control the discharge of pollutants from flow through, recirculating and net pens systems. EPA described the bases for these requirements in section VIII of the preamble to the proposed regulation (67 FR 57895).

EPA held three public meetings to provide an overview of the proposed rule and opportunities for the regulated community and other interested parties to ask questions on issues pertaining to the proposed rule.

EPA received several requests to extend the comment period to allow more time to address the issues on which EPA solicited public comment. The requests for an extension pointed out that this is a very busy season for a large portion of this industry. Many sectors are involved in harvest through the fall months. EPA agrees that many producers may need more time to develop comments to the proposal. The comment period for the proposed rule is extended until January 27, 2003.

EPA is scheduled to take final action on effluent limitations guidelines and new source performance standards for this industry by June 2004. EPA is using its best efforts to comply with this deadline and expects to meet the schedule even with this extension of the comment period.

Dated: November 25, 2002.

G. Tracy Mehan, III, Assistant Administrator for Water.
[FR Doc. 02–30466 Filed 11–29–02; 8:45 am]
BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 764
[OPPT–2002–0006; FRL–7183–9]
RIN 2070–AC17

Acrylamide and N-methylolacrylamide Grouts; Withdrawal of Proposed Ban

AGENCY: Environmental Protection Agency (EPA).

ACTION: Withdrawal of proposed rule.

SUMMARY: EPA is hereby withdrawing a proposed rule that would have prohibited the manufacture, importation, distribution, and use of acrylamide and N-methylolacrylamide (NMA) grouts. In 1991, EPA proposed the rule in order to protect grouters from neurotoxic and carcinogenic risks arising from significant dermal and inhalation exposure to the acrylamide and NMA in these grouts. EPA found that grouters were exposed when using these grouts, even while wearing the best practical personal protective equipment (PPE) available at the time the rule was proposed. EPA has found that there is now affordable PPE that provides adequate protection from exposure to the acrylamide and NMA in these grouts. EPA has determined that as long as appropriate PPE is used during grouting operations, it is no longer necessary to prohibit the use of these grouts to protect the health of grouters.

FOR FURTHER INFORMATION CONTACT: For general information contact: Barbara Cunningham, Acting Director, Environmental Assistance Division (7408M), Office of Pollution Prevention and Toxics, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460; telephone number: (202) 554–1404; e-mail address: TSCA-Hotline@epa.gov.

For technical information contact: John Bowser, Office of Pollution Prevention and Toxics, Chemical Control Division (7405M), Office of Pollution Prevention and Toxics, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460; telephone number: 202–564–8082; e-mail address: bowser.john@epa.gov.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

You may be potentially affected by this action if you manufacture, import, process, distribute in commerce, or use acrylamide or N-methylolacrylamide (NMA) grout. Potentially affected categories and entities may include, but are not limited to:

• Chemical manufacturers or importers (NAICS code 32519), e.g., persons who manufacture (defined by statute to include import) acrylamide or NMA grout.
• Chemical processors (NAICS code 32519), e.g., persons who process acrylamide or NMA grout.
• Chemical distributors (NAICS code 42269), e.g., persons who distribute acrylamide or NMA grout in commerce.
• Municipalities (NAICS code 22132), e.g., persons who use acrylamide or NMA grout for sealing sewer lines and manholes, and for structural water control and geotechnical grouting.
• Grouters and sewer rehabilitators (NAICS code 23491), e.g., persons who use acrylamide or NMA grout for sealing sewer lines and manholes, and for structural water control and geotechnical grouting.

This listing is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be affected by this action. Other types of entities not listed in the table in this unit could also be affected. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether or not this action applies to certain entities. If you have any questions regarding the applicability of this action to a particular entity, consult the technical person listed under FOR FURTHER INFORMATION CONTACT.

