts of hazardous constituents in different media. If the preliminary assessment conducted by the permit applicant indicates that releases to each of the media are possible, the permit applicant must further evaluate whether releases will occur and demonstrate ways to minimize the potential releases. This allows the permit writer to develop specific monitoring, analysis, and reporting guidelines for each particular unit.

C. Conforming Changes

Conforming changes are in other sections of Part 270 to accommodate the new Subpart X regulations. The Agency is not proposing to make changes to the Part 124 permit processing procedures. Issuance of permits for miscellaneous units would be subject to Part 124 in the same manner as other hazardous waste permits.

VII. Applicability to State Hazardous Waste Management Programs

A. Applicability of Rules in Authorized States

Under section 3006 of RCRA, the Agency may authorize qualified States to administer and enforce the RCRA program within the State. (See 40 CFR Part 271 for the standards and requirements for authorization.) Following authorization, the Agency retains enforcement authority under sections 3008, 7003, and 3013 of RCRA, although authorized States have primary enforcement responsibility.

Prior to the Hazardous and Solid Waste Amendments of 1984 (HSWA), a State with final authorization administered its own hazardous waste program, rather than the Agency administering the federal program in that State. The Federal requirements no longer applied in the authorized State, and the Agency could not issue permits for any facilities that the State was authorized to permit. When new, more stringent Federal requirements were promulgated or enacted, the State was obliged to enact equivalent authority within specified time frames. New Federal requirements did not take effect in an authorized State until the State adopted the requirements as State law.

In contrast, under section 3006(g) of RCRA, 42 U.S.C. 6927, new requirements and prohibitions imposed by HSWA take effect in authorized States at the same time that they take effect in nonauthorized States. The Agency is directed to carry out those requirements and prohibitions in authorized States, including the issuance of permits, until the State is granted authorization to do so. While States must still adopt HSWA-related provisions as State law to retain final authorization. HSWA applies in authorized States in the interim.

B. Effect on State Authorizations

Today's announcement promulgates standards that are not effective in authorized States because the requirements are not being imposed pursuant to HSWA. Thus, the requirements will be applicable only in those States that do not have interim or final authorization. In authorized States, the requirements will not be applicable until the State revises its program to adopt equivalent requirements under State law.

Under 40 CFR 271.21(e)(2), States that have final authorization must modify their programs to reflect equivalent requirements and by July 1, 1989, must submit the modifications to the Agency

for approval. This deadline can be extended in certain cases (40 CFR 271.21(e)(3)). Once the Agency approves the modification, the State requirements become Subtitle C RCRA requirements.

States with authorized RCRA programs may already have requirements similar to those in today's rule. These State regulations have not been assessed against the federal regulations being promulgated today to determine whether they meet the tests for authorization. Thus, a State is not authorized to carry out requirements in lieu of the Agency until the State program modification is submitted to the Agency and approved. Of course, States with existing standards may continue to administer and enforce their standards as a matter of State law.

States that submit their official applications for final authorization less than 12 months after the effective date of these standards are not required to include equivalent standards in their applications. However, they must modify their programs by the deadlines set forth in § 271.21(e). States that submit official applications for final authorization 12 months after the effective date of these standards must include standards equivalent to these standards in their applications. The requirements a State must meet when submitting its final authorization application are set forth in 40 CFR 271.3.

The Agency is precluded from issuing permits to new units in States authorized to implement RCRA in lieu of the Agency. However, 40 CFR 264.1(f)(2) provides an exception: the Agency may issue permits in authorized States if the unit was not regulated under RCRA at the time of the State's authorization and its standards for permitting the unit were promulgated *after* the State received final authorization. Thus, according to this provision, the Agency may issue a permit to a new facility under Subpart X in an authorized State. The Agency's permitting authority would cease, however, once the State modified its program, in accordance with § 271.21(e), to reflect the Federal Subpart X standards.

VIII. Effective Dates

Today's rule is effective 30 days from date of publication (in compliance with section 553(d) of the Administrative Procedures Act). EPA believes that it has a sound basis for suspending the statutory six-month effective date (RCRA Section 3010(b)) for this regulatory amendment. Section 3010(b) provides that EPA may shorten the effective date for good cause found and published with the regulation. The Agency believes that there is good cause to suspend this six-month period because of the demand by the regulated community to apply for and obtain Subpart X permits. Currently, persons are prohibited from building new Subpart X facilities or expanding existing interim status facilities that will be covered under Subpart X. By shortening the effective date of today's rule to 30 days, the Agency enables such persons to obtain the necessary permits expeditiously. Since such permits are not required to be obtained within the six-month period, shortening the effective date will not burden the regulated community.

IX. Regulatory Analyses

A. Regulatory Impact Analysis

Under Executive Order No. 12291, the Agency must judge whether a regulation is "major" and thus subject to the requirement of a Regulatory Impact Analysis. The notice published today is not major because the rule will not result in an effect on the economy of $100 million or more, will not result in increased costs or prices, will not have significant adverse effects on competition, employment, investment, productivity, and innovation, and will not significantly disrupt domestic or export markets. Therefore, the Agency has not prepared a Regulatory Impact Analysis under the Executive Order.

This regulation was submitted to the Office of Management and Budget for review as required by Executive Order No. 12291.

B. Regulatory Flexibility Act

The Regulatory Flexibility Act (5 U.S.C. 601 *et seq.)* requires each Federal agency to consider the effects of their regulations on small entities and to examine alternatives that may reduce these effects. With respect to today's rule, there is no means of anticipating exactly how many miscellaneous units, if any, will be owned and operated by small entities. In general, the Agency believes that the large amounts of capital required and the technical complexity necessary to establish safe and secure miscellaneous units will mean that larger entities will predominate. Therefore, the Agency certifies that this regulation will not have a significant impact on a substantial number of small entities.

C. Paperwork Reduction Act

The information collection requirements contained in this rule have been approved by the Office of Management and Budget (OMB) under the provisions of the Paperwork Reduction Act of 1980, 44 U.S.C. 3501 *et seq.* have been assigned OMB control number 2050–0074.

X. Supporting Documents

In preparing the final rule, the Agency has used the following major sources of information. They have been placed in the rulemaking docket at U.S. Environmental Protection Agency, EPA RCRA Docket (sub-basement), 401 M Street, SW., Washington, DC 20460. The docket is open from 9:00 a.m. to 4:00 p.m., Monday through Friday, except for Federal holidays. The public must make an appointment to review docket materials by calling (202) 475–9327.

The major sources are: 1. Public Comments on the November 7, 1986, proposal to regulate miscellaneous units. All the public comments received on the proposal are included in the docket at EPA Headquarters. These comments were considered by EPA in developing today's final rule.

2. Background Document: Subpart X Comments and Responses, Versar Inc. (November 1987). This document provides the Agency's response to specific comments to the proposal.

List of Subjects

40 CFR Part 144

Administrative practice and procedure, Hazardous materials, Waste treatment and disposal.

40 CFR Part 260

Administrative practice and procedures, Confidential business information, Hazardous materials, Waste treatment and disposal.

40 CFR Part 264

Hazardous material, Packaging and containers, Reporting requirements, Security measures, Surety bonds, Waste treatment and disposal.

40 CFR Part 270

Administrative practice and procedures, Reporting and recordkeeping requirements, Hazardous materials, Waste treatment and disposal, Water pollution control, Water supply, Confidential business information.

Date: November 25, 1987

Lee M. Thomas,

Administor.

For the reasons set out in the preamble, Parts 144, 260, 264, and 270 of Chapter I of Title 40 of the Code of Federal Regulations are amended as follows.

PART 144—UNDERGROUND INJECTION CONTROL PROGRAM

1. The authority citation for Part 144 continues to read as follows:

Authority: Pub. L. 93–523, as amended by Pub. L. 95–190, Pub. L. 96–63, Pub. L. 96–502, and Pub. L. 99–339, 42 U.S.C. 300f *et seq.*

2. Section 144.31(a) is amended by adding the following sentence at the end of the paragraph to read as follows:

§ 144.31 Application for a permit; authorization by permit.

(a) * * * A RCRA permit applying the standards of Part 264 Subpart X will constitute a UIC permit for hazardous waste injection wells for which the technical standards in Part 146 are not generally appropriate.

* * * * *

PART 260—HAZARDOUS WASTE MANAGEMENT SYSTEM: GENERAL

3. The authority citation for Part 260 is revised to read as follows:

Authority: 42 U.S.C. 6905, 6912(a), 6921 through 6927, 6930, 6934, 6935, 6937, 6938, 6939, and 6974.

4. Section 260.10 is amended by adding the definition "Miscellaneous Unit" in alphabetical order and revising the definition "Landfill" to read as follows:

§ 260.10 Definitions.

* * * * *

"Landfill" means a disposal facility or part of a facility where hazardous waste is placed in or on land and which is not a pile, a land treatment facility, a surface impoundment, an underground injection well, a salt dome formation, a salt bed formation, an underground mine, or a cave.

* * * * *

"Miscellaneous unit" means a hazardous waste management unit where hazardous waste is treated, stored, or disposed of and that is not a container, tank, surface impoundment, pile, land treatment unit, landfill, incinerator, boiler, industrial furnace, underground injection well with appropriate technical standards under 40 CFR Part 146, or unit eligible for a research, development, and demonstration permit under § 270.65.

* * * * *

PART 264—STANDARDS FOR OWNERS AND OPERATORS OF HAZARDOUS WASTE TREATMENT, STORAGE, AND DISPOSAL FACILITIES

5. The authority citation for Part 264 is revised to read as follows:

Authority: 42 U.S.C. 6905, 6912(a), 6924, and 6925.

6. Section 264.10 is amended by revising paragraph (b) to read as follows:

§ 264.10 Applicability.

* * * * *

(b) Section 264.18(b) applies only to facilities subject to regulation under Subparts I through O and Subpart X of this part.

7. Section 264.15 is amended by revising the last sentence of paragraph (b)(4) to read as follows:

§ 264.15 General inspection requirements.

* * * * *

(b) * * *

(4) * * * At a minimum, the inspection schedule must include the terms and frequencies called for in §§ 264.174, 264.194, 264.226, 264.253, 264.254, 264.303, 264.347, and 264.602, where applicable.

* * * * *

8. Section 264.18 is amended by revising the introductory text of paragraph (b)(1)(ii) to read as follows:

§ 264.18 Location standards.

* * * * *

(b) * * *

(1) * * *

(ii) For existing surface impoundments, waste piles, land treatment units, landfills, and miscellaneous units, no adverse effects on human health or the environment will result if washout occurs, considering:

* * * * *

9. Section 264.73 is amended by revising paragraph (b)(6) to read as follows:

§ 264.73 Operating record.

* * * * *

(b) * * *

(6) Monitoring, testing or analytical data, and corrective action where required by Subpart F and §§ 264.226, 264.253, 264.254, 264.276, 264.278, 264.280, 264.303, 264.309, 264.347, and 264.602;

* * * * *

10. Section 264.90 is amended by adding a new paragraph (d) to read as follows:

§ 264.90 Applicability.

* * * * *

(d) Regulations in this subpart may apply to miscellaneous units when necessary to comply with §§ 264.601 through 264.603.

