

## V. Statutory and Executive Order Reviews

Under the Clean Air Act, the Administrator is required to approve a SIP submission that complies with the provisions of the Clean Air Act and applicable Federal regulations. 42 U.S.C. 7410(k); 40 CFR 52.02(a). Thus, in reviewing SIP submissions, EPA's role is to approve state choices, provided that they meet the criteria of the Clean Air Act. Accordingly, this action merely approves state law as meeting Federal requirements and does not impose additional requirements beyond those imposed by state law. For that reason, this action:

- Is not a significant regulatory action subject to review by the Office of Management and Budget under Executive Orders 12866 (58 FR 51735, October 4, 1993) and 13563 (76 FR 3821, January 21, 2011);
  - Is not an Executive Order 13771 (82 FR 9339, February 2, 2017) regulatory action because SIP approvals are exempted under Executive Order 12866;
  - Does not impose an information collection burden under the provisions of the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*);
  - Is certified as not having a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*);
  - Does not contain any unfunded mandate or significantly or uniquely affect small governments, as described in the Unfunded Mandates Reform Act of 1995 (Pub. L. 104-4);
  - Does not have Federalism implications as specified in Executive Order 13132 (64 FR 43255, August 10, 1999);
  - Is not an economically significant regulatory action based on health or safety risks subject to Executive Order 13045 (62 FR 19885, April 23, 1997);
  - Is not a significant regulatory action subject to Executive Order 13211 (66 FR 28355, May 22, 2001);
  - Is not subject to requirements of Section 12(d) of the National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272 note) because application of those requirements would be inconsistent with the Clean Air Act; and
  - Does not provide EPA with the discretionary authority to address, as appropriate, disproportionate human health or environmental effects, using practicable and legally permissible methods, under Executive Order 12898 (59 FR 7629, February 16, 1994).
- In addition, the SIP is not approved to apply on any Indian reservation land

or in any other area where EPA or an Indian tribe has demonstrated that a tribe has jurisdiction. In those areas of Indian country, the rule does not have tribal implications and will not impose substantial direct costs on tribal governments or preempt tribal law as specified by Executive Order 13175 (65 FR 67249, November 9, 2000).

### List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Carbon monoxide, Incorporation by reference, Intergovernmental relations, Lead, Nitrogen dioxide, Ozone, Particulate matter, Reporting and recordkeeping requirements, Sulfur oxides, Volatile organic compounds.

Dated: March 18, 2019.

**Cathy Stepp,**

*Regional Administrator, Region 5.*

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## ENVIRONMENTAL PROTECTION AGENCY

### 40 CFR Part 751

[EPA-HQ-OPPT-2018-0844; FRL-9989-30]

**RIN 2070-AK48**

### Methylene Chloride; Commercial Paint and Coating Removal Training, Certification and Limited Access Program

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Advance notice of proposed rulemaking.

**SUMMARY:** Under the Toxic Substances Control Act (TSCA), EPA has the authority to apply a suite of regulatory tools to address unreasonable risks from chemical substances, including authority to regulate the distribution in commerce for a particular use and to regulate any manner or method of commercial use, to the extent necessary so that the chemical substance no longer presents unreasonable risk. EPA is issuing an advance notice of proposed rulemaking (ANPRM) to solicit public input on training, certification, and limited access requirements that could address any unreasonable risks that EPA could potentially find to be presented by methylene chloride when used for commercial paint and coating removal. Such a program could allow access to paint and coating removal products containing methylene chloride only to commercial users who are certified as properly trained to engage in use

practices that do not present unreasonable risks.

**DATES:** Comments must be received on or before May 28, 2019.

**ADDRESSES:** Submit your comments, identified by docket identification (ID) number EPA-HQ-OPPT-2018-0844, at <http://www.regulations.gov>. Follow the online instructions for submitting comments. Once submitted, comments cannot be edited or withdrawn. EPA may publish any comment received to its public docket. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Multimedia submissions (audio, video, etc.) must be accompanied by a written comment. The written comment is considered the official comment and should include discussion of all points you wish to make. EPA will generally not consider comments or comment contents located outside of the primary submission (*i.e.*, on the web, cloud, or other file sharing system). For additional submission methods (*e.g.*, mail or hand delivery), the full EPA public comment policy, information about CBI or multimedia submissions, and general guidance on making effective comments, please visit <http://www2.epa.gov/dockets/commenting-epa-dockets>.

**Docket.** The docket for this action, identified by docket identification (ID) number EPA-HQ-OPPT-2018-0844, is available at <http://www.regulations.gov>. A public version of the docket is available for inspection and copying between 8:30 a.m. and 4:30 p.m., Monday through Friday, excluding federal holidays, at the U.S. Environmental Protection Agency, EPA Docket Center Reading Room, WJC West Building, Room 3334, 1301 Constitution Avenue NW, Washington, DC 20004. A reasonable fee may be charged for copying.

**FOR FURTHER INFORMATION CONTACT:** For technical information contact: Niva Kramek, Chemical Control Division, Office of Pollution Prevention and Toxics, Environmental Protection Agency, 1200 Pennsylvania Ave. NW, Washington, DC 20460-0001; telephone number (202) 564-4830; email address: [kramek.niva@epa.gov](mailto:kramek.niva@epa.gov).

For general information contact: The TSCA-Hotline, ABVI-Goodwill, 422 South Clinton Ave. Rochester, NY 14620; telephone number: (202) 554-1404; email address: [TSCA-Hotline@epa.gov](mailto:TSCA-Hotline@epa.gov).