II. Background

A. What Action Did the Agency Propose to Take?

In 1991, EPA proposed to prohibit the manufacture, distribution in commerce, and use of acrylamide grout (56 FR 49863, October 2, 1991) (FRL–3767–7). In addition, EPA proposed to prohibit all uses of NMA grout, except its use for
sewer line repair. EPA proposed to ban that use 3 years following promulgation. EPA proposed that action because, based on the information available to EPA at that time, EPA determined that it was necessary to protect grouters (i.e., the individuals who routinely use acrylamide and NMA grouts in the workplace) from the neurotoxic and carcinogenic risks arising from significant exposures to the acrylamide and NMA present in these grouts. EPA found that workers experienced significant exposure even while wearing personal protective equipment (PPE) (Ref. 1). For more information on acrylamide and NMA grouts and their uses, see Unit II. of the preamble to the proposed rule. For more information on the health effects of acrylamide and NMA, see Unit III. of the preamble to the proposed rule. EPA issued the proposed rule under the authority of sections 6(a) and 8(a) of TSCA. EPA based its action on its determination that the use of acrylamide and NMA grouts presented an unreasonable risk of injury to human health, and that a prohibition of their manufacture, distribution in commerce, and use, was the least burdensome action available to protect adequately against these risks.

B. What Grouting Processes Were Covered by the Proposed Rule?

Grout is injected into and around concrete, rock, and soil to strengthen its surrounding soil and “gels,” thereby sealing the fissures and preventing water infiltration. Manhole sealing is accomplished manually by a worker using a hand-held device to inject grout into holes that have been drilled into the sides of the manhole. Manhole sealing is invariably the primary concern.

C. How are Workers Exposed to Acrylamide and NMA Grouts?

The following information is drawn from EPA’s “Assessment of Airborne Exposure and Dermal Contact to Acrylamide During Chemical Grouting Operations”; “Regulatory Impact Analysis of the TSCA Section 6 Final Rule for Acrylamide Grout”; and “Economic Analysis of a Proposed Ban on Chemical Grouts Containing Acrylamide and N-methylolacrylamide,” and the related Addendums (Refs. 1, 2, 3, 4, and 5). Monitoring of acrylamide grouting operations conducted in 1987 by EPA at four grouting sites, as well as the inherent nature of sewer grouting work, established that workers were being dermally exposed to acrylamide despite the use of PPE recommended at the time. A subsequent field evaluation of acrylamide grouting operations by the Occupational Safety and Health Administration (OSHA) (Ref. 6) also confirmed the potential occurrence of significant exposures for workers using the same recommended PPE. The following two sections describe exposures experienced in different applications. Dermal exposures were invariably the primary concern.

1. Dermal exposure—a. Manhole sealing. Sealing manholes presents the greatest opportunity for dermal exposures because it is performed with hand-held injection devices in tightly confined areas for extended periods. Workers engaged in this process must be protected from exposures to liquid acrylamide grout resulting from runoff and splashes. Opportunities for exposure to liquid grout also occur during mixing, gel testing, equipment disassembly, and clean up.

In the 1987 study, EPA measured dermal exposures of workers who were sealing manholes while using the PPE recommended at the time, including disposable Tyvek® coveralls, eye goggles, half-mask air purifying respirators, and rubber gloves. Workers sealing manholes experienced dermal exposure ranging from 2.6 to 5.0 milligrams/hour (mg/h).

b. Sewer line sealing. Sewer line sealing generates less of an opportunity for dermal exposures because it is done with closed-circuit video cameras and remotely controlled grout delivery systems, so that little or no exposures occur during application. As with manhole sealing, however, dermal contact can occur during mixing, gel testing, equipment disassembly, and clean up.

EPA’s 1987 monitoring study found dermal exposure levels in this application ranging from 0.61 to 1.8 mg/h—less than one-third the level experienced sealing manholes.

c. Effectiveness of Tyvek® protective coveralls. In the 1987 study, acrylamide was found on dermal exposure monitoring pads placed inside the Tyvek® protective coveralls and against the skin of workers engaged in both sewer line and manhole sealing activities. This finding indicates that Tyvek® coveralls are not an effective barrier to acrylamide.