11. Section 264.111 is amended by revising paragraph (c) to read as follows:

§ 264.111 Closure performance standard.

* * * * *

(c) Complies with the closure requirements of this subpart, including, but not limited to, the requirements of §§ 264.178, 264.197, 264.228, 264.258, 264.280, 264.310, 264.351, and 264.601 through 264.603.

12. Section 264.112 is amended by revising paragraph (a)(2) to read as follows:

§ 264.112 Closure plan; amendment of plan.

* * * * *

(a) * * *

(2) The Director's approval of the plan must ensure that the approved closure plan is consistent with §§ 264.111 through 264.115 and the applicable requirements of §§ 264.90 *et seq.*, 264.178, 264.197, 264.228, 264.258, 264.280, 264.310, 264.351, and 264.601. Until final closure is completed and certified in accordance with § 264.115, a copy of the approved plan and all approved revisions must be furnished to the Director upon request, including request by mail.

* * * * *

13. Section 264.114 is amended by revising the first sentence to read as follows:

§ 264.114 Disposal or decontamination of equipment, structures, and soils.

During the partial and final closure periods, all contaminated equipment, structures, and soils must be properly disposed of or decontaminated, unless otherwise specified in §§ 264.228, 264.258, 264.280, or 264.310, or under the authority of § 264.601 and § 264.603.

* * *

14. Section 264.117 is amended by revising paragraphs (a)(1)(i) and (a)(1)(ii) to read as follows:

§ 264.117 Post-closure care and use of property.

(a) (1) * * *

(i) Monitoring and reporting in accordance with the requirements of Subparts F, K, L, M, N, and X of this part; and

(ii) Maintenance and monitoring of waste containment systems in accordance with the requirements of Subparts F, K, L, M, N, and X of this part.

* * * * *

15. Section 264.118 is amended by revising paragraphs (b)(1) and (b)(2)(i) and (b)(2)(ii) to read as follows:

§ 264.118 Post-closure plan; amendment of plan.

* * * * *

(b) * * *

(1) A description of the planned monitoring activities and frequencies at which they will be performed to comply with Subparts F, K, L, M, N, and X of this part during the post-closure care period; and

(2) * * *

(i) The integrity of the cap and final cover or other containment systems in accordance with the requirements of Subparts F, K, L, M, N, and X of this part; and

(ii) The function of the monitoring equipment in accordance with the requirements of Subparts, F, K, L, M, N, and X of this part; and

* * * * *

16. Section 264.142 is amended by revising the introductory text of paragraph (a) to read as follows:

§ 264.142 Cost estimate for closure.

(a) The owner or operator must have a detailed written estimate, in current dollars, of the cost of closing the facility in accordance with the requirements in §§ 264.111 through 264.115 and applicable closure requirements in §§ 264.178, 264.197, 264.228, 264.258, 264.280, 264.310, 264.351, and 264.601 through 264.603.

* * * * *

17. Section 264.144 is amended by revising the introductory text of paragraph (a) to read as follows:

§ 264.144 Cost estimate for post-closure care.

(a) The owner or operator of a disposal surface impoundment, disposal miscellaneous unit, land treatment unit, or landfill unit, or of a surface impoundment or waste pile required under §§ 264.228 and 264.258 to prepare a contingent closure and post-closure plan, must have a detailed written estimate, in current dollars, of the annual cost of post-closure monitoring and maintenance of the facility in accordance with the applicable post-closure regulations in §§ 264.117 through 264.120, 264.228, 264.258, 264.280, 264.310, and 264.603.

* * * * *

Section 264.147 is amended by revising the first sentence of paragraph (b) introductory text to read as follows:

§ 264.147 Liability requirements.

* * * * *

(b) *Coverage for nonsudden accidental occurrences.* An owner or operator of a surface impoundment, landfill, land treatment facility, or miscellaneous disposal unit that is used to manage hazardous waste, or a group of such facilities, must demonstrate financial responsibility for bodily injury and property damage to third parties caused by nonsudden accidental occurrences arising from operations of the facility or group of facilities. * * *

* * * * *

19. Part 264 is amended by adding Subpart X consisting of §§ 264.600 through 264.999 to read as follows:

Subpart X—Miscellaneous Units

Sec.

Subpart X—Miscellaneous Units

§ 264.600 Applicability.

The requirements in this subpart apply to owners and operators of facilities that treat, store, or dispose of hazardous waste in miscellanenous units, except as § 264.1 provide otherwise.

§ 264.601 Environmental performance standards.

A miscellaneous unit must be located, designed, constructed, operated, maintained, and closed in a manner that will ensure protection of human health and the environment. Permits for miscellaneous units are to contain such terms and provisions as necessary to protect human health and the environment, including, but not limited to, as appropriate, design and operating requirements, detection and monitoring requirements, and requirements for responses to releases of hazardous waste or hazardous constituents from the unit. Permit terms and provisions shall include those requirements of Subparts I through 0 of this part, Part 270, and Part 146 that are appropriate for the miscellaneous unit being permitted. Protection of human health and the environment includes, but is not limited to:

(a) Prevention of any releases that may have adverse effects on human heath or the environment due to migration of waste constituents in the ground water or subsurface environment, considering:

(1) The volume and physical and chemical characteristics of the waste in the unit, including its potential for migration through soil, liners, or other containing structures;

(2) The hydrologic and geologic characteristics of the unit and the surrounding area;

(3) The existing quality of ground water, including other sources of contamination and their cumulative impact on the ground water;

(4) The quantity and direction of ground-water flow;

(5) The proximity to and withdrawal rates of current and potential ground-water users;

(6) The patterns of land use in the region;

(7) The potential for deposition or migration of waste constituents into subsurface physical structures, and into the root zone of food-chain crops and other vegetation;

(8) The potential for health risks caused by human exposure to waste constituents; and

(9) The potential for damage to domestic animals, wildlife, crops, vegetation, and physical structures caused by exposure to waste constituents;

(b) Prevention of any releases that may have adverse effects on human health or the environment due to migration of waste constituents in surface water, or wetlands or on the soil surface considering:

(1) The volume and physical and chemical characteristics of the waste in the unit;

(2) The effectiveness and reliability of containing, confining, and collecting systems and structures in preventing migration;

(3) The hydrologic characteristics of the unit and the surrounding area, including the topography of the land around the unit;

(4) The patterns of precipitation in the region;

(5) The quantity, quality, and direction of ground-water flow;

(6) The proximity of the unit to surface waters;

(7) The current and potential uses of nearby surface waters and any water quality standards established for those surface waters;

(8) The existing quality of surface waters and surface soils, including other sources of contamination and their cumulative impact on surface waters and surface soils;

(9) The patterns of land use in the region;

(10) The potential for health risks caused by human exposure to waste constituents; and

(11) The potential for damage to domestic animals, wildlife, crops, vegetation, and physical structures caused by exposure to waste constitutents.

(c) Prevention of any release that may have adverse effects on human health or the environment due to migration of

waste constituents in the air, considering:

(1) The volume and physical and chemical characteristics of the waste in the unit, including its potential for the emission and dispersal of gases, aerosols and particulates;

(2) The effectiveness and reliability of systems and structures to reduce or prevent emissions of hazardous constituents to the air;

(3) The operating characteristics of the unit;

(4) The atmospheric, meterologic, and topographic characteristics of the unit and the surrounding area;

(5) The existing quality of the air, including other sources of contamination and their cumulative impact on the air;

(6) The potential for health risks caused by human exposure to waste constituents; and

(7) The potential for damage to domestic animals, wildlife, crops, vegetation, and physical structures caused by exposure to waste constituents.

§ 264.602 Monitoring, analysis, inspection, response, reporting, and corrective action.

Monitoring, testing, analytical data, inspections, response, and reporting procedures and frequencies must ensure compliance with §§ 264.601, 264.15, 264.33, 264.75, 264.76, 264,77, and 264.101 as well as meet any additional requirements needed to protect human health and the environment as specified in the permit.

§ 264.603. Post-closure care.

A miscellaneous unit that is a disposal unit must be maintained in a manner that complies with § 264.601 during the post-closure care period. In addition, if a treatment or storage unit has contaminated soils or ground water that cannot be completely removed or decontaminated during closure, then that unit must also meet the requirements of § 264.601 during post-closure care. The post-closure plan under § 264.118 must specify the procedures that will be used to satisfy this requirement.

§§ 264.604 through 264.999 [Reserved]

PART 270—EPA ADMINISTERED PERMIT PROGRAMS: THE HAZARDOUS WASTE PERMIT PROGRAM

20. The authority citation for Part 270 is revised to read as follows:

Authority: 42 U.S.C. 6905, 6912, 6925, 6927, 6939, and 6974.

21. Section 270.14 is amended by revising paragraphs (b)(5) and (b)(13) to read as follows:

§ 270.14 Contents of Part B: General requirements.

* * * * *

(b) * * *

(5) A copy of the general inspection schedule required by § 264.15(b). Include, where applicable, as part of the inspection schedule, specific requirements in §§ 264.174, 264.194, 264.226, 264.254, 264.273, 264.303, and 264.602.

* * * * *

(13) A copy of the closure plan and, where applicable, the post-closure plan required by §§ 264.112 and 264.118. Include, where applicable, as part of the plans, specific requirements in §§ 264.178, 264.197, 264.228, 264.258, 264.280, 264.310, 264.351, 264.601, and 264.603.

* * * * *

22. Part 270 is amended by adding a new § 270.23 to Subpart B to read as follows:

§ 270.23 Specific Part B information requirements for miscellaneous units.

Except as otherwise provided in § 264.600, owners and operators of facilities that treat, store, or dispose of hazardous waste in miscellaneous units must provide the following additional information:

(a) A detailed description of the unit being used or proposed for use, including the following:

(1) Physical characteristics, materials of construction, and dimensions of the unit;

(2) Detailed plans and engineering reports describing how the unit will be located, designed, constructed, operated, maintained, monitored, inspected, and closed to comply with the requirements of §§ 264.601 and 264.602; and

(3) For disposal units, a detailed description of the plans to comply with the post-closure requirements of § 264.603.

(b) Detailed hydrologic, geologic, and meteorologic assessments and land-use maps for the region surrounding the site that address and ensure compliance of the unit with each factor in the environmental performance standards of § 264.601. If the applicant can demonstrate that he does not violate the environmental performance standards of § 264.601 and the Director agrees with such demonstration, preliminary hydrologic, geologic, and meteorologic assessments will suffice.

(c) Information on the potential pathways of exposure of humans or environmental receptors to hazardous waste or hazardous constituents and on the potential magnitude and nature of such exposures.

(d) For any treatment unit, a report on a demonstration of the effectiveness of the treatment based on laboratory or field data.

(e) Any additional information determined by the Director to be necessary for evaluation of compliance of the unit with the environmental performance standards of § 264.601.

(The information requirements in this section have been approved by the Office of Management and Budget and assigned OMB Control Number 2050–0074.)

§§ 270.24 through 270.29 [Reserved].