**SUPPLEMENTARY INFORMATION:**

## I. Executive Summary

### A. Does this action apply to me?

This notice is directed to stakeholders who may be interested in future EPA regulations on methylene chloride for commercial paint and coating removal. This notice may be of interest to entities that are manufacturing or importing or may manufacture or import methylene chloride (e.g., entities identified under North American Industrial Classification System (NAICS) codes 325 and 324110). It also may be of interest to processors, distributors, and users of methylene chloride for commercial paint and coating removal, as well as individuals with expertise in worker training to reduce chemical exposures, people with expertise to certify a level of competence in managing chemical risks, and those that distribute chemicals at retail or business to business sales outlets. Industrial hygienists, health and safety professionals, trade unions, medical professional, occupational health experts, and non-governmental organizations may have interest and expertise.

Since other entities may also be interested, the Agency has not attempted to describe all the specific entities and corresponding NAICS codes for entities that may be interested in or affected by this action.

If you have any questions regarding the applicability of this notice to a particular entity, consult the technical information contact listed under **FOR FURTHER INFORMATION CONTACT**.

### B. What is the Agency's authority for taking this action?

Under TSCA section 6(a) (15 U.S.C. 2605(a)), if EPA determines that a chemical substance presents an unreasonable risk of injury to health or the environment under the conditions of use, EPA must by rule apply one or more requirements to the extent necessary so that the chemical substance or mixture no longer presents such risk. The determination of unreasonable risk is made without consideration of costs or other non-risk factors.

TSCA sections 6(a)(2) and (5) authorize EPA to regulate the distribution in commerce for a particular use and any manner or method of commercial use, respectively, of a chemical found to present unreasonable risk. Potential training, certification, and limited access program requirements could be promulgated under those authorities as part of rulemaking under the authority of TSCA section 6(a).

With respect to a chemical substance listed in the 2014 update to the TSCA Work Plan for Chemical Assessments, for which a completed risk assessment was published prior to the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act, TSCA section 26(l)(4) (15 U.S.C. 2625(l)(4)) provides that EPA as a matter of discretion "may publish proposed and final rules under [TSCA section 6(a)] that are consistent with the scope of the completed risk assessment for the chemical substance and consistent with other applicable requirements of [TSCA section 6]." Methylene chloride is such a chemical substance. It is listed in the 2014 update to the TSCA Work Plan and the 2014 final risk assessment includes consumer and commercial uses of paint and coating removal (Refs. 1 and 2).

### C. What action is the Agency taking?

EPA is issuing this ANPRM to solicit public input on training, certification, and limited access requirements that could address any unreasonable risks that EPA could potentially find to be presented by methylene chloride in commercial paint and coating removal. Such a program could allow access to paint and coating removal products containing methylene chloride only to commercial users who are certified as properly trained to engage in use practices that ensure that the chemical use does not present any such unreasonable risks.

### D. Why is the Agency taking this action?

EPA is taking this action to receive public input on the development of training, certification, and limited access requirements that could address any unreasonable risks that EPA could potentially find to be presented by methylene chloride in commercial paint and coating removal under TSCA section 6(a).

For methylene chloride in consumer paint and coating removal, EPA separately has made a final determination of unreasonable risk and has issued a final rule under TSCA section 6(a) to address those unreasonable risks, elsewhere in this issue of the **Federal Register**. For commercial paint and coating removal uses of methylene chloride, EPA has not finalized the proposed determination of unreasonable risk which published in the **Federal Register** of January 19, 2017 (82 FR 7464) (FRL-9958-57). EPA continues to explore regulatory options that could address any commercial uses of methylene chloride in paint and coating removal that EPA could potentially find to present unreasonable risks. EPA would finalize any

determination of unreasonable risk as part of a final regulation.

## II. Background

### A. Context of This ANPRM

In 2017, EPA issued a proposed rule on methylene chloride in paint and coating removal uses (82 FR 7464, January 19, 2017) (FRL-9958-57). EPA received public comments indicating interest in a potential training, certification, and limited access program to address unreasonable risks for commercial uses of methylene chloride. Those and other comments received, as well as EPA's proposed and final rule and supporting materials, including the report of a Small Business Advocacy Review (SBAR) Panel, are in Docket Number EPA-HQ-OPPT-2016-0231.

Specifically, when developing the proposed rule, EPA engaged in discussions with experts on and users of paint removers (Ref. 3) and conducted formal consultations (82 FR 7525). For example, EPA is required by the Regulatory Flexibility Act to convene an SBAR Panel and seek information and advice from Small Entity Representatives (SERs), who are individuals that represent small entities likely to be subject to any final regulations. During the SBAR Panel for EPA's planned proposed rule for Methylene Chloride and N-Methylpyrrolidone (NMP) in Paint Removers, a SER recommended that EPA consider and seek public comment on a training and certification program similar to the Lead Renovation, Repair and Painting (RRP) rule. Specifically, the comments from SERs during the pre-panel meeting on March 17, 2016, and the oral and written comments during the panel meeting on June 15, 2016, include: (1) A suggestion from a commercial user that in the absence of a ban on methylene chloride, EPA consider limiting the sale of methylene chloride to paint stores or to licensed painters; (2) support from a commercial furniture refinisher for a regulatory option that would restrict methylene chloride use to trained and licensed users while making the product unavailable to consumers; (3) the description from a commercial painter of how some states handle licensing for paint contractors. The SER stated that "licensing could be similar to the Lead RRP rule. The licensing process [sic] annually could be somewhat costly (e.g., \$400-\$500), which could possibly keep the average homeowner at bay" (Ref. 4).