2. Inhalation exposure. Inhalation exposure to acrylamide and NMA can occur during mixing, application, equipment disassembly, and clean up. It may also occur when water from spilled solutions evaporates, and the remaining dry powder becomes airborne. In EPA’s 1987 field study, monitored inhalation exposures to acrylamide ranged from one-fifth to one-twentieth of measured dermal exposures. There was little variation in inhalation exposures between sealing manholes and sealing sewer lines; both applications generated virtually identical air concentrations. Eight-hour time-weighted average (TWA) exposures within the breathing zones of workers ranged from 0.008 to 0.12 mg/m$^3$. Three of the breathing zone samples exceeded the American Conference of Governmental Industrial Hygienist’s (ACGIH) Threshold Limit Value (TLV), and the National Institute of Occupational Safety and Health Recommended Exposure Limit (NIOSH REL) of 0.03 mg/m$^3$, although none exceeded the current 0.3 mg/m$^3$ OSHA permissible exposure limit (PEL).

D. What is the Role of PPE in Protecting Workers?

Based on the 1987 field study described above, the Agency concluded that even under the best of circumstances—in which informed and motivated workers were properly using the best practical PPE and practices available at the time the study was conducted—acrylamide exposures would remain unacceptably high. In 2001, while preparing to promulgate the proposed rule, EPA examined current data on PPE for use with acrylamide and NMA grout to determine what equipment is currently in use and whether equipment is available that can provide effective and adequate protection for workers (Refs. 7, 8, 9, 10, 11, 12, 13, and 14). EPA found that...
effective and affordable equipment is now available, although it is not yet in general use by grouting workers.

1. **PPE currently being used with acrylamide grout may not be effective.** In the fall of 2001, EPA conducted a telephone survey to determine what kind of protective equipment was being used by acrylamide grout applicators (Ref. 14). EPA found that the most common type of PPE used to prevent dermal exposure during acrylamide grouting operations was a combination of Tyvek® overalls and gloves. Latex, nitrile, and rubber were the most frequently reported glove types. This type of PPE is the same as was being recommended and used in 1987 when EPA conducted its field study (Ref. 1).

In the EPA field study, dermal exposure monitoring pads were placed under the Tyvek monitoring pads were placed under the skin of the workers. In every case, acrylamide was found on the dermal exposure monitoring pads at the end of the workday. This finding indicates that acrylamide penetrated the Tyvek® protective clothing. The following information is drawn from EPA documentation (Ref. 7). Tyvek® is a proprietary, porous non-woven polyethylene fabric designed for disposable use as protection against exposure to dry particulate matter, not liquids. Because Tyvek® is a porous fabric, the most important factor in determining its effectiveness as a barrier to a liquid is the ability of the liquid to penetrate the pores of the fabric. The ability of a liquid to penetrate the pores is affected, in part, by the total amount of force exerted on the liquid on the outer surface of the suit and by the surface tension of the liquid. If enough pressure is applied to liquid on the outer surface of Tyvek®, it can push the liquid through, e.g., kneeling down while wearing a suit with acrylamide on the outer surface of the suit could put enough pressure on the acrylamide to push it through the suit. In general, the lower the surface tension of a liquid, the easier it is for it to pass through the pores of the fabric. Surface tension causes a liquid to tend to contract to the smallest area possible. In other words, a liquid with a high surface tension would tend to form droplets on the surface of another material. Low surface tension liquids on the other hand tend to spread out over the surface. Liquids with sufficiently low surface tension can pass through the pores without the application of external pressure. EPA has not been able to find empirical data on the surface tension of aqueous acrylamide solutions such as liquid acrylamide grout. EPA estimates, however, that the surface tension of an aqueous acrylamide solution is well below the level at which the manufacturer of Tyvek® says liquids are likely to penetrate the fabric.

The amount of liquid that gets on the fabric is also important, particularly if the liquid has a low surface tension. When a porous fabric such as Tyvek® comes in contact with enough low surface tension liquid, it can readily become saturated, even if the liquid is in a mist form when it makes initial contact with the fabric. Saturation of protective clothing such as a Tyvek® suit may actually increase the potential for dermal exposure, because it can hold the liquid against the skin longer than would have occurred otherwise.