[FR Doc. 87–27997 Filed 12–9–87; 8:45 am]
BILLING CODE 6560–50–M

federal register

Thursday
December 10, 1987

Part V

Department of Health and Human Services

Food and Drug Administration

21 CFR Part 182

Sulfiting Agents; Proposal To Revoke GRAS Status for Use on "Fresh" Potatoes Served or Sold Unpackaged and Unlabeled to Consumers; Proposed Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 182

[Docket No. 81N-0314]

Sulfiting Agents; Proposal To Revoke GRAS Status for Use on "Fresh" Potatoes Served or Sold Unpackaged and Unlabeled to Consumers

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is proposing to exclude from generally recognized as safe (GRAS) status the use of sulfur dioxide, sodium sulfite, sodium and potassium bisulfite, and sodium and potassium metabisulfite (collectively known as sulfiting agents or sulfites) on "fresh" potatoes that are intended to be served or sold unpackaged and unlabeled to the consumer. This proposed action is based on FDA's review of currently available information which has raised significant questions about the safety of this use. In addition, the agency is specifically requesting comments on whether the agency should extend the proposal to the use of sulfites in or on canned, frozen, or dehydrated potatoes that are served or sold unpackaged or unlabeled to the consumer.

The information supporting this proposed action includes comments received in response to a proposal to affirm the GRAS status of sulfiting agents published in the **Federal Register** of July 9, 1982 (47 FR 29956); the January 31, 1985, final report of the Federation of American Societies for Experimental Biology (FASEB) on the Reexamination of the GRAS Status of Sulfiting Agents; recently published reports in the medical literature; consumer complaints received by the agency; recommendations made by FDA's ad hoc Advisory Committee on Hypersensitivity to Food Constituents; and other relevant information.

DATE: Comments by February 8, 1988.

ADDRESS: Written comments to the Dockets Management Branch (HFA–305), Food and Drug Administration, Rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Robert L. Martin, Center for Food Safety and Applied Nutrition (HFF–334), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–426–9463.

SUPPLEMENTARY INFORMATION:

I. FDA's Concerns

Because of recent developments, FDA has become increasingly concerned about the safety of the use of sulfiting agents on "fresh" potatoes that are intended to be sold or served unpackaged and unlabeled to the consumer. The term " 'fresh' potatoes" applies to all sulfite-treated potato products that are not canned, frozen, or dehydrated. The specific use of sulfites on "fresh" potatoes is discussed in greater detail below.

"Fresh" potatoes usually are sold or served in the retail segment of the food industry. "Retail food establishments" consist of food service establishments, food stores, and food vending machine locations. For purposes of this document, the term "food service establishment" means any place where food is prepared and intended for individual portion service and includes the site at which individual portions are provided. The term includes any such place regardless of whether consumption is on or off the premises and regardless of whether there is a charge for the food. The term covers commercial and institutional operations and includes temporary or mobile facilities.

For purposes of this document the term "food store" means any establishment or section of an establishment where food and food products are offered to the consumer and intended for off-premise consumption. Included are such places as convenience stores, retail bakeries, the food section of department stores, and supermarkets. "Food vending machine" means any self-service device that, upon insertion of a coin, paper currency, token, card, or key, dispenses unit servings of food, either in bulk or in packages, without the necessity of replenishing the device between each vending operation.

There are three bases for FDA's concerns about the safety of the use of sulfiting agents on "fresh" potatoes. First, the agency has received reports of deaths and life-threatening responses allegedly caused by sulfite-treated "fresh" potatoes. These reported adverse responses have occurred in retail food establishments, where the potatoes were unlabeled.

Second, FDA is concerned about the significant potential for misuse of products containing sulfiting agents by retail food personnel. The levels of sulfiting agents on potatoes that are treated at the retail level are likely to vary widely and depend directly upon the care exercised by retail food personnel in following the processing protocol.

Third, FDA's concerns stem from current lifestyle trends and practices. More Americans than ever before eat a substantial proportion of their meals in food service establishments and other such facilities (Ref. 27). This particular trend suggests that the potential for inadvertent exposure to sulfite-treated "fresh" potatoes that are unpackaged, and consequently unlabeled, is increasing and will probably continue to increase in response to consumer demand.

In light of these concerns, FDA has reviewed the GRAS status of the use of sulfites on "fresh" potatoes.

II. Background/Regulatory History

Sulfiting agents have a long history of use as food ingredients. Since November 20, 1959 (24 FR 9368), these food ingredients have been listed as generally recognized as safe (GRAS) for use as chemical preservatives.

In 1976, during the course of the agency's review of the safety of GRAS substances (Ref. 1), the Select Committee on GRAS Substances (the Select Committee) of FASEB issued a report on the health aspects of the use of sulfiting agents as food ingredients (Ref. 2). Subsequently, in the **Federal Register** of July 9, 1982 (47 FR 29956), FDA proposed to affirm, with specific limitations, the GRAS status of the use of certain sulfiting agents (Ref. 3).

The agency received numerous comments on the 1982 proposal. Some comments reported new uses of the sulfiting agents, significant recent expansion of some old uses, widespread use by the retail segment of the food industry, and many uses that are unlabeled. Other comments reported the possibility that a significant number of individuals may experience potentially severe allergic-type responses upon consuming foods treated with sulfiting agents. (The agency is using the term "allergic-type responses" to describe the various types of symptoms that individuals have suffered after eating sulfite-treated food. These responses in some ways resemble the responses to allergens. However, the scientific community is unsure at this time about the actual mechanism of responses elicited by the sulfite ingredient.)

The agency also received a citizen petition regarding the use of sulfiting agents in food and drugs. The petition echoed many of the concerns expressed in the comments and urged the agency to take certain regulatory actions to restrict the use of sulfites in food.

A number of the comments that FDA has received, as well as portions of the citizen petition, are relevant to the specific action being proposed in this document. The agency has taken these comments into consideration in the development of this proposed action.

The new information received in response to the 1982 proposal prompted the agency to request the establishment of an advisory committee to examine the phenomenon of allergic-type responses to the use of sulfiting agents in food.

Thus, in the **Federal Register** of April 16, 1984 (49 FR 10521), FDA announced that the Secretary of the Department of Health and Human Services had established an ad hoc Advisory Committee on Hypersensitivity to Sulfiting Agents in Foods (now the ad hoc Advisory Committee on Hypersensitivity to Food Constituents (the Advisory Committee)) to function under FDA's Center for Food Safety and Applied Nutrition. The Advisory Committee held four open meetings to review and evaluate available information and data relevant to allergic-type responses in humans that are associated with a number of food ingredients, including sulfiting agents. The Advisory Committee's views, as recorded in transcripts of committee meetings, on the uses of sulfites on potatoes, particularly with respect to continued GRAS status of "fresh" potato use, are discussed below.

The new information received in response to the 1982 proposal also prompted the agency to ask FASEB to reexamine the GRAS status of the use of sulfiting agents. FASEB established an ad hoc Review Panel on the Reexamination of the GRAS Status of Sulfiting Agents (the Panel). On July 9, 1984 (49 FR 27994), FDA announced the formation of the Panel.

The Panel evaluated recent scientific publications and new information and data submitted to FDA in response to its 1982 proposal. The Panel supplemented this information with additional materials acquired independently of FDA and conducted an open meeting on November 29, 1984, at which individuals and organizations presented their views on sulfite-related issues. On January 31, 1985, FASEB issued its final report (Ref. 4).

In that report, although finding that for the majority of the population "there is no evidence * * * to suspect a hazard," the Panel concluded that for the fraction of the public that is sulfite sensitive, "there is evidence * * * that demonstrates or suggests reasonable grounds to suspect a hazard of unpredictable severity to such individuals when they are exposed to sulfiting agents in some foods at levels that are now current and in the manner now practiced."

The Advisory Committee met on December 12 and 13, 1985, to review and to evaluate available information relevant to the use of sulfiting agents in food (Ref. 29). The Advisory Committee concluded that there exists, in the available literature, acceptable evidence and information that clearly shows that a subgroup of asthmatics is at moderate to severe risk for a severe reaction upon exposure to sulfites. In addition, the Advisory Committee stated that there is information to suggest that there may also be other individuals at risk.

The agency recognizes the difficulty and complexity of assessing the safe use of substances that, like numerous foods, including nuts and shellfish, are generally safe for the majority of the public but that may pose acute hazards for small subpopulations. When eating in retail food establishments, individuals who know they are sensitive to particular foods understand the need to protect themselves by avoiding consumption of those foods. As a general rule, FDA's policy is to address such circumstances by requiring package labeling that will disclose the presence of the ingredient to purchasers. This general principle is reflected in previously-issued regulations governing sulfites in packaged foods, as described below.

In the **Federal Register** of April 3, 1985 (50 FR 13306), FDA published a proposal to clarify the circumstances in which the presence of sulfiting agents must be declared on the label of foods. This proposal made clear that when a sulfiting agent is present in a detectable amount in a finished food, regardless of whether it has been directly added or indirectly added via one or more of the ingredients of the food, it is present in that food at a significant level and must be declared on the label. The proposal defined a detectable amount of sulfiting agent to be 10 parts per million. The agency issued a final regulation adopting this proposal on July 9, 1986 (51 FR 25012). Thus, the regulation is now in effect and sulfite-sensitive individuals can, by reading the label, avoid packaged food products containing sulfiting agents to which they might be sensitive.

The agency believes, however, that labeling is not likely to be an effective means of protecting sulfite-sensitive individuals from certain sulfited foods, including fruits and vegetables served or sold raw to consumers and "fresh" unpackaged potatoes that are served or sold by retail food establishments. These types of foods are traditionally unlabeled when presented to consumers and are presented to consumers as "fresh," thereby suggesting that preservatives have not been used in their preparation. Furthermore, ingestion of these types of foods has been reported to be associated with life-threatening responses in sulfite-sensitive individuals and, in at least 10 cases, with death.

Because of these reported problems, in the **Federal Register** of August 14, 1985 (50 FR 32830), FDA proposed to amend its regulations to make clear that use of sulfites on fruits and vegetables (except potatoes) intended to be served raw or sold raw to consumers is not GRAS. The agency adopted this regulation on July 9, 1986 (51 FR 25021). This regulation became effective on August 8, 1986.

In addition, because of the health problems reported to be associated with the use of sulfites on unpackaged and unlabeled "fresh" potatoes served or sold in retail food establishments, FDA has decided that it should act with regard to this use. In this document, FDA is announcing its preliminary conclusion that a consensus no longer exists among qualified experts that the use of sulfiting agents on "fresh" potatoes that are intended to be served or sold unpackaged and unlabeled to consumers is safe. To reflect this preliminary conclusion, the agency is proposing to amend Part 182.

If the agency confirms its preliminary conclusion, this use of sulfiting agents would constitute the use of an unapproved food additive. As a result, the use of sulfites on "fresh" potatoes that are served or sold unpackaged and unlabeled to the consumer would cause these Potatoes to be adulterated and in violation of section 402(a)(2)(C) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 342(a)(2)(C)). However, if the agency receives comments that convince FDA that a form of labeling will provide effective public health protection and prevent death and serious illness in unsuspecting consumers, the agency will reevaluate its conclusions regarding the safety of "fresh" potato use, contingent on such labeling.