The proposed rule described a training and certification program similar to the lead-based paint RRP

program to reduce proposed unreasonable risks from methylene chloride in paint and coating removal as a regulatory option receiving limited evaluation. EPA asked for comments on this type of program. EPA received one comment in response (from the Environmental Defense Fund), which indicated strong opposition to the proposal due to the challenges the commenter cited with EPA's implementation of the RRP rule and the higher costs of a training and certification program than the proposed option that prohibited most manufacture, processing, distribution, and commercial use of methylene chloride for paint and coating removal (Ref. 5).

In a related comment on the proposed rule, the Department of Defense said that EPA should adopt for methylene chloride a risk management approach similar to the second co-proposed regulatory option for another chemical used in paint and coating removal, N-methylpyrrolidone (NMP), which, among other requirements, would have required use of adequate personal protective equipment and hazard communication for commercial users, so that the chemical would be removed from general consumer use yet preserved for commercial and industrial uses where there are no technically feasible substitutes and where workers can be protected using updated, properly adopted industrial hygiene standards (Ref. 6).

Given these comments and information provided by the public, EPA is interested in soliciting additional public input, through this ANPRM, for a program for training, certification, and limited access for methylene chloride for commercial paint and coating removal.

Furniture refinishing with methylene chloride is an example of one of these uses. In the proposed rule, EPA preliminarily identified unreasonable risks from exposures during furniture refinishing with methylene chloride but did not propose restrictions on this use; instead, EPA was interested in gathering additional information on this use of methylene chloride, including the availability of substitutes. To this end, EPA, in collaboration with the Small Business Administration's (SBA) Office of Advocacy, conducted a workshop on furniture refinishing in Boston, MA on September 12, 2017 (82 FR 41256) (FRL-9966-83). A transcript of the meeting and speaker presentations are available in Docket Number EPA-HQ-OPPT-2017-0139. Some commenters and workshop participants supported a prohibition on methylene chloride in

commercial furniture refinishing in the interest of protecting the health of workers, while others opposed such a restriction, stating that a prohibition on methylene chloride would severely affect their ability to do business in this sector.

Following the close of the comment period for the proposed rule, in May 2018, the Halogenated Solvents Industry Alliance, a trade association that represents several formulators of paint and coating removal products containing methylene chloride, submitted a White Paper through SBA to EPA. The White Paper includes a discussion of training and certification for methylene chloride in paint and coating removal, and encourages EPA to adopt a training, certification, and limited access program for methylene chloride in paint and coating removal similar to that enacted in the United Kingdom, which is discussed in more detail in Unit II.B (Ref. 7).

#### *B. Other Training, Certification, and Limited Access Programs*

EPA has some experience with programs that require training, certification, or restricted access to chemicals. EPA has also identified additional regulatory or voluntary programs that members of the public may find useful to consider as examples when preparing their comments.

*1. Restricted Use Pesticides under FIFRA.* Under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), some pesticides are categorized as restricted use pesticides (RUPs). RUPs are not available for purchase or use by the general public. The classification restricts a product, or its uses, to use by a certified applicator or someone under the certified applicator's direct supervision. Federal law requires any person who uses or supervises the use of RUPs to be certified in accordance with EPA regulations and state, territorial and tribal laws. There are 14 federal categories of certification (40 CFR 171.101). EPA authorizes states, territories, Tribes, and federal agencies to certify applicators. Applicators must be recertified periodically to maintain certification. This is generally accomplished through continuing education courses every three to five years. Training is primarily conducted by university extension services as well as by associations, industry, non-profit organizations, private companies, and federal and state government agencies. RUPs may only be purchased by certified applicators or persons purchasing for use by a certified applicator; dealers must maintain records of each RUP sale, including the

identity of the buyer, the licensure of the certified applicator, and the identity and quantity of the RUP product sold. Regulation and enforcement related to RUPs is primarily by states, territories, and tribes, whose certification plans must meet EPA's standards, though they may have differing regulations regarding certification, use, and dealer registration. EPA's role is to establish minimum standards of competency for pesticide applicators that apply or supervise the use of RUPs; provide oversight of state, territory, Tribal and federal agency certification programs to ensure they meet certain standards; and to manage the risks of RUPs through mandatory label use directions and precautions established through registration and reregistration processes (Ref. 8).

*2. Refrigerants Certification under the Clean Air Act.* EPA regulations under sections 608 and 609 of the Clean Air Act restrict the purchase of refrigerants to individuals with certifications (or their employees, in certain circumstances); these refrigerants are sold only through refrigerant distributors and wholesalers (with some exceptions for automotive equipment). Distributors must maintain records of sales. If certain requirements are met, small volumes of automotive refrigerants can be directly sold to consumers. Generally, EPA requires that anyone who maintains, services, repairs, or disposes of refrigeration and air conditioning equipment in a manner that could release refrigerants into the atmosphere must be a certified technician. Training is by third parties that are certified by EPA, and technicians are required to pass an EPA-issued test. The tests are specific to the type of equipment the technician seeks to work on. Tests must be administered by an EPA-approved certifying organization. There are four types of certifications under section 608 (by type of appliance). EPA's role is to provide exam questions and to certify technician certification programs. EPA does not maintain a database of certified technicians; instead, certification (in the form of physical cards) are provided by the certification provider, who maintains records of technicians' certification (40 CFR 82.161).