Another concern involves the construction of Tyvek® suits. The seams of these suits are not generally sealed to prevent penetration by liquids. Liquids can pass through gaps in the seams of such a garment regardless of their ability to pass through the fabric. This is particularly true of liquids, which have low viscosity, such as uncured acrylamide grout. Low viscosity fluids flow easily, and have the ability to penetrate cracks and crevices such as the seams of an unsealed garment.

The only way to be sure of the effectiveness of Tyvek® against any liquid is to test the fabric against the liquid. EPA is unaware of any such tests of Tyvek® against aqueous acrylamide solutions in general, or acrylamide grout in particular, although in the 1987 field study, acrylamide was found on dermal exposure pads worn inside Tyvek® protective overalls. The manufacturer of Tyvek® does not claim that it is an effective barrier against liquid acrylamide solutions. While it is possible that PPE made with Tyvek® may be effective in some situations for use with certain liquid chemicals, it appears unlikely that PPE made with Tyvek® will be an effective barrier against aqueous acrylamide solutions.

b. **Concerns regarding the use of latex, nitrile, and generic “rubber” gloves with acrylamide grout.** The following information is drawn from EPA documentation (Ref. 7). EPA believes that gloves should provide an effective barrier to acrylamide for a full work shift (at least 8 hours) to be considered acceptable for use in acrylamide grouting operations. A supplier of nitrile gloves reports that its 15 mil thick nitrile gloves are effective for at least 8 hours of exposure to acrylamide (Ref. 9). Nitrile gloves too thin may not provide adequate protection against uncured acrylamide grout over an 8-hour period. Certain types of rubber gloves may be acceptable for protection against uncured acrylamide grout, but other types may not be. For example, it is likely that natural rubber, or latex will not be effective for protection against uncured acrylamide grout, while butyl rubber is more likely to provide adequate protection. Only testing of the individual material and selected gauge will determine its effectiveness against uncured acrylamide grout.

2. **Effective and affordable PPE for acrylamide is now available.** An affordable and effective PPE combination for protection against dermal exposure to acrylamide during grouting operations would be a PPE product such as a Tychem® SL suit, along with nitrile gloves of an appropriate thickness (Ref. 7). Tychem® SL is a nonporous laminate of Tyvek® and Saranex® 23P film (Ref. 11). It is designed to serve as a barrier to liquids and vapors. It is a widely available material and has been tested by an independent laboratory and shown to provide an effective barrier to acrylamide for 8 hours.

3. **PPE for NMA.** NMA grout is a chemical mixture consisting of about 90% NMA monomer and small amounts of acrylamide, formaldehyde, and methylene bisacrylamide. In EPA’s judgement, the structural properties of NMA grout and acrylamide grout are sufficiently similar that materials that provide an effective barrier against acrylamide are likely to provide an effective barrier to NMA (Ref. 15).

E. **Is the Use of Acrylamide Grout Related to the Finding of Acrylamide in Cooked Food?**

Earlier this year, the Swedish National Food Administration reported that it had found acrylamide in certain foods (Refs. 19, 20, and 21). Government agencies in Great Britain, Norway, and Switzerland subsequently reported similar findings (Refs. 22, 23, 24, 25, 26, and 27). Detection of acrylamide in foods has also been confirmed by the U.S. Food and Drug Administration (FDA) (www.cfsan.fda.gov). Acrylamide was detected in fried and baked foods, but not in raw or boiled foods, leading the researchers to conclude that acrylamide is formed during the cooking process and is not present prior to cooking. The absence of acrylamide in uncooked foods indicates that environmental contamination from the use of acrylamide grout is not the source of the acrylamide. FDA is working with other government agencies to coordinate research related to assessment of risk from exposure to acrylamide. FDA is also investigating the mechanisms by
which acrylamide is formed during the cooking process, and what steps can be
taken to minimize its formation. EPA has no evidence or reason to believe that
use of acrylamide grout is in any way related to the acrylamide found in foods
after cooking.