III. The Use of Sulfiting Agents on Potatoes

Sulfiting agents are added to potatoes to inhibit oxidation, to inhibit both nonenzymatic and enzymatic browning, and to maintain crispness. The amount of sulfite used varies with the desired technical effect and with any concurrent or subsequent physical processing that the potato may receive. The point at

which sulfites are applied to the potato also varies with the desired technical effect and with any concurrent or subsequent physical processing.

For purposes of this document, the term " 'fresh' potatoes" refers to potatoes that receive a minimal amount of physical processing. The term includes potatoes that are treated with sulfites and refrigerated before cooking and those that are treated with sulfites, blanched in oil or water, and refrigerated before cooking. Sulfites are used to prevent enzymatic oxidation in both types of products and to control microbial contamination in the blanched products. Shelf life for these products is minimal, usually 2 to 10 days. Even though these products have received a chemical treatment, potato processors usually refer to them as "fresh" potatoes. The term " 'fresh' potatoes" applies to all sulfite-treated potato products that are not canned, frozen, or dehydrated.

In addition, restaurateurs may purchase a large number of commercial products that consist principally of sulfite salts to make dipping solutions for freshly peeled or cut potatoes. Label directions for these commercial products, also referred to as "potato whiteners," advise users to dissolve a specified amount of the product in water, to dip the freshly peeled potatoes (whole or cut-up) in the solution for a stated period of time, and to drain the potatoes before refrigerating or cooking. FDA considers this use to be included in the present proposal.

Sulfiting agents are also added to canned, dehydrated, and frozen potatoes. In the canned potato industry, sulfites may be added to flume water (transport water) to prevent enzymatically mediated discoloration. In the frozen potato industry, sulfites may be added to holding tanks to prevent enzymatic oxidation of potato ends and scraps that are subsequently used to make products such as frozen hash browns. In the dehydrated potato industry, sulfiting agents are used to prevent both enzymatic and nonenzymatic browning and may be applied to the peeled or cut potato, as well as to the cooked product before drying.

Historically, the use of sulfiting agents on potatoes has been considered GRAS so long as the use is in accordance with current good manufacturing practice (CGMP). As set forth in § 182.1, CGMP restricts the quantity of sulfites added to potatoes to levels that do not exceed those reasonably required to accomplish their intended technical effect. Current practice results in residual levels of sulfites in potato products ranging from 10 parts per million (ppm) to about 1,400 ppm sulfur dioxide equivalents. (All sulfite levels in this document are total sulfites expressed as sulfur dioxide equivalents, i.e., the amount of sulfur dioxide that can be released by a sulfiting agent or a food such as potatoes that contains a sulfiting agent.) This range reflects variations in the amount of sulfites used to prepare different potato products discussed above, as well as the technologies currently used to produce this array of products. It also reflects varying degrees of care exercised by retail food personnel and manufacturers in following use instructions and processing protocols.

Data submitted to or gathered by FDA show that frozen potatoes; canned potatoes and canned potato products; dehydrated potatoes; and refrigerated potatoes, as packaged or sold, may contain 15 to 1,300 ppm.; 15 to 250 ppm; 50 to 700 ppm; and 30 to 1,400 ppm sulfur dioxide equivalents, respectively (Refs. 4, 23, 24, 25, and 30). The agency has received information about ongoing research designed to establish the minimum amounts of sulfites required to achieve intended technical effects and is interested in receiving the results of these and any other investigations concerning the use of sulfites in the processing of potatoes. The agency is particularly interested in receiving reports of research involving the minimum levels of sulfites necessary to achieve intended effects; data on the level of sulfites present "as served;" the likelihood of sulfites being bound or unbound "as served" (and the health significance of bound and unbound residues that remain in "fresh" potato products); information relevant to the determination of potential "thresholds" for adverse effects; information on sulfite use by retail establishments (as opposed to "fresh" potato processors); and research for alternatives to sulfites. FDA is also soliciting comments and information on the threshold assessment prepared in connection with this proposal, in terms of the economic impact of a finding that the use of sulfiting agents on "fresh" potatoes is not GRAS, and of the economic impact of extending the proposal to other potato products (canned, frozen, or dehydrated) intended to be served unpackaged and unlabeled to consumers. Any information submitted should specify the assumptions used in evaluating alternatives to sulfite use. The agency intends to address the issue of CGMP use levels of sulfites on some potato products in a future **Federal Register** document that will address the GRAS status of the use of sulfites on foods.

IV. Safety Review

Information currently available indicates that allergic-type responses to sulfiting agents are most likely to occur among asthmatic individuals. Although prevalence estimates vary, among the estimated 10 million asthmatic patients in the U.S. population, as many as 1 in 10 (or 1 million persons) may be sulfite-sensitive (Ref. 4). Although there is less certainty about the degree to which nonasthmatic persons may also be sulfite-sensitive, nonasthmatics have been involved in some of the cases reported in the medical literature (Refs. 7 and 28).

A. Consumer Complaints

Since 1982, FDA has received and placed on file at the Dockets Management Branch, complaints from approximately 1,400 consumers who reported adverse responses after eating food known or suspected to contain sulfiting agents. Among the reported adverse responses have been 26 deaths, 17 of which may have been associated with sulfites.

In approximately 12 percent of the reports, the complainant alleged that a potato product known or suspected to contain a sulfiting agent was associated with an adverse response. The spectrum of reported responses to potato products is broad, ranging from mild discomfort to very severe and even life-threatening responses. FDA investigators followed up on all reports of serious adverse effects to the extent possible, although delayed reporting limited the potential for followup in some cases.

Included among these reports are a number that are of particular relevance to this proceeding. FDA received a report about an individual, diagnosed by oral challenge as a sulfite-sensitive asthmatic patient who went into a coma for 3 weeks and suffered severe motor and neurological damage after consuming a meal in a food service establishment that included cottage fried ("fresh") potatoes. FDA's analysis of samples of the potatoes used by the food service establishment at the time of this adverse response indicated that the potatoes contained 1,410 ppm sulfur dioxide equivalents before cooking and 1,390 ppm sulfur dioxide equivalents after cooking. FDA inspection of the plant where these potatoes were processed revealed that raw potatoes were peeled by abrasion, steam-cooked with water containing sodium bisulfite (approximately 1,260 to 1,570 ppm sulfur

dioxide equivalents), sliced, and refrigerated before distribution.

A second case, reported by a Los Angeles physician, describes the death of an individual, previously diagnosed by a physician as a sulfite-sensitive asthmatic, who died after consuming a food service establishment meal that included "fresh" cottage fries. FDA's analysis of the "fresh" cottage fries received by the food service establishment at the time of the incident indicated that the product (shredded, raw, refrigerated potatoes containing sodium bisulfite) contained 96 ppm sulfur dioxide equivalents. An analysis of the same product supplied to the food service establishment about 30 days after the incident gave values of 615 and 582 ppm sulfur dioxide equivalents before and after cooking, respectively. No explanation could be given for the large difference in the findings of the two analyses.

A third report describes the death of an individual, diagnosed by oral challenge as a sulfite-sensitive asthmatic, who died after consuming a meal in a Texas military food service establishment that included hash brown potatoes. Samples of the potatoes received by the food service establishment were not obtained and analyzed for sulfite content.

A fourth report describes the death of an asthmatic individual, suspected of being sulfite sensitive, who died after consuming a food service establishment meal that included "fresh" hash brown potatoes. Los Angeles County's analysis of the "fresh" hash brown potatoes received by the food service establishment about 30 days after the incident showed that the product (shredded, raw, refrigerated potatoes treated with sodium bisulfite) contained 242 ppm sulfur dioxide equivalents.

A fifth report describes the death of an asthmatic individual suspected of being sulfite sensitive, who died after consuming "fresh" cottage-fried potatoes. The presence of sulfites on the potatoes was confirmed through analysis by the coroner's office. The Orange County coroner's office stated that sulfites in the potatoes, resulting in an asthmatic reaction, was a contributing factor in this person's death after he consumed a food service establishment meal that included "fresh" potatoes that had been sulfite treated.

Significantly, all of these reports of life threatening or fatal adverse reactions involving potato products that contain sulfites involved "fresh" potatoes.

FDA has received at least 61 reports of serious adverse reaction involving potato products apparently associated with sulfites. These reports represent about 12 percent of the reports that FDA has evaluated and classified as associated with sulfites. A complete and accurate breakdown of these reactions by specific processing technique (i.e., "fresh," dehydrated, canned, or frozen), is not possible because the potato products cited in many of these reports were described in various ways both by complainants and persons recording complaint data.

Analysis of these 61 reports of serious adverse reaction shows that 75 percent of the allergic-type responses involving potato products (reports may involve multiple incidents) occurred in food service establishments and 10 percent occurred in the home. No specific location was listed for 15 percent.

B. The Panel's Report

As noted above, FDA requested early in 1984 that FASEB reexamine the GRAS status of sulfiting agents. In response, FASEB established the Panel, which considered all relevant information on the use of sulfiting agents. This information included recent scientific publications, information submitted to FDA in response to its 1982 proposal, data on the levels of sulfiting agents currently used in the processing of foods and on the levels of sulfiting agents found in various foods as consumed, new toxicological information on sulfiting agents, and data regarding the ability of sulfiting agents to cause allergic-type responses in sensitive individuals. The Panel also had access to the consumer complaints (numbering approximately 300) that FDA had received by that time. (FDA has subsequently received approximately 1,100 additional consumer complaints.) In addition, the Panel conducted an open meeting on November 29, 1984, at which individuals and representatives of organizations presented data, information, and views on a range of sulfite-related issues. The Panel made its final report available to FDA on January 31, 1985.

1. Exposure

The Panel estimated that the mean dietary intake of sulfiting agents is about 10 milligrams sulfur dioxide equivalents per capita per day (0.17 milligram per kilogram body weight per day). (For purposes of comparison, 10 milligrams of sulfur dioxide equivalents are contained in a 160-gram serving of potatoes containing 62.5 ppm sulfur dioxide equivalents.) The Panel also estimated that the 99th percentile intake probably does not exceed 180 milligrams sulfur dioxide equivalents per capita per day (3 milligrams per kilogram body weight per day). The latter figure represents regular consumption of foods containing high levels of sulfites, such as wine, shrimp, "instant" potatoes, dried apricots, and "tossed salad" (Ref. 4). (Since the publication of the Panel's report, FDA has prohibited the use of sulfiting agents in raw vegetables, such as those used in "tossed salad" (51 FR 25021).)

2. Sulfite-Sensitivity Responses

The Panel reviewed the evidence for the occurrence of adverse responses in certain individuals after ingesting foods containing sulfiting agents. This evidence included numerous published findings from clinical experiments involving the exposure of both asthmatic and nonasthmatic individuals to sulfiting agents. The Panel also reviewed hundreds of reports submitted by consumers, physicians, and FDA field investigators of adverse responses occurring after consumption of foods known to contain or suspected of containing sulfiting agents. A summary of the Panel's findings follows.

a. *Types of responses.* The most frequently reported response following exposure to sulfites or sulfur dioxide has been bronchial hyperreactivity (bronchoconstriction and bronchospasm), although other responses such as shock, gastrointestinal disturbances, and urticaria/angioedema as well as flushing, hypotension, and tingling sensations have also been reported (Ref. 5).

b. *Clinical studies.* Clinical investigators have attempted to document adverse responses to sulfites. Many of the studies were conducted on individuals or groups of individuals who previously reported an adverse response to a sulfite-containing food. To quantify adequately the presence and severity of adverse sulfite-sensitivity responses, clinical investigators have exposed individuals to measured quantities of sulfiting agents. The investigators have then reported the extent of any adverse response in terms of a drop in patients' forced expiratory volume at 1 second (FEV_1).