There is also a separate technician certification program for anyone who services motor vehicle air conditioning for consideration. EPA requires training of technicians under section 609 by third parties that are certified by EPA. EPA reviews and approves the training materials. There is an exemption for consumer do-it-yourself servicing of motor vehicle air conditioning that does

not exist for servicing of stationary refrigeration and air conditioning equipment (40 CFR 82.161).

3. *Lead-Based Paint Renovation, Repair and Painting (RRP) and Abatement Programs.* EPA has extensive understanding of certification and training requirements from implementing the Residential Lead-based Paint Hazard Reduction Act. Specifically, the Lead Renovation, Repair, and Painting Rule requires that firms performing renovation, repair, and painting projects that disturb lead-based paint in homes, child care facilities and pre-schools built before 1978 have their firm certified by EPA (or an EPA authorized state or Tribe), use certified renovators who are trained by EPA-approved training providers and follow lead-safe work practices. Training is by third parties who are accredited by EPA or by the state (in 14 states) or one Tribe. EPA or an authorized state or Tribe provides certification to firms or individuals who have completed the training course accredited by EPA or an EPA authorized program. Both trainers and renovators must be certified. Likewise, EPA's Lead Abatement Program regulations establish training and certification requirements for individuals and firms that provide lead-based paint inspection, risk assessment, project design, and abatement services in homes, child care facilities and pre-schools built before 1978. Training for this program is also provided by third parties that have been accredited by EPA or one of the 44 authorized programs in 39 states, 3 Tribes, Puerto Rico, or the District of Columbia (40 CFR 745 and 73 FR 21692, April 22, 2008).

4. *Asbestos Certification Program.* In addition, under the Asbestos Hazard Emergency Response Act, EPA has established a training and accreditation program for asbestos professionals who conduct asbestos inspections or who design or conduct asbestos response actions at schools and public and commercial buildings. Most states are authorized to administer these requirements (40 CFR 763.80).

5. *European Restriction.* A training, certification, and limited access program for methylene chloride is already in place outside the United States. In the European Union, the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) restricts the sale and professional use of methylene chloride in paint and coating removal. Under the conditions of the REACH restriction, distribution to consumers is prohibited, but member states may allow professionals to use paint strippers and allow methylene

chloride-containing paint strippers to be placed on the market for use by those professionals, provided that the member state establishes appropriate provisions for the protection of the health and safety of those professionals, including a certification to demonstrate proper training and competence to safely use paint strippers containing methylene chloride. REACH also requires that the training must cover, at a minimum: (a) Awareness, evaluation and management of risks to health, including information on existing substitutes or processes, which, under their conditions of use, would be less hazardous to the health and safety of workers; (b) use of adequate ventilation; and (c) use of appropriate personal protective equipment that complies with other regulations (Ref. 9).

6. *United Kingdom Certification Program.* In the United Kingdom, methylene chloride is regulated through various European Union and UK regulations, including REACH; EU Classification, Labelling and Packaging Regulations; the UK REACH Enforcement Regulations; and other UK regulations covering workers. The United Kingdom decided to allow use of methylene chloride by professionals primarily to avoid hazards created when renovating surfaces with lead-based paint. Currently the United Kingdom's certification program is the only known training program that exists in the European Union as a derogation to the REACH restriction on methylene chloride in paint and coating removal. The Health and Safety Executive has a program that restricts use of methylene chloride for paint and coating removal to trained professionals. To purchase methylene chloride, professionals must pay a fee to a third-party training provider and take a four-hour course on safe use practices. After the training, the person must pass an examination to demonstrate competency, and obtain certification. Trained professionals can then purchase the product at specialty trade outlets and must demonstrate that they have obtained certification. Internet sales must also confirm that the purchaser has a certification. The UK government maintains a data base of professionals with a unique identifying number that provides proof of meeting the certification requirements. The program originated in 2016, and, to date, approximately 500 professionals have applied for certification. Consumer use of methylene chloride-containing paint strippers is not permitted in the United Kingdom (Ref. 10).

7. *Methylene Chloride Standard.* The Occupational Safety and Health Administration (OSHA) requires

employers to protect employees from occupational exposure to methylene chloride. OSHA's methylene chloride standard specifies the permissible exposure limits for methylene chloride and also includes provisions for, among other things, exposure monitoring, engineering controls, work practice controls, medical surveillance, respiratory protection, hazard communication, employee training, personal protective equipment, and recordkeeping (29 CFR 1910.1052).

The OSHA methylene chloride standard requires, among other information and training requirements, that the employer train affected employees as required under OSHA's hazard communication standard (29 CFR 1910.1200, 29 CFR 1915.1200, or 29 CFR 1926.59, as appropriate). The training requirements of the hazard communication standard include at least: The methods and observations that may be used to detect the presence or release of a hazardous chemical in the work area; the hazards of the chemicals in the work area; the measures employees can take to protect themselves from these hazards, such as appropriate work practices, emergency procedures, and personal protective equipment to be used; and the details of the hazard communication program developed by the employer, including, among other things, the safety data sheet.

The OSHA methylene chloride standard also contains, among other information and training requirements, provisions that are triggered only when an employee's exposure exceeds or can reasonably be expected to exceed the standard's "action level" of 12.5 parts per million (ppm) calculated as an eight (8)-hour time-weighted average (TWA). In such cases, for example, the employer must inform each affected employee of the quantity, location, manner of use, release, and storage of methylene chloride and the specific operations in the workplace that could result in exposure to methylene chloride, particularly noting where exposures may be above the standard's permissible exposure limits.