III. What Action is the Agency Taking Today?

A. Withdrawal of the Proposed Rule

EPA is withdrawing the 1991 proposal to ban the manufacture, importation, distribution, and use of
acrylamide and NMA grouts. This action reflects the Agency’s conclusion that affordable and effective PPE is now
available, and that workers who properly use such equipment can be
adequately protected while using acrylamide and NMA grouts. The
Agency no longer believes that it is necessary to ban acrylamide and NMA
grouts to protect workers.

B. Rationale for Withdrawal of the Proposed Rule

The 1991 proposed rule was based in large part on the determination that, even when grouters used the best
practical protective equipment and techniques available at the time of the
proposal, they were still exposed to potentially significant levels of
acrylamide and NMA. Given the advancements in protective equipment
and techniques that have occurred since the 1991 proposed rule was issued, EPA
determined that effective and affordable means of protecting grouters are now available without banning the
use of acrylamide or NMA.

On January 24, 2002, EPA met with the National Association of Sewer Service Companies (NASSCO), and
Avanti International Incorporated, the sole supplier of acrylamide and NMA
grouts in the United States (Ref. 16). EPA informed them of its findings
concerning the inadequacies of the PPE currently in general use in the industry
and of the existence of more suitable
PPE. At the meeting NASSCO and
Avanti International expressed general agreement with EPA’s findings and pledged to take measures to incorporate the new information into their product stewardship and worker safety programs.

Following the meeting, Avanti International modified its Safe Operating Practices Program (SOPP) manual (Refs. 17, 18, and 28). The revised manual recommends that employees who may be exposed to acrylamide grout use protective clothing made from materials such as Tychem® SL which have been shown to be
effective in laboratory tests with acrylamide. The revised SOPP also
recommends that workers wear chemical resistant boots and gloves that have been shown to be effective against acrylamide, and use full face respirators with P100/organic vapor cartridges. The revised SOPP includes a checklist of appropriate housekeeping procedures for workers to follow when handling acrylamide grout. Avanti International has also developed a program that
addresses safe handling and mixing of chemical grouts, including
demonstrations of the recommended PPE and acrylamide grout mixing/handling procedures (Ref. 28).

NASSCO stated that it has decided to develop an industry standard guideline (ISG) on safe operating procedures for the use of acrylamide grout (Refs. 17 and 18). The ISG is expected to adopt the recommendations on PPE contained in Avanti International’s SOPP.

NASSCO also stated that its guideline on safe operating procedures would be referenced in a baseline standard for the application of chemical grouts being
developed by the American Society for Testing and Materials (ASTM).

EPA welcomes these voluntary commitments by industry to improve
worker safety for grouters. EPA expects that as Avanti International and
NASSCO introduce and fully implement their revised programs, the use of
effective PPE and adherence to improved work practices will become
standard practice throughout the industry. EPA believes that the best way to provide safety information to users of NMA and acrylamide grouts is for grout
suppliers to provide the information to their customers through material safety data sheets (MSDSs), training programs and other product stewardship efforts.

In view of the existence of affordable and effective PPE, and the expectation
that it will be generally adopted by the grouting industry, EPA believes that it is not necessary at this time to promulgate the proposed rule to protect grouting workers. EPA will continue to follow Avanti International’s and NASSCO’s efforts and to encourage them to make appropriate modifications to their worker safety programs. EPA will monitor measures taken to protect workers in all sectors of the grouting industry. If EPA determines that workers are not being protected from exposure to acrylamide or NMA, it will reassess the issue to determine whether further action is necessary.

IV. References

The official record for this action has been established under docket ID
number OPPT–2002–0006. Other
documents relevant to this action can be found in docket OPPTS–62089, which is the docket for the proposed ban on acrylamide and NMA. References
identified below by a number starting with OPPTS–62089 are located in the
docket for the proposed ban. Unit I.B describes the official record and how
you can access the public version of the official record. The following is a listing of the documents that have been placed in the official record for this action:

1. USEPA, OTS, EED, FSB.

“Assessment of Airborne Exposure and Dermal Contact to Acrylamide During Chemical Grouting Operations.” (OPPTS–62089–B1–004) EPA 560/ 5–