For example, in 1973, Kochen reported that a mildly asthmatic child experienced acute, transient asthmatic reactions following ingestion of freshly opened sulfite-containing foods (Ref. 6). Reports about this type of reaction were relatively rare until recently. However, challenge testing was not carried out to determine if sulfites were the causative agents in this case. Subsequently, Prenner and Stevens, in 1976, presented

a case report of anaphylaxis occurring in a 50-year old nonasthmatic male who consumed a restaurant meal that included a green salad sprayed with a product containing bisulfite (Ref. 7). Oral challenge with a total dose of 10 milligrams of sodium bisulfite (6.3 milligrams sulfur dioxide equivalents) resulted in erythema, itching, nausea, a feeling of warmness, coughing, and bronchoconstriction for about 1 hour. Lung function measurements were not made nor was a placebo administered as a part of the challenge.

In 1977, Freedman interviewed 272 asthmatic patients and reported that 30 experienced exacerbations of asthma following ingestion of orange drinks made with sodium bisulfite (Ref. 8). Fourteen of the 30 patients were challenged with a single dose of sodium metabisulfite solution containing 25 milligrams sulfur dioxide equivalents. Within 2 to 25 minutes, 8 of the 14 patients challenged gave a positive response, defined as a drop of at least 12 percent in FEV_1.

In one case, Baker et al. reported bronchospasm in an asthmatic patient following ingestion of canned crabmeat salad with a vinegar dressing (Ref. 9). Oral challenge of this patient with sodium metabisulfite resulted in severe bronchospasm within 30 minutes. No reaction was observed after ingestion of the canned crabmeat alone when given as a clinical challenge. In a second patient whose asthma was provoked by wine, a single-blind oral challenge with a capsule containing 500 milligrams sodium metabisulfite (337 milligrams sulfur dioxide equivalents) caused a drop in peak respiratory flow rate from about 440 liters per minute before challenge to 100 liters per minute 30 minutes after challenge. Challenge with a placebo capsule did not produce a significant pulmonary change in the second patient.

In 1983, Schwartz reported the clinical presence of vague, general symptoms following oral challenge with metabisulfite in two patients who developed dizziness, weakness, nausea, chest tightness, tachycardia, and dyspnea associated with restaurant meals (Ref. 10). Pulmonary function studies during an oral metabisulfite challenge showed no changes.

Stevenson and Simon reported in 1981 on clinical investigations on four patients with histories of severe bronchoconstriction and anaphylaxis associated with consumption of restaurant meals (Ref. 11). Single-blind oral challenges were administered to these patients in the fasting state and while they were taking their usual medications. Placebo capsules were administered orally every 30 minutes on the first morning of testing, and capsules containing 1, 5, 10, 25, or 50 milligrams of potassium bisulfite (0.53, 2.7, 5.3, 13.3, or 26.5 milligrams sulfur dioxide equivalents) were given sequentially every 30 minutes on the second day. FEV_1 values were measured at 30-minute intervals on both days.

All four patients reacted to bisulfite challenges, developing asthmatic symptoms 10 to 15 minutes after ingestion of a provocative dose (10, 25, or 50 milligrams of potassium bisulfite or 5.3, 13.3, or 26.5 milligrams sulfur dioxide equivalents, respectively). FEV_1 decreased 34 to 49 percent at 30 to 90 minutes after provocation. Systemic symptoms including flushing, tingling, and faintness occurred in all subjects. Subsequent oral challenge with sulfite solutions of six sulfite-sensitive asthmatic patients produced responses equal to the responses observed after oral capsule challenge but at levels approximately one-half of the provocative capsule dose (Ref. 12). Fifteen additional asthmatic patients with a history of increased asthmatic responses associated with consumption of food and beverages were serially challenged with capsules containing 5, 10, 25, and 50 milligrams sodium metabisulfite (3.4, 6.7, 16.9, and 33.7 milligrams sulfur dioxide equivalents) (Ref. 13). Only one of these patients had a significant response to the challenge. In that case, administration of 5 milligrams sodium metabisulfite (3.4 milligrams sulfur dioxide equivalents) produced a fall of 28 percent in FEV_1 in 2 minutes.

Capsules containing 1.4, 14, 144, or 288 milligrams potassium metabisulfite (0.94, 8.1, 82.9, or 166 milligrams sulfur dioxide equivalents) were sequentially administered to 134 patients selected from a clinic population of 1,073 patients having asthma and related allergic symptoms (Ref. 14). Decreases in FEV_1 values of at least 15 percent were reported in 50 of the 134 patients challenged. Based upon these challenges, Buckley et al. (1985) estimated that 4.6 percent of asthmatic patients respond to sulfite challenge (Ref. 14).

In another clinical study, lettuce treated with sodium bisulfite was employed as an oral challenge to evaluate pulmonary function of five stable, previously documented sulfite-sensitive asthmatic patients after consumption of food containing sulfiting agents (Refs. 15 and 16). Three-ounce portions of lettuce were dipped according to package instructions in a commercial vegetable freshener containing sodium bisulfite or in a similar commercial product that did not contain a sulfite salt. Approximately 10 milliliters of solution (80 to 90 milligrams bisulfite or 50 to 57 milligrams sulfur dioxide equivalents) adhered to the lettuce after draining. All five patients showed a significant decrease in FEV_1 (mean decrease 44 percent, range 31 to 64 percent) after consuming the sulfite-treated lettuce. None reacted to the control lettuce. Four of the patients were described as having moderate asthmatic responses, while the fifth had a life-threatening response requiring extensive emergency treatment (Ref. 16).

Not all clinical investigations reviewed by the Panel provided equally convincing and strong evidence for an association between exposure to sulfites and adverse responses. In one study performed by Sonin and Patterson in 1985, 12 patients with idiopathic anaphylaxis, 9 of whom had a history of reactions associated with restaurant meals, and 10 control subjects were challenged with increasing oral doses of sodium metabisulfite dissolved in lemonade (Ref. 17). A similar extent of mild nonspecific irritant and subjective symptoms were reported in both groups of patients. No anaphylactic responses occurred in the 12 patients with idiopathic anaphylaxis. No bronchospasm occurred, although pulmonary function was abnormal in three of these patients.

Similarly, in a presentation made at the open meeting of the Panel, Taylor reported that oral capsule challenge of 100 non-steroid-dependent asthmatic patients with potassium metabisulfite resulted in no cases of sulfite sensitivity that could be confirmed by double-blind challenge (Ref. 18). However, single-blind challenges of 69 steroid-dependent asthmatic patients resulted in a decrease in FEV_1 of at least 20 percent in 14 cases. Double-blind challenges of five of these steroid-dependent patients resulted in significant decreases in FEV_1 in only two cases.

In another study, FEV_1 values did not decline and no manifestations of sulfite sensitivity were reported following administration of bisulfite to five steroid-dependent asthmatic patients without histories of responses associated with restaurant meals (Ref. 11).

Experience with oral challenge testing of sulfites has led to differing opinions concerning the extent of sensitivity responses to sulfiting agents. Based upon their clinical work with capsule and solution challenges of a group of asthmatic patients, Simon et al. (Ref. 19) and Simon (Ref. 16) estimate that 5 to 10 percent of the 10,000,000 asthmatic

patients in the United States may be sensitive to orally ingested sulfiting agents. Buckley et al. suggest a prevalence of 4.6 percent for sulfite sensitivity based on capsule challenges of selected members of a clinic population having asthma and related unusual allergic symptoms (Ref. 14). A lower prevalence of sulfite sensitivity (1 to 2 percent of the overall asthmatic population) is estimated by Taylor (Ref. 18) whose clinical results with capsule challenge suggest that sulfite sensitivity is limited to steroid-dependent asthmatic patients. Patterson and colleagues have yet to identify sulfite sensitivity among idiopathic anaphylactic patients selected from an extensive asthmatic population and consider that sulfite sensitivity may be a minor problem (Ref. 20). Although a number of individuals have been clinically tested for sulfite sensitivity by oral challenge, there is no compilation of data available on the distribution of asthmatic and nonasthmatic patients sensitive to sulfiting agents according to age, sex, race, genetic traits, ethnicity, and other variables.

c. *Individual case reports.* The Panel reviewed copies of all the consumer complaints that had been sent to FDA, which, at the time the Panel did its work, numbered about 300. These included reports by individual consumers who were both asthmatic and nonasthmatic. The Panel also reviewed some more thorough case reports submitted by physicians. Some of the consumer and physician reports included additional information from followup investigations conducted by FDA field personnel. The Panel concluded that, taken together, these reports indicate an association between adverse responses and the ingestion of meals that include foods containing sulfiting agents.

3. The Panel's Conclusions and Recommendations

The Panel concluded that "for the majority of the population there is no evidence in the available information on (the sulfiting agents) that demonstrates or suggests reasonable arounds to suspect a hazard to the public when these substances are used at levels that are now current and in the manner now practiced. However, it is not possible to determine without additional data whether a significant increase in consumption would constitute a dietary hazard."

The Panel also concluded that "there is evidence in the available information * * * that demonstrates or suggests reasonable grounds to suspect a hazard of unpredictable severity to [sulfite-sensitive] individuals when they are exposed to sulfiting agents in some foods at levels that are now current and in the manner now practiced."

The Panel found that in some cases, sensitive individuals have had life-threatening reactions following exposure to sulfiting agents. The Panel specifically found that "there is * * * some evidence that associates consumption of some types of potatoes, processed for restaurant use and shown by laboratory analysis to contain sulfites, with life-threatening reactions in asthmatic patients." Although the Panel noted that "a cause and effect relationship between consumption of sulfite-containing foods and the onset of adverse reactions in sulfite-sensitive individuals has not been conclusively established," it also noted that "the reported associations are sufficiently numerous and the reactions sufficiently severe to deserve serious attention." The Panel further stated that "practical means need to be found to protect sulfite-sensitive individuals from the potential hazards of sulfites." The Panel concluded that "additional labeling requirements alone would not assure protection."

The Panel further concluded that "it would seem advisable to specify safe conditions of the use of sulfites in situations where levels shown to elicit adverse reactions in sulfite-sensitive individuals are likely to occur at the point of consumption." The Panel stated that "this is particularly likely when sulfite treated * * * precut potato products are dispensed in food service establishments or sold in grocery stores, and consumers, servers, and store personnel are not aware that sulfiting agents are present." The Panel noted that "information * * * indicates that use of sulfites on fresh produce in food service establishments is being discouraged * * * and that use has decreased * * *." The Panel stated that "voluntary curtailment of sulfite use on such products is an important step in reducing opportunities for unsuspecting sulfite-sensitive individuals to be exposed, and discontinuance of these uses should be encouraged by appropriate use of the regulatory process."