OSHA's methylene chloride standard's respiratory protection provisions require respirator use during periods when an employee's exposure to airborne concentrations of methylene chloride exceeds the standard's permissible exposure limits and at other times specified in the standard. The standard also requires employers to implement a respiratory protection program in accordance with paragraph (b) through (m) (except paragraph (d)(1)(iii)) of OSHA's respiratory

protection standard, which covers each employee required by the standard to use a respirator. The respiratory protection standard specifies that: The employer must develop and implement a written respiratory protection program with required worksite-specific procedures and elements; the program requirements must be administered by a suitably-trained program administrator; and the program must include provisions for employee training, as well as respirator selection, fit testing, medical evaluation, respirator use, and respirator cleaning, maintenance, repair, and other provisions. The respirator standard also requires that employers ensure that employees required to use respirators be trained and able to demonstrate knowledge central to the safe use of respirators, including, for example, knowledge on why the respirator is necessary and how improper fit, usage, or maintenance can compromise the protective effect of the respirator.

The OSHA standards also contain requirements on the timing and frequency of training (*e.g.*, initial training, retraining, etc.). Please consult OSHA's methylene chloride, hazard communication, and respiratory protection standards for additional requirements (including additional information and training requirements) contained in those standards.

### III. Training, Certification, and Limited Access for Methylene Chloride

One regulatory approach EPA is considering is a regulation that could limit access to methylene chloride for commercial paint and coating removal by only allowing use by those individuals who have certified that they are able to engage in safe work practices such that any unreasonable risk is not present. EPA acknowledges that other, more restrictive regulatory approaches may be appropriate for some conditions of use of methylene chloride for which EPA determines unreasonable risk is present. Several considerations related to commercial uses of methylene chloride for paint and coating removal suggest that regulations allowing for limited access to the chemical, rather than a full prohibition on distribution for all commercial paint and coating removal, could be effective at addressing any unreasonable risks that EPA could potentially find to be present while allowing continued use. For example, workplaces that have robust environment, safety and health protection programs and are in compliance with OSHA's methylene chloride standard (which contains requirements for the use of engineering

controls, personal protective equipment, training, and other requirements to protect employees from methylene chloride exposure) are likely to address any risks EPA could potentially find to be present from exposure to methylene chloride during commercial paint and coating removal so that they are no longer unreasonable. EPA notes that because more than 90 percent of methylene chloride manufactured (including imported) in the U.S. is estimated to be used for purposes other than paint and coating removal, employers and employees in those sectors may have considerable experience in work practices or other controls that could be transferred to paint and coating removal processes (Ref. 11).

While all comments regarding any aspect of a training, certification, and limited access program for methylene chloride for commercial paint and coating removal are welcome, comments on the following key areas are requested.

1. Is a training, certification, and limited access program an appropriate method for reducing any unreasonable risks that EPA could potentially find to be presented by commercial paint and coating removal with methylene chloride?

2. Would such a program address any such unreasonable risks such that those risks are no longer unreasonable?

3. What metrics should EPA consider using as part of measuring the effectiveness of a training, certification, and limited access program for methylene chloride for commercial paint and coating removal? What types of measurements or indicators could EPA use to evaluate how a training, certification, and limited access program addresses any unreasonable risk?

4. Would a training, certification, and limited access program allow some commercial paint and coating removal with methylene chloride to continue? Would the program create barriers to use such that most commercial operations would choose not to use methylene chloride for paint and coating removal in favor of less restricted alternatives?

5. Do commercial users of methylene chloride for purposes other than paint and coating removal have experience with work practices, controls, training, or other topics that EPA should consider?

6. Should EPA consider requirements other than a training, certification, and limited access program for commercial uses of methylene chloride in paint and coating removal?

#### A. Training

Training for safe work practices could be part of the requirements needed to obtain a certification of ability to engage in safe work practices for commercial paint and coating removal with methylene chloride. The training required could include training on: How to handle, use, and dispose of methylene chloride for paint and coating removal so that any unreasonable risks EPA could potentially find to be present are not present; proper use of engineering controls and personal protective equipment; accident prevention; emergency response; preparing and maintaining proper records; the hazards associated with use of methylene chloride for paint and coating removal; the route(s) of worker exposure; methods of detecting the presence of methylene chloride; symptoms of overexposure; medical treatment for overexposure; and explanation of Safety Data Sheets and labeling requirements. EPA could also require that the training be tailored to describe measures that address specific exposure scenarios for methylene chloride for paint and coating removal, such as those scenarios that have resulted in fatalities.

While all comments regarding any aspect of training for safe work practices regarding methylene chloride for commercial paint and coating removal are welcome, comments on the following key areas are requested.

1. Who should receive training? Individual commercial users, employers, or both?

2. Who should provide training? What should EPA's role be? Training providers could be EPA or a third party, including states, manufacturers, trade associations, or others.

3. What topics should the training include?

4. Should EPA accredit training providers? Should EPA accept state, Tribal, or territorial accreditation of training providers?

5. How should the training be delivered?

6. How long should the training be?

7. Should periodic refresher training or updates be required?

8. Should there be a fee for training and/or for accreditation of training providers? If so, what would be an appropriate fee?

9. Can training for commercial use of methylene chloride in paint and coating removal be combined with training on another topic, such as a chemical with similar risks or properties? Could training on methylene chloride be part of a larger training for a particular

industry sector (such as certification in automotive repair)?