2. USEPA, OTS, ETD, RIB.

“Regulatory Impact Analysis of the TSCA Section 6 Final Rule for

3. USEPA, OTS, ETD, RIB. “Economic Analysis of a Proposed Ban on Chemical Grouts Containing Acrylamide and N-

4. USEPA, OTS, ETD, RIB. “Economic Analysis of a Proposed Ban on Chemical Grouts Containing Acrylamide and N-

5. USEPA, OTS, ETD, RIB. “Economic Analysis of the TSCA Section 6 Final Rule for Acrylamide Grout;


7. USEPA, OPPT. “Personal Protective Equipment (PPE) Recommendations and Documentation for Acrylamide Grout”
with attachments by Faraci, J., 2002.


V. Congressional Review Act

The Congressional Review Act, 5 U.S.C. 801 et seq., does not apply because this action is not a rule, as that term is defined in 5 U.S.C. 804(3).

List of Subjects in 40 CFR Part 764

Environmental protection, Administrative practice and procedure, Reporting and recordkeeping requirements.

Dated: November 15, 2002.

Christine T. Whitman, Administrator.

[FR Doc. 02–30470 Filed 11–29–02; 8:45 am]

BILLING CODE 6560–50–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

42 CFR Part 73

RIN 0920–AA08

Possession, Use, and Transfer of Select Agents and Toxins; Notice of Public Meeting

AGENCY: Centers for Disease Control and Prevention, Department of Health and Human Services.

ACTION: Notice of public meeting.

SUMMARY: The Centers for Disease Control and Prevention (CDC) announces a public meeting on Possession, Use and Transfer of Select Agents and Toxins.

DATES: December 16, 2002, 9 a.m.—12 p.m. and 1:30 p.m.—4 p.m.

ADDRESSES: The meeting will be held at the Wilbur J. Cohen Building/Voice of America Building in the Cohen Auditorium. While open to the public, seating capacity may be limited. The Wilbur J. Cohen Building/Voice of America Building is located at 330 Independence Avenue SW, Washington, DC, 20201. No parking is available at the Cohen Building. The nearest Metro stop is Federal Center SW.

FOR FURTHER INFORMATION CONTACT: Minh Thomas, Select Agent Program, Centers for Disease Control and Prevention, 1600 Clifton Road, MS E–79, Atlanta, Georgia 30333, phone (404) 498–2259.

SUPPLEMENTARY INFORMATION: Notice is hereby given of a public meeting to obtain comment on 42 CFR Part 73, Interim Final Rule for Select Agents. On June 12, 2002, the President signed Public Law 107–188, Public Health Safety and Bioterrorism Preparedness and Response Act of 2002. The Act specifies that both the Department of Health and Human Services and the Department of Agriculture will issue their Interim Final Rule implementing the Act on or before 180 days of enactment. DHHS will issue its Interim Final Rule on or about December 9, 2002, and USDA will issue its Interim Final Rule on or about December 9, 2002. These rules will describe implementation of the Act.

Matters to be Considered: The meeting will begin with an overview of the DHHS Interim Final Rule, followed by an overview of the USDA Interim Final Rule. The Department of Justice has also been invited to provide an overview of the personnel requirements specified by the Act. A public comment period will follow the presentations. Each individual or group making public comment will be limited to a total time of 2 minutes.

Special Accommodations: These meetings are physically accessible to people with disabilities. Requests for special accommodations may be directed to Tony Johnson, National Center for Infectious Diseases, Centers for Disease Control and Prevention, 1600 Clifton Road, MS C–19, Atlanta, Georgia 30333, phone (404) 639–0100. Procedure: Any member of the public who wishes to submit oral or written comments at the meeting should contact Angie Frey, Select Agent Program, Centers for Disease Control and Prevention at (404) 498–2272 on or before December 12, 2002. Written comments received by CDC on or before December 12, 2002 will be provided at the meeting. Submit written comments to Select Agent Program, ATTN: Comment for Public Meeting, Centers for Disease Control and Prevention, 1600 Clifton Road, MS E–79, Atlanta, Georgia 30333. Each individual or group wishing to make oral comment will be limited to a total of 2 minutes. Persons attending this meeting are advised that