C. The Advisory Committee's Conclusions and Recommendations

FDA's ad hoc Advisory Committee on Hypersensitivity to Food Constituents (the Advisory Committee) met on December 12 and 13, 1985, to review and to evaluate available information on the use of sulfiting agents in food, including potatoes. The Advisory Committee concluded, in part, that "There * * * exists acceptable evidence in the literature that sulfites do cause problems * * * that a review of the available information clearly shows that a subgroup of asthmatics is at moderate to severe risk for a severe reaction upon exposure to sulfites." The Advisory Committee added that "there is information to suggest that there may be other individuals at risk * * *."

The Advisory Committee voted unanimously to encourage FDA to include "fresh" potatoes in its August 14, 1985, proposal (50 FR 32830) to rescind the GRAS status of sulfites on fresh fruits and vegetables. The Advisory Committee cited two reasons for rescinding the GRAS status of the use of sulfites on "fresh" potatoes. First, "there are some very strong cases of reactions that have occurred * * * to 'fresh' potato products." Second, "there is adequate evidence that abusive uses of sulfites are occurring with some frequency in this particular segment of the food processing industry and that those abusive uses of sulfite in particular can represent hazards." The Advisory Committee further stated that the term " 'fresh' potato" included sulfite-treated potato products that are not canned, dehydrated, or frozen.

In addition, the Advisory Committee stated that "sulfites are not necessary in frozen potatoes" and voted unanimously to "advocate a continued exclusion of sulfites * * * from these products." In a subsequent discussion, the Advisory Committee further explained "that [the frozen potato] industry does not need sulfites and does not currently use sulfites in frozen potatoes." In addition, the Advisory Committee stated that its recommendation was intended "to avoid the possible future circumstance, however remote, that someone would decide to process frozen potatoes with 500 parts per million total sulfur dioxide residues."

The Advisory Committee also discussed its concern relative to canned and dehydrated potato products: it was concerned about these products "to the extent that they would have to be labeled if they contained sulfite and that the sulfites are necessary, [and] that the minimum amounts [of sulfites] necessary to achieve the desired effects are being used * * *." The Advisory Committee further stated that "if someone discovers a way to process dehydrated potatoes without sulfites, then * * * the minimum amount necessary to achieve [the] desired effects is zero, [but] that circumstance does not exist at the present time."

V. Discussion

A. Proposed Action

Under 21 U.S.C. 321(s), for the use of a substance to be GRAS, there must be a consensus among qualified experts that that use has been shown to be safe. In this proposal, FDA is announcing that based on the data and information that have become available to it since the publication of its July 9, 1982, proposal on sulfiting agents; on the conclusions that the Panel reached in its 1985 reexamination of the GRAS status of sulfites; and the deliberations of the Advisory Committee; and on the agency's evaluation of the Panel's report and of the statements of the Advisory Committee, the agency has tentatively concluded that there is no longer a basis to find that the use of sulfites on "fresh" potatoes that are intended to be served or sold unpackaged and unlabeled to consumers is GRAS. FDA has reached this tentative conclusion based on the following factors and considerations:

1. There are people within the U.S. population whose number, according to some estimates, may be as high as 1 million, who are sulfite-sensitive and who may suffer allergic-type responses upon ingesting foods treated with sulfiting agents.

2. The responses of susceptible individuals to substances to which they are sensitive are often unpredictable and can be extremely severe, even fatal. In the case of sulfite-treated "fresh" potatoes, the reported responses have included death and permanent motor and neurological damage. These incidents represent evidence that the use of sulfites on "fresh" potatoes has resulted in harm. Moreover, potatoes are cited in about 12 percent of the consumer complaints of serious adverse responses to sulfites received by FDA (Ref. 26), second only to fresh fruits and vegetables. An accurate breakdown of whether the potatoes were "fresh," canned, frozen, or dehydrated is not possible for all reported responses because of the manner in which the complainants described the potato products.

3. The declaration of the presence of sulfites on the label of packaged foods that contain these ingredients provides an effective means by which sulfite-sensitive individuals can avoid such sulfite-treated foods. However, the agency is not aware of any effective means by which sulfite-sensitive individuals can be advised of the presence of sulfites on unpackaged "fresh" potatoes served or sold in retail food establishments.

(i) Potato products in many retail food establishments are normally presented to consumers in a finished, cooked form, without any labeling and without any indication of how the potato was processed. Finished, cooked potato products are not distinguishable based on their method of processing. For example, the common french fry may be made from truly fresh potatoes (i.e., no added preservatives), "fresh" potatoes as defined in this document, frozen potatoes, or even dehydrated potatoes. Thus, consumers in retail food establishments are presented with potato products that may contain sulfite residues. However, they are not presented with any ready means to determine whether sulfite residues are present on these potato products.

(ii) FDA believes that labeling by such means as menu statements or signs in retail food establishments is not a practical alternative. Labeling is not customarily used in many of these establishments, and a labeling requirement would be extremely difficult to enforce at any level of government, be it Federal, State, or local. At one time, FDA encouraged the States to require retail food establishments to place signs at their salad bars advising consumers of their use of sulfites. This effort proved to be unsatisfactory.

Another labeling alternative, however, is that processors who supply potatoes to retail food establishments could be required to clearly label the potatoes as containing sulfites, so that employees could provide information to consumers who know that they are sulfite sensitive and inquire of the establishment's employees whether or not sulfites are used. The agency also recognizes that labeling may be feasible in some circumstances, for example, on vending machines that already carry descriptive labeling or in controlled institutional settings. The agency invites comments on the practicality and desirability of the types of labeling approaches discussed above.

4. The levels of sulfiting agents on potatoes that are treated in retail food establishments are likely to vary widely and will depend upon the care exercised by retail food personnel in following use instructions for sulfite application. Thus, a significant potential exists for misuse of products that contain sulfiting agents and are used to treat potatoes.

5. Given the difficulty of informing consumers of the use of sulfites on "fresh" potatoes served in retail food establishments and the possibility for misuse of sulfites on the potatoes served in these establishments, it is not surprising that there is strong evidence that the use of sulfites on "fresh" potatoes served in retail establishments has resulted in severe allergic-type responses.

6. The concern created by these allergic-type responses apparently has undermined any consensus that may have existed within the scientific community that the use of sulfites on "fresh" potatoes that are unpackaged and unlabeled is GRAS. The Panel and the Advisory Committee, two groups composed of experts qualified by scientific training and experience to evaluate the safety of the use of sulfites, both expressed concerns about the use of these ingredients on potatoes:

(i) The Panel found that there is an association between the consumption of some types of potatoes and severe allergic-type responses. The Panel expressed a particular concern about the dispensing of sulfite-treated precut potatoes in food service establishments or grocery stores without labeling to advise consumers of the presence of sulfites.

(ii) The Advisory Committee also expressed concerns about the use of sulfites on potatoes. First, it encouraged FDA to rescind the GRAS status of the use of sulfites on "fresh" potatoes. The Advisory Committee cited evidence that abusive use of sulfites occurs with some frequency in this segment of the food industry (Ref. 29, p. 360). Second, the Advisory Committee stated that it was not concerned about sales to consumers of dehydrated and canned potatoes, so long as those products are labeled when they contain sulfites (Id., p. 410). Finally, the Advisory Committee expressed its belief that sulfites are not necessary on frozen potatoes (Id., pp. 363; 410–411).

7. FDA has carefully considered the concerns and recommendations of the Panel and the Advisory Committee and has made the following tentative determinations:

(i) FDA has tentatively determined that a consensus does not exist that the use of sulfites on "fresh" potato products that are intended to be served in food service establishments, food stores, or vending machines without packaging and without labeling is safe. This tentative determination is based on the recent reports of severe, life-threatening responses in asthmatic individuals who have consumed sulfited "fresh" potato products in food service establishments; the Panel's expressed concern about the safety of sulfited precut potatoes dispensed without labeling in retail food establishments; and the Advisory Committee's view that the use of sulfites on "fresh" potatoes is not GRAS.

(ii) FDA has found that, in spite of the Advisory Committee's belief that

sulfites are not used or necessary on frozen potatoes, these ingredients are being used in this type of processing. New information submitted to FDA indicates that some processors may be using sulfites at fairly high levels in frozen potatoes. Notably, FDA received a survey of potato products compiled by the Department of Health Services of California (Ref. 23) in 1986, which confirms that sulfites are used in a variety of frozen potato products. This survey of 151 samples of potatoes included 64 samples of frozen potato products, about half (33) of which contained sulfite residues. These residues ranged from 14 to 1,282 parts per million total sulfur dioxide equivalents. The agency is aware, however, that many processors have discontinued use of sulfites in their frozen potato products, a fact that gives support to the Advisory Committee's views and raises questions as to whether sulfites are necessary for this type of product. In addition, restaurateurs may use frozen potato products as substitutes for the "fresh" potatoes they now use, should the agency take final action confirming its tentative determination that the use of sulfites in "fresh" potato products intended to be served without packaging or labeling is not GRAS. Although the Advisory Committee did not include frozen potatoes in its recommendation to revoke GRAS status for "fresh" potatoes, it did advocate "continued exclusion of sulfites from these products" (Ref. 29, pp. 408–410). Given the potential difficulty in distinguishing between frozen products and other types of potatoes in the restaurant setting, the Advisory Committee's views, and a potential increase in exposure to fairly high levels of sulfites, as reported in the California data, as a result of substitution of frozen for "fresh" potatoes, the agency is particularly concerned about this use. Therefore, FDA is specifically requesting data on current use of sulfites in frozen potatoes and soliciting comments on the propriety of extending the proposal to exclude the use of sulfites on unpackaged and unlabeled frozen potatoes from GRAS status.

(iii) FDA recognizes that an argument can be made that a consensus does not exist that the use of sulfites in or on canned, dehydrated, or frozen potato products that are intended to be served in food service establishments, food stores, or vending machines without packaging and without labeling is safe. This argument would be based on the general information regarding reported allergic-type responses to the use of sulfites in or on a variety of potato products and the fact that the Advisory Committee's discussions indicated that members might be concerned about the safe use of sulfited canned, dehydrated, and presumably frozen potatoes if such products were presented to consumers without labeling.

(iv) As a result, the agency is (1) proposing to amend Part 182 to exclude the use of sulfites on "fresh" potatoes that are intended to be sold or served unpackaged and unlabeled to consumers from those uses that are GRAS under the regulations for the sulfiting agents, and (2) requesting comments on whether to extend the scope of the proposed action to include the use of sulfites in or on canned, dehydrated, or frozen potatoes that are intended to be sold or served unpackaged and unlabeled to consumers.

(v) FDA believes that the action that it is proposing to take is consistent with the observations of the Panel and the Advisory Committee.

8. FDA has excluded from this proposed action potatoes that are presented to the consumer in a packaged and labeled form, because individuals who are sulfite sensitive can avoid inadvertent exposure to sulfites by reading the ingredient list on these products. As noted above, FDA believes that the new labeling requirements for packaged sulfite-treated food published in the **Federal Register** of July 9, 1986 (51 FR 25012), adequately address any potential allergic-type problems that may be caused by this exclusion. The agency intends to further address the GRAS status of the use of sulfites on potatoes that are served or sold to the consumer in a labeled package in a future **Federal Register** document.