10. Should there be different training for distributors, workers, and employers? What should be the training for self-employed commercial users, or for users who may also be employee-owners?

11. As discussed in detail earlier in this Notice, OSHA requires employers to protect employees from occupational exposure to methylene chloride. What experiences do employers or employees have complying with OSHA's regulatory scheme or the regulatory scheme of an OSHA-approved State Plan? How should any training requirements EPA develops complement and/or supplement OSHA's regulatory scheme?

12. Are there any examples of training programs that would be suitable for commercial use of methylene chloride in paint and coating removal?

13. What are the metrics for evaluating whether or not training is successful in educating the commercial user on risks of methylene chloride in paint and coating removal, and how to reduce exposures so that those risks are addressed?

14. Should there be a mandatory period of apprenticeship allowing for monitoring and observation after the training where the employer and/or management could interject if safe work practices are not properly adhered to?

15. How can training address the needs of diverse work scenarios and commercial users with various levels of experience with methylene chloride and safe work practices?

16. How could training ensure that workers in facilities where methylene chloride is used for paint and coating removal but who are not directly engaged in that activity are not subject to any unreasonable risks EPA could potentially find to be present?

17. What would be required for successful completion of training?

18. Are there existing best practices in training, certification, or accreditation programs from states, industry, or other stakeholders EPA should consider?

19. What types of commercial uses of methylene chloride might be good or poor candidates for a training, certification, and limited access program?

20. How should EPA involve stakeholders in the development of content for training, certification and limited access programs?

### B. Certification

This component of the program could mandate that commercial users be certified as able to engage in safe work practices with methylene chloride for

paint and coating removal. In the context of this ANPRM, certification could provide documentation to EPA, distributors, and, potentially, interested members of the public that an individual is able to engage in safe work practices with methylene chloride for commercial paint and coating removal. To the extent knowledge of other pertinent Federal or state requirements (e.g., OSHA occupational health standard for methylene chloride) is considered an integral component of the ability to engage in safe work practices, attesting to such knowledge may be a prerequisite to or a part of obtaining certification.

While all comments regarding any aspect of certification of ability to engage in safe work practices regarding methylene chloride for commercial paint and coating removal are welcome, comments on the following key areas are requested.

1. How can commercial users demonstrate to EPA that they will be engaging in commercial paint and coating removal (rather than personal use or consumer paint and coating removal)?

2. Who should be certified? Individual commercial users, workplaces/firms, or both?

3. Who should be the certifying body? What should EPA's role be?

4. What requirements for certification would be most effective for commercial users to demonstrate that they can engage in safe work practices for paint and coating removal with methylene chloride?

5. Should certification be awarded upon completion of training? What type of training programs would be acceptable for earning certification? Would they need to provide specific information on methylene chloride, or would general safe handling and use of volatile chemicals be sufficient? How would interested commercial users know which training programs would allow them to earn the certification?

6. If certification was awarded at the completion of training, should a test be required? If so, what kind (e.g., knowledge tests, practical demonstrations, or other types of exams)? Who should develop the exam: EPA or third parties? Should EPA develop a program for, separately, certifying testing bodies?

7. Should certification be earned based on other criteria, such as evidence of exposure reduction equipment or practices already in place? If so, what documentation would be suitable? How recent would such documentation need to be? If such certification included documentation of a business

relationship or contract with a workplace safety consultant, what type of credential or licensing would that consultant be required to have?

8. Should certification be earned based on development of a workplace plan for exposure reduction, similar to the requirements of the National Emission Standards for Hazardous Air Pollutants: Paint Stripping and Miscellaneous Surface Coating Operations at Area Sources (73 FR 1737, January 9, 2008)? Under those regulations, commercial users are required to notify EPA (or a delegated State authority) that they have developed a management plan but are not required to submit the plan to EPA. Instead, they must "keep a written copy of the plan on site and post a placard or sign outlining the evaluation criteria and management techniques" (73 FR 1742). Should similar criteria be required for certification of ability to engage in safe work practices for methylene chloride for paint and coating removal?

9. Should certification be earned in connection with a separate but related credential or license? Should certification be linked to other expertise, such as credentials or licensing by third parties in chemical safety, occupational or industrial health and safety, or other relevant area of expertise? If so, what specific credential or licenses should EPA consider? How could EPA verify that those third-party credentials or licenses are in good standing? Similarly, should an entity other than EPA provide certification of ability to engage in safe work practices with methylene chloride for paint and coating removal?

10. What information should be provided by an individual or employer who is seeking certification? Should EPA require personal information such as name and phone number, employment information such as name and address of employer? Should EPA require confirmation of status as a commercial user? If so, what documentation should be provided?

11. Should individuals or employers seeking certification be required to submit a statement that they are able to engage in safe work practices with methylene chloride for commercial paint and coating removal?

12. What kind of records should be required for certification? How long should records be kept by either individual commercial users or employers?

13. EPA places particular emphasis on the public health and environmental conditions affecting minority populations, low-income populations, and indigenous peoples. Additionally,

under TSCA, EPA is required to consider risks to susceptible subpopulations such as workers. How could EPA ensure that any requirements for certification are clearly communicated to all potential certified commercial users, and that all workers are able to engage in safe work practices for methylene chloride in paint and coating removal?