B. Prior Sanctions

The agency recognizes that the use of sulfites on potatoes predates 1958, and that the use of one or more of the sulfiting agents on one or more specific potato products may be the subject of a prior sanction. FDA acknowledged one such prior sanction in its July 9, 1982, proposal on sulfiting agents (47 FR 29956). In that proposal, FDA stated that the use of sodium bisulfite as a dip to prevent darkening of fresh peeled, uncooked potatoes was prior-sanctioned (Ref. 21).

FDA has reviewed all available information related to the health effects of the use of sulfites on "fresh" potatoes. The agency believes that, even though a prior sanction may exist for the use of sulfiting agents as a dip for fresh peeled potatoes, reliance on that sanction would likely not be a sufficient justification to continue this use of sulfiting agents. Having considered the recent reports of serious allergic-type responses to sulfited "fresh" potatoes including dipped potatoes; the fact that the incidents occurred when the potatoes were not labeled; and the other information discussed above, FDA believes that these reports and information demonstrate that the use of sulfiting agents as a dip for "fresh" potatoes may render the potatoes injurious to health if these potatoes are not packaged and labeled.

Therefore, FDA tentatively concludes that this use of sulfiting agents on "fresh" potatoes intended to be served or sold unpackaged and unlabeled to consumers would cause the food to be adulterated within the meaning of section 402(a)(1) of the act. On this basis, in accordance with 21 CFR 181.5(c), FDA is proposing to revoke the prior sanction for the use of sulfites on "fresh" potatoes. FDA requests that any other claimed prior sanctions for the use of sulfites on potatoes be brought to its attention as comments on this proposal. The agency will consider these claimed prior sanctions based on the available evidence.

VI. Other Relevant Information

A. General Comments and Submissions

FDA has received a number of submissions and comments from industry, medical professionals or associations, government officials or agencies, and many consumers regarding the use of sulfites on potatoes since the publication of its July 9, 1982, proposal to affirm the GRAS status of certain sulfiting agents with specific limitations. In addition, agency personnel have met with representatives of the "fresh" potato industry and the dehydrated potato industry on various occasions since August 1985. Memoranda of these meetings have been added to the public record on sulfiting agents.

The agency has taken all these submissions and comments into consideration in the development of this proposed regulation.

B. Citizen Petition (Docket No. 82P–0343)

On October 28, 1982, the agency received a citizen petition signed by three consumers, a physician, a scientist, and representatives of the Center for Science in the Public Interest (CSPI), Washington, DC. The petitioners requested that FDA amend certain food standards and rescind certain food additive regulations, prior sanctions, and advisory opinions that permit the

use of sulfiting agents at a level of more than 350 micrograms per serving. The petitioners also requested that FDA require warning labels on any food products in which sulfiting agents had to be used in amounts greater than 350 micrograms per serving to perform essential public health functions.

In a supplement to this petition, submitted on March 15, 1983, the petitioners requested that FDA withdraw the prior sanction permitting the use of sodium bisulfite on potatoes and institute appropriate enforcement action against certain products labeled for use on potatoes, because potatoes are a significant source of thiamine (vitamin B_1). The petitioners submitted data to support their claim that potatoes are a significant source of thiamine, and that products instructing users to apply sulfiting agents to potatoes are misbranded. The petitioners suggested that FDA issue an appropriate regulatory letter to all manufacturers of such products.

FDA has considered the requests made in the CSPI petition and its supplement that relate to the use of sulfiting agents on potatoes. (In the July 9, 1986, final rule, FDA responded to the petitioners' request that relates to the use of sulfites in salad bars. The agency will respond to the other issues raised in the petition in another **Federal Register** document.)

FDA acknowledges that it has never authorized the use of sulfites on foods that are recognized as a significant source of thiamine. Foods that can serve as significant sources of vitamins, including thiamine, are defined in 21 CFR 101.9(c)(7)(v) as those that supply at least 10 percent of the minimum daily requirement for vitamins, which in the case of thiamine is 0.15 milligram.

FDA has calculated the amount of thiamine present in an average serving (based on food consumption data of the U.S. Department of Agriculture 1977–1978 Nationwide Food Consumption Survey and food composition data in revised Agriculture Handbook No. 8–11) of seven different potato products, including baked potatoes, boiled potatoes, creamed-type potato casseroles, mashed potatoes, home-fried potatoes, french-fried potatoes, and potato salad. The amount of thiamine present in an average serving of these dishes, as consumed, ranges from 0.036 milligram in creamed-type potato casseroles to 0.15 milligram in boiled potatoes (Ref. 22). The median amount of thiamine per serving for these potato dishes is 0.11 milligram, and the average amount of thiamine is 0.10 milligram.

On the basis of these data, the agency has determined that although one specific potato dish (boiled potatoes) meets the criteria for a significant source of thiamine, the great majority do not. Given this fact and the fact that most individuals eat a variety of potato dishes rather than a steady diet of boiled potatoes, FDA tentatively concludes that potatoes are not a significant source of thiamine.

Thus, FDA tentatively concludes that it cannot, on the basis of thiamine content alone, grant the petitioners' request that it withdraw the prior sanction for the use of sodium bisulfite on potatoes, or the petitioners' request that the agency undertake an enforcement action against products containing sulfiting agents that are labeled for use on potatoes.

Nonetheless, FDA has tentatively concluded, on the basis of other information discussed above, that it is necessary for the agency to take action against the use of sulfiting agents on "fresh" potatoes intended to be served or sold unpackaged and unlabeled to consumers. It is proposing that action in this document. FDA is proposing to grant the petitioners' requests to the extent that the action sought in the requests is the action proposed in this document. Moreover, the agency is also proposing in this document to revoke the prior sanction for the use of sulfities in dipping solutions for potatoes that are served or sold unpackaged and unlabeled to consumers.

Should this proposed rule become final, the use of sulfites on "fresh" potatoes intended to be served or sold unpackaged and unlabeled to consumers would cause the food to be adulterated within the meaning of section 402 of the act. In addition, the agency is specifically requesting comments on whether to extend the scope of the proposed action to include the use of sulfites in canned, dehydrated, or frozen potatoes that are intended to be sold or served unpackaged and unlabeled to consumers.

VII. Conclusions

This proposed rulemaking announces that currently available information has created significant questions about whether the use of sulfiting agents on "fresh" potatoes that are served or sold unpackaged and unlabeled to consumers is safe. As a result, FDA believes that the use of sulfites on "fresh" potatoes that are served or sold in this manner to consumers can no longer be considered to be GRAS. Therefore, the agency is proposing in this document to amend Part 182 to exclude the use of sulfiting agents on unpackaged and unlabeled "fresh" potatoes from the uses of sulfiting agents that are considered to be GRAS. Such use of sulfiting agents would constitute the use of an unapproved food additive and would, therefore, cause any food to which they have been added to be adulterated and in violation of section 402(a)(2)(C) of the act. The comment period for this proposal is 60 days.

The agency requests comments from all interested persons on all relevant issues relating to this proposal. The agency especially seeks comments relating to the following issues:

1. Whether FDA should extend the scope of the proposed action to include the use of sulfites in or on canned, dehydrated, or frozen potatoes that are intended to be sold or served unpackaged and unlabeled to consumers;

2. Additional evidence concerning whether there is an association between exposure to sulfite-treated potatoes and allergic-type responses in sulfite-sensitive individuals;

3. Scientific evidence pertaining to the safe conditions of use of sulfiting agents on potatoes; and

4. Practical alternatives to the use of sulfiting agents on potatoes.

In commenting on whether FDA should extend the scope of the proposed action to include the use of sulfites on canned, dehydrated, or frozen potatoes, interested persons should provide views and information on whether sulfites can be safely used on potatoes that are served unpackaged but with appropriate labeling. The agency would appreciate comments on whether labeling would be possible and effective in nonrestaurant food service establishments, such as cafeterias and military mess halls.

VIII. Economic Impact

FDA has examined the economic impact of a finding that the use of sulfites on "fresh" potatoes intended to be served or sold unpackaged and unlabeled to the consumer is not GRAS. FDA finds that the benefit of this regulation will be to prevent allergic-type responses from consumption of sulfite-treated potatoes (unpackaged and unlabeled) in retail food establishments in a sulfite-sensitive population that may number up to 1,000,000 people. Among the possible adverse responses is death, as demonstrated by the fact that there have been four reported deaths allegedly associated with the ingestion of sulfite-treated potato products in retail food establishments in the last several years. However, it is not possible at this time to estimate the savings in health costs from this action.

In developing an economic threshold assessment for this document, FDA has relied on extensive input from diverse sources, including input provided on behalf of the National Coalition of Fresh Potato Processors. The cost impact of this rule will depend on: (1) The level of use of sulfited "fresh" potatoes by the restaurant industry at the time this regulation becomes effective and (2) the adjustments in demand for various potato products resulting from independent decisions by thousands of restaurants and institutional food service establishments as they seek the best substitute for sulfited "fresh" potatoes in their individual circumstances.

Given forces now at work—avoidance of adverse publicity, concern about liability exposure, and continued publication of scientific literature about sulfite hazards—some shift away from sulfited "fresh" potatoes, even absent this regulation, appears to be likely, at least among major, corporate restaurateurs. Gauging the extent of such voluntary displacement, and its speed, is difficult.

With regard to the second factor, restaurants and institutional food service establishments have a variety of sulfite-free options. Some are labor intensive (e.g., peel their own or more frequent delivery of precuts), others are technology dependent (e.g., chemical substitutes), and still others are dependent on consumer tastes and preferences (e.g., baked or frozen alternatives). The restaurant industry will likely choose a mixture of these options depending on individual restaurant circumstances. Cost differences among these options may vary from restaurant to restaurant. They may be zero in some situations, but will more than likely range between $0.02 to $0.04 per pound for alternative chemicals and more frequent delivery schedules.

Total cost impacts are estimated to range between $2 and $18 million, and placement within this range is primarily dependent on the rate of voluntary conversion to sulfite substitutes of uncertain cost and effectiveness. Despite the uncertainty in this estimate, however, the agency concludes that this rule does not constitute a major rule as defined by Executive Order 12291 or require a Regulatory Flexibility Analysis under the Regulatory Flexibility Act of 1980.

A threshold assessment for this proposed rule is on file in the Dockets Management Branch (address above), and FDA invites comments on the economic impact of the actions proposed in this document.

The agency also requests substantive data concerning this proposed action or other regulatory options to be used in a regulatory impact analysis or a regulatory flexibility analysis. After the agency has received comments and had an opportunity to evaluate the relevant data, the agency will prepare a regulatory impact analysis or a regulatory flexibility analysis, if appropriate. The agency will provide an opportunity for comment on any economic impact documents it prepares, before it proceeds to a final rule.

IX. Environmental Impact

The agency has carefully considered the potential environmental effects of this action and has concluded that the action will not have a significant impact on the human environment and that an environmental impact statement is not required. The agency's finding of no significant impact and the evidence supporting that finding, contained in an environmental assessment, may be seen in the Dockets Management Branch (address above) between 9 a.m. and 4 p.m., Monday through Friday. This action was considered under FDA's final rule implementing the National Environmental Policy Act (21 CFR Part 25).

X. References

The following references have been placed on display in the Dockets Management Branch and may be seen by interested persons between 9 a.m and 4 p.m., Monday through Friday.