14. Should existing standards for the development of certification programs be considered? If so, should they be voluntary or required? Specifically, ASTM E2659–018 is a standard for developing and administering a quality certificate program. The standard includes requirements for the both certifying entity and for the certificate program for which it issues certificates. Because ASTM–E2659–18 does not address guidance pertaining to certification of individuals, ISO/IEC 17024: 2012 would be used to develop and maintain a certification program for individuals; certification could demonstrate competency and the ability to use methylene chloride for paint and coating removal properly.

15. How can commercial users in industry sectors that are prohibited from using methylene chloride in paint and coating removal be identified if they attempt to obtain certification?

16. Should EPA or a third party have a centralized database of certified commercial users? If so, what information should be available internally (to EPA and other authorized regulatory entities) and externally (for distributors and other members of the public)?

17. How could EPA best balance the protection of certified commercial users' personal information with the need for distributors to access some of that information? Should access to such a database be limited to EPA and authorized, or permitted, distributors? How could EPA ensure that individuals with the same or similar personal details (such as name or business address) can be distinguished in the database?

18. If EPA should not have a centralized database of certified commercial users, where should the record of certification be maintained? How should distributors access and verify that certification?

19. Should certified commercial users also receive an identification card or physical credential? If so, what elements would users find useful for demonstrating that a physical credential was legitimate? How could such a credential be replaced if lost?

20. Should EPA propose to allow methylene chloride for commercial

paint and coating removal under the supervision of a certified commercial user?

21. What if a certified user changes employers? Would a new certification be required? Should users be required to update information on employment?

22. Under what circumstances should EPA rescind certification?

23. Should certification include a fee? If so, what would be an appropriate fee?

24. Should certification expire?

Would requirements for renewal be different from initial certification requirements? How frequently should certifications be renewed, if ever?

### *C. Limited Access to Methylene Chloride*

This component of the program could limit the sale of methylene chloride for paint and coating removal. This could allow for continued access and use of methylene chloride for specific paint and coating removal uses by certified commercial users or trained individuals while preventing access to methylene chloride-containing paint and coating removers by non-certified commercial users.

While all comments regarding any aspect of a program to provide for limited access to methylene chloride for commercial paint and coating removal to certified commercial users are welcome, comments on the following key areas are requested.

1. Should there be restrictions on how methylene chloride for paint and coating removal is distributed? Should certain types of distributors be prohibited from distribution of methylene chloride for paint and coating removal?

2. How should distributors verify that a prospective purchaser (individual or commercial entity) is certified? Should there be an online database or examination of physical credential or both? Are there other methods, or combination of methods, that EPA should consider?

3. How can distributors identify commercial users? Should they be required to do so?

4. How could distributors identify whether the identity of the prospective purchaser matched the commercial user to which certification was awarded? Should distributors be required to check government-issued photo ID or verify identity in another way? Should distributors develop their own protocols?

5. How could e-commerce sales be subject to a limited access program? For example, how at the point of sale and/or at the point of delivery can certification status of the purchaser be verified? How could online purchasers

demonstrate that they were certified to purchase the product, and confirm their identity?

6. A key component of a program that limits access to methylene chloride would be how, at the point of sale, a distributor would verify that a prospective purchaser is a certified commercial user of methylene chloride for paint and coating removal. Should EPA detail specific requirements for how the distributor checks those certifications, trains any staff that sells the products, or maintains records? Should distributors be responsible for developing protocols that would be sufficient to limit access only to certified commercial users?

7. What costs do distributors estimate they would incur under a limited access program? Specifically, what would be the costs for: Equipment needed to physically restrict access to the chemical products; equipment and staff time for verifying certification and identity of the commercial user purchasing the product; training and staff time to understand the required procedures; and generating and maintaining records?

8. Should a permit for distributors be required? If so, what should the cost be? What requirements would need to be met for issuance of a distribution permit? Should permits be required to be renewed?

9. What records should be maintained? These could include records that document how certification was verified for each purchaser of methylene chloride for paint and coating removal, how the distributor ensures that only individuals with certification are able to access methylene chloride for paint and coating removal; and details of sales of the chemical for paint and coating removal, including the name and certification identifier of each purchaser of methylene chloride, and the quantity of the chemical product sold. How long should such records be maintained?

10. To what extent, if any, should additional parties—such as states, academia, or trade associations—be involved in a limited access program development or implementation?

11. What might the effects of a limited access program be on a small business?

12. Should a potential future online database of certified commercial users be incorporated into existing EPA databases (such as those under CDX), or should it be a stand-alone, sole-purpose database?

13. What experiences do manufacturers, processors, or distributors have with sales of methylene chloride for paint and

coating removal to professional users in the UK, given the requirements for limited access that are in place there?

#### IV. Request for Comment and Additional Information

EPA is seeking comment on all information outlined in this ANPRM and any other information, which may not be included in this notice, but which you believe is important for EPA to consider.

EPA specifically invites public comment and any additional information in response to the questions and issues identified in Unit III. Instructions for providing written comments are provided under **ADDRESSES**, including how to submit any comments that contain CBI. No one is obliged to respond to these questions, and anyone may submit any information and/or comments in response to this request, whether or not it responds to every question in this notice.

#### V. References

The following is a listing of the documents that are specifically referenced in this document. The docket includes these documents and other information considered by EPA, including documents referenced within the documents that are included in the docket, even if the referenced document is not physically located in the docket. For assistance in locating these other documents, please consult the technical person listed under **FOR FURTHER INFORMATION CONTACT**.

1. EPA. TSCA Work Plan Chemicals. [http://www.epa.gov/sites/production/files/2014-02/documents/work\\_plan\\_chemicals\\_web\\_final.pdf](http://www.epa.gov/sites/production/files/2014-02/documents/work_plan_chemicals_web_final.pdf). Retrieved February 25, 2016.
2. EPA. TSCA Work Plan Chemical Risk Assessment Methylene Chloride: Paint Stripping Use. CASRN 75-09-2. EPA Document# 740-R1-4003. August 2014. Office of Chemical Safety and Pollution Prevention. Washington, DC. [https://www.epa.gov/sites/production/files/2015-09/documents/dcm\\_opptworkplanra\\_final.pdf](https://www.epa.gov/sites/production/files/2015-09/documents/dcm_opptworkplanra_final.pdf).
3. EPA. Summary of Stakeholder Engagement, Proposed Rule Under TSCA § 6 Methylene Chloride and NMP in Paint and Coating Removal. 2016.
4. EPA. Final Report of the Small Business Advocacy Review Panel on EPA's Planned Proposed Rule on the Toxic Substances Control Act (TSCA) Section 6(a) as amended by the Frank R. Lautenberg Chemical Safety for the 21st Century Act for Methylene Chloride and N-Methylpyrrolidone (NMP) in Paint Removers. Office of Chemical Safety and Pollution Prevention. Washington, DC. 2016.
5. Public Comment. Comments submitted by Lindsay McCormick, Chemicals and Health Project Manager, on behalf of

Environmental Defense Fund. EPA-HQ-OPPT-2016-0231-0912.

6. Public Comment. DoD Comments on MeCl and NMP 19 Jan 17 Notice of Proposed Rulemaking Methylene Chloride and N-Methylpyrrolidone; Rulemaking under TSCA Section 6(a). EPA-HQ-OPPT-2016-0231-0519.
7. Halogenated Solvents Industry Alliance. Responsibly Regulating Methylene Chloride in Paint Removal Products: an Alternative Approach to Flawed Proposal Published by EPA on January 19, 2017.
8. EPA. How to Get Certified as a Pesticide Applicator. <https://www.epa.gov/pesticide-worker-safety/how-get-certified-pesticide-applicator>. Accessed December 18, 2018.
9. REACH Restriction. Annex XVII to REACH—Conditions of restriction. Entry 59 Dichloromethane containing Paint Strippers. <https://echa.europa.eu/documents/10162/0ea58491-bb76-4a47-b1d2-36faa1e0f290> (Accessed December 18, 2018).
10. The Reach Enforcement (Amendment) Regulations 2014 (SI 2014/2882). <http://www.legislation.gov.uk/uk/si/2014/2882/made>.
11. EPA. Economic Analysis of Final Rule TSCA Section 6 Action on Methylene Chloride in Paint and Coating Removal (EPA Docket EPA-HQ-OPPT-2016-0231; RIN 2070-AK07). Office of Pollution Prevention and Toxics. Washington, DC.

#### VI. Statutory and Executive Order Reviews

Under Executive Order 12866 (58 FR 51735, October 4, 1993) and Executive Order 13563 (76 FR 3821, January 21, 2011), this action was submitted to the Office of Management and Budget (OMB) for review. Any changes made in response to OMB recommendations have been documented in the docket.

Since this document does not impose or propose any requirements, and instead seeks comments and suggestions for the Agency to consider in possibly developing a subsequent proposed rule, the various other review requirements that apply when an agency imposes requirements do not apply to this action. Nevertheless, as part of your comments on this document, you may include any comments or information that you have regarding the various other review requirements.

In particular, EPA is interested in any information that could help the Agency to assess the potential impact of a rule on small entities pursuant to the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*); to consider voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act (NTTAA) (15 U.S.C. 272 note); to consider environmental health or safety

effects on children pursuant to Executive Order 13045, entitled “Protection of Children from Environmental Health Risks and Safety Risks” (62 FR 19885, April 23, 1997); or to consider human health or environmental effects on minority or low-income populations pursuant to Executive Order 12898, entitled “Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations” (59 FR 7629, February 16, 1994).

The Agency will consider such comments during the development of any subsequent proposed rule as it takes appropriate steps to address any applicable requirements.

#### List of Subjects in 40 CFR Part 751

Environmental protection, Chemicals, Export notification, Hazardous substances, Import certification, Methylene chloride, Recordkeeping.

Dated: March 15, 2019.

Andrew Wheeler,  
Administrator.

[FR Doc. 2019-05865 Filed 3-26-19; 8:45 am]

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### 42 CFR Part 100

#### National Vaccine Injury Compensation Program: Statement of Reasons for Not Conducting Rulemaking Proceedings

**AGENCY:** Office of the Secretary, Department of Health and Human Services (HHS).

**ACTION:** Denial of petition for rulemaking.

**SUMMARY:** In accordance with the Public Health Service Act, notice is hereby given concerning the reasons for not conducting rulemaking proceedings to add autism, asthma, and tics as injuries associated with vaccines to the Vaccine Injury Table (Table). Also, this document provides reasons for not conducting rulemaking proceedings to add Pediatric Infection-Triggered, Autoimmune Neuropsychiatric Disorder (PITAND) and/or Pediatric Autoimmune Neuropsychiatric Syndrome (PANS); Pediatric Autoimmune Neuropsychiatric Disorders Associated with Streptococcal Infections (PANDAS) as injuries associated with pertussis, pneumococcal conjugate and Haemophilus influenza type b vaccines; and Experimental Autoimmune Encephalomyelitis/Acute Demyelinating