1. Select Committee on GRAS Substances, "Insights on Food Safety Evaluation," Life Sciences Research Office, Federation of American Societies for Experimental Biology, prepared under FDA contract 223–81–2394, December 1982, and references cited therein.

2. Select Committee on GRAS Substances, "Evaluation of Health Aspects of Sulfiting Agents as Food Ingredients," Life Sciences Research Office, Federation of American Societies for Experimental Biology, prepared under FDA contract 223–75–2004, 1976.

3. "Sulfiting Agents; Proposed Affirmation of GRAS Status with Specific Limitations; Removal from GRAS Status as Direct Human Food Ingredient," 47 FR 29956; July 9, 1982.

4. Select Committee on GRAS Substances, "The Reexamination of the GRAS Status of Sulfiting Agents," Life Sciences Research Office, Federal of American Societies for Experimental Biology, prepared under FDA contract 223–83–2020, January 28, 1985.

5. National Institute of Allergy and Infectious Diseases, American Academy of Allergy and Immunology, Committee on Adverse Reactions to Foods, "Adverse Reactions to Foods," NIH publication No. 84–2442, 1984, 220 p. (available from U.S. Government Printing Office, Washington, DC).

6. Kochen, J., "Sulfur Dioxide, a Respiratory Tract Irritant, Even if Ingested," *Pediatrics*, 52:145–146, 1973.

7. Prenner, B. M., and J. J. Stevens, "Anaphylaxis after Ingestion of Sodium Bisulfite," *Annuals of Allergy*, 37:180–182, 1976.

8. Freedman, B. J., "Asthma Induced by Sulphur Dioxide, Benzoate and Tartrazine Contained in Orange Drinks," *Clinical Allergy*, 7:407–415, 1977.

9. Baker, G. J., P. Collett, and D. H. Allen, "Bronchospasm Induced by Metabisulfite-Containing Foods and Drugs," *Medical Journal of Australia*, 2:614–616, 1981.

10. Schwartz, H. J., "Sensitivity to Ingested Metabisulfite: Variations in Clinical Presentation," *Journal of Allergy and Clinical Immunology*, 71:487–489, 1983.

11. Stevenson, D. D., and R. A. Simon, "Sensitivity to Ingested Metabisulfites in Asthmatic Subjects," *Journal of Allergy and Clinical Immunology*, 68:26–32, 1981.

12. Goldfarb, G., and R. Simon, "Provocation of Sulfite Sensitive Asthma," *Journal of Allergy and Clinical Immunology*, 73:135, 1984 (Abstract).

13. Koepke, J. W., and J. C. Selner, "Sulfur Dioxide Sensitivity," *Annals of Allergy*, 48:258, 1982 (Abstract).

14. Buckley, C. E., III, H. A. Saltzman, and H. O. Sieker, "The Prevalence and Degree of Sensitivity to Ingested Sulfites," *Journal of Allergy and Clinical Immunology*, 1985 (Abstract), In press.

15. Howland, W. C., and R. A. Simon, "Restraurant-Provoked Asthma: Sulfite Sensitivity," *Journal of Allergy and Clinical Immunology*, 1985 (Abstract), In press.

16. Simon, R. A., Oral presentation given at the open meeting of the Ad Hoc Review Panel on the Reexamination of the GRAS Status of Sulfiting Agents held November 29, 1984, Bethesda, MD.

17. Sonin, L., and R. Patterson, "Metabisulfite Challenge in Patients with Idiopathic Anaphylaxis," *Journal of Allergy and Clinical Immunology*, 75:67–69, 1985.

18. Taylor, S. L., Oral presentation given at the open meeting of the Ad Hoc Review Panel on the Reexamination of the GRAS Status of Sulfiting Agents held November 29, 1984, Bethesda, MD.

19. Simon, R. A., L. Green, and D. D. Stevenson, "The Incidence of Ingested Metabisulfite Sensitivity in an Asthmatic Population," *Journal of Allergy and Clinical Immunology*, 69:118, 1982 (Abstract).

20. Patterson, R., Northwestern University, Evanston, IL, Letter plus attachments, dated July 9, 1984, to S. A. Anderson, Federation of American Societies for Experimental Biology, Bethesda, MD.

21. Letter from F. Leslie Hart, Chief, Boston District, FDA, to W. B. Farnham, Chief Chemist, State Department of Health, Vermont, dated September 19, 1952.

22. Memorandum from John E. Vanderveen, Director, Division of Nutrition, to John Taylor, Director, Division of Regulatory Guidance, "Thiamine Content of Potato Products in Reference to Sulfiting Agents," January 7, 1986.

23. Fan, A. M., S. A. Book, "The Potential Public Health Impact of the Use of Sulfiting

Agents in Potato Products: An Evaluation with Specific Reference to Sensitivity Reactions," A report to the Food and Drug Branch, Department of Health Service (California) from the Community Toxicology Unit, May 1986.

24. Memorandum from Sandra N. Whetstone to the Record, "Update on California Sulfite Incident," April 13, 1984, Food and Drug Administration, Washington, DC.

25. Recall No. F-674-6, "Lite Canned Mixed Vegetables April 18, 1986, Food and Drug Administration, Washington, DC.

26. Memorandum from the Health and Injury Related Surveillance Subprogram, Postmarketing Surveillance System to the Health Hazards Evaluation Board, "Quarterly Report on Adverse Reactions Associated With Sulfiting Agents," October 1, 1986, Food and Drug Administration, Washington, DC.

27. United States Department of Agriculture, "Nationwide Food Consumption Survey 1977-78," Report No. H-6, Attached Tables of Dollar Expenditures.

28. Habenicht, H.A., et al., "Sensitivity to Ingested Metabisulfites, Cause of Bronchospasm and Urticaria," *Immunology and Allergy Practice*, 5:243-245, 1983.

29. Transcript, Meeting of the ad hoc Advisory Committee on Hypersensitivity to Food Constituents, held December 12 and 13, 1985, Washington, DC.

30. Finne, G., "Effect of Treatment Conditions on the Residual Sulfite Concentration and Shelf-Life of Fresh Raw Peeled Potatoes," ASMI, Submitted to the National Coalition of Fresh Potato Processors, January 15, 1987.

XI. Comments

Interested persons may, on or before February 8, 1988, submit to the Dockets Management Branch (address above) written comments regarding this proposal. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

List of Subjects in 21 CFR Part 182

Food ingredients, Spices and flavorings.

Therefore, under the Federal Food, Drug, and Cosmetic Act, it is proposed that Part 182 be amended as follows:

PART 182—SUBSTANCES GENERALLY RECOGNIZED AS SAFE

1. The authority citation for 21 CFR Part 182 continues to read as follows:

Authority: Secs. 201(s), 402, 409, 701, 52 Stat. 1046-1047 as amended, 1055-1056 as amended, 72 Stat. 1784-1788 as amended (21 U.S.C. 321(s), 342, 348, 371); 21 CFR 5.10 and 5.11.

2. In § 182.3616 by revising paragraph (c) to read as follows:

§ 182.3616 Potassium bisulfite.

* * * * *

(c) *Limitations, restrictions, or explanation.* This substance is generally recognized as safe when used in accordance with good manufacturing practice, except that it is not used in meats; in food recognized as a source of vitamin B_1; on fruits or vegetables intended to be served raw to consumers or sold raw to consumers, or to be presented to the consumer as fresh; and on "fresh" potatoes that are intended to be served or sold unpackaged and unlabeled to the consumer. For purposes of this paragraph the term " 'fresh' potatoes" applies to any form of potato other than frozen, canned, or dehydrated potatoes.

3. In § 182.3637 by revising paragraph (c), to read as follows:

§ 182.3637 Potassium metabisulfite.

* * * * *

(c) *Limitations, restrictions, or explanation.* This substance is generally recognized as safe when used in accordance with good manufacturing practice, exempt that it is not used in meats; in food recognized as a source of vitamin B_1; or fruits or vegetables intended to be served raw to consumers or sold raw to consumers, or to be presented to the consumer as fresh; and on "fresh" potatoes that are intended to be served or sold unpackaged and unlabeled to the consumer. For purposes of this paragraph the term " 'fresh' potatoes" applies to any form of potato other than frozen, canned, or dehydrated potatoes.

4. In § 182.3739 by revising paragraph (c), to read as follows:

§ 182.3739 Sodium bisulfite.

* * * * *

(c) *Limitations, restrictions, or explanation.* This substance is generally recognized as safe when used in accordance with good manufacturing practice, except that it is not used in meats; in food recognized as a source of vitamin B_1; on fruits or vegetables intended to be served raw to consumers or sold raw to consumers, or to be presented to the consumer as fresh; and on "fresh" potatoes that are intended to be served or sold unpackaged and unlabeled to the consumer. For purposes of this paragraph the term " 'fresh' potatoes" applies to any form of potato other than frozen, canned, or dehydrated potatoes.

5. In § 182.3766 by revising paragraph (c), to read as follows:

§ 182.3766 Sodium metabisulfite.

* * * * *

(c) *Limitations, restrictions, or explanation.* This substance is generally recognized as safe when used in accordance with good manufacturing practice, except that it is not used in meats; in food recognized as a source of vitamin B_1; on fruits or vegetables intended to be served raw to consumers or sold raw to consumers, or to be presented to the consumer as fresh; and on "fresh" potatoes that are intended to be served or sold unpackaged and unlabeled to the consumer. For purposes of this paragraph the term " 'fresh' potatoes" applies to any form of potato other than frozen, canned, or dehydrated potatoes.

6. In § 182.3798 by revising paragraph (c), to read as follows:

§ 182.3798 Sodium sulfite.

* * * * *

(c) *Limitations, restrictions, or explanation.* This substance is generally recognized as safe when used in accordance with good manufacturing practice, except that it is not used in meats; in food recognized as a source of vitamin B_1; on fruits or vegetables intended to be served raw to consumers or sold raw to consumers, or to be presented to the consumer as fresh; and on "fresh" potatoes that are intended to be served or sold unpackaged and unlabeled to the consumer. For purposes of this paragraph the term " 'fresh' potatoes" applies to any form to potato other than frozen, canned, or dehydrated potatoes.

7. In § 182.3862 by revising paragraph (c), to read as follows:

§ 182.3862 Sulfur dioxide.

* * * * *

(c) *Limitations, restrictions, or explanation.* This substance is generally recognized as safe when used in accordance with good manufacturing practice, except that it is not used in meats; in food recognized as a source of vitamin B_1; on fruits or vegetables intended to be served raw to consumers or sold raw to consumers, or to be presented to the consumer as fresh; and on "fresh" potatoes that are intended to be served or sold unpackaged and unlabeled to the consumer. For purposes of this paragraph the term " 'fresh' potatoes" applies to any form of potato other than frozen, canned, or dehydrated potatoes.

Frank E. Young,

Commissioner of Food and Drugs.

Otis R. Bowen,

Secretary of Health and Human Services.

Dated: April 9, 1987.

Editorial Note: This document was received at the Office of the Federal Register December 7, 1987.

[FR Doc. 87-28291 Filed 12-9-87; 8:45 am]

BILLING CODE 4160-01-M