ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 82

[FRL–7912–1]

RIN 2060–AM56

Protection of Stratospheric Ozone: Extension of Global Laboratory and Analytical Use Exemption for Essential Class I Ozone Depleting Substances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: EPA is proposing to extend the global laboratory and analytical use exemption for production and import of class I ozone depleting substances from December 31, 2005, to December 31, 2007, consistent with recent actions by the Parties to the Montreal Protocol on Substances that Deplete the Ozone Layer. The exemption allows persons in the United States to produce and import controlled substances for laboratory and analytical uses that have not been already identified by EPA as nonessential. EPA also is proposing to clarify the applicability of the laboratory and analytical use exemption to production and import of methyl bromide after the January 1, 2005, phaseout date.

DATES: Written comments on this proposed rule must be received by the EPA Docket on or before July 12, 2005.

ADDRESSES: Submit your comments, identified by Docket ID No. OAR–2004–0064, by one of the following methods:

- Federal eRulemaking Portal: *http://www.regulations.gov.* Follow the on-line instructions for submitting comments.
- Agency Web site: *http://www.epa.gov/edocket.* EDOCKET, EPA's electronic public docket and comment system, is EPA's preferred method for receiving comments. Follow the on-line instructions for submitting comments.
- Mail: Air and Radiation Docket, Environmental Protection Agency, Mailcode 6102T, 1200 Pennsylvania Ave., NW., Washington, DC 20460, Attention: Docket ID No. OAR–2004–0064.
- Hand Delivery: EPA Docket Center, (EPA/DC) EPA West, Room B102, 1301 Constitution Ave., NW., Washington, DC, Attention Docket ID No. OAR–2004–0064. Deliveries are only accepted during the Docket's normal hours of operation, and special arrangements should be made for deliveries of boxed information.

Instructions: Direct your comments to Air Docket ID No. OAR–2004–0064. EPA's policy is that all comments received will be included in the public docket without change and may be made available online at *http://www.epa.gov/edocket,* including any personal information provided, unless the comment includes information claimed to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Do not submit information that you consider to be CBI or otherwise protected through EDOCKET, regulations.gov, or e-mail.

The EPA EDOCKET and the federal regulations.gov Web sites are ''anonymous access'' systems, which means EPA will not know your identity or contact information unless you provide it in the body of your comment. If you send an e-mail comment directly to EPA without going through EDOCKET or regulations.gov, your e-mail address will be automatically captured and included as part of the comment that is placed in the public docket and made available on the Internet.

If you submit an electronic comment, EPA recommends that you include your name and other contact information in the body of your comment and with any disk or CD–ROM you submit. If EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, EPA may not be able to consider your comment. Electronic files should avoid the use of special characters, any form of encryption, and be free of any defects or viruses.

Docket: All documents in the docket are listed in the EDOCKET index at *http://www.epa.gov/edocket.* Although listed in the index, some information is not publicly available, namely CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available either electronically in EDOCKET or in hard copy at the Air Docket, EPA/DC, EPA West, Room B102, 1301 Constitution Ave., NW., Washington, DC. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566–1744, and the telephone number for Docket ID No. OAR–2004–0064 is (202) 566–1742.

Materials related to previous EPA actions on the essential use program are contained in EPA Air Docket No. A–93–39. Docket A–93–39 may be reviewed at the Public Reading Room.

FOR FURTHER INFORMATION CONTACT: Scott Monroe, Essential Use Program Manager, by regular mail: U.S. Environmental Protection Agency, Stratospheric Protection Division (6205J), 1200 Pennsylvania Avenue, NW., Washington, DC 20460; by courier service or overnight express: 1301 L Street, NW., Washington, DC 20005, by telephone: 202–343–9712; or by e-mail: *monroe.scott@epa.gov.*

SUPPLEMENTARY INFORMATION:

Table of Contents

I. Extension of the Global Laboratory and Analytical Use Exemption
II. Applicability of the Global Laboratory and Analytical Use Exemption to Methyl Bromide
III. Statutory and Executive Order Reviews
A. Executive Order 12866: Regulatory Planning and Review
B. Paperwork Reduction Act
C. Regulatory Flexibility Act
D. Unfunded Mandates Reform Act
E. Executive Order 13132: Federalism
F. Executive Order 13175: Consultation and Coordination with Indian Tribal Governments
G. Executive Order 13045: Protection of Children from Environmental Health Risks and Safety Risks
H. Executive Order 13211: Actions that Significantly Affect Energy Supply, Distribution, or Use
I. National Technology Transfer and Advancement Act

I. Extension of the Global Laboratory and Analytical Use Exemption

The Montreal Protocol on Substances that Deplete the Ozone Layer (Protocol) is the international agreement to reduce and eventually eliminate the production and consumption [1] of all stratospheric ozone depleting substances (ODSs). The elimination of production and consumption of ODSs is accomplished through adherence to phase-out schedules for specific class I ODSs [2], including: chlorofluorocarbons (CFCs), halons, carbon tetrachloride, and methyl chloroform. The Clean Air Act, as amended in 1990 and 1998, requires EPA to promulgate regulations implementing the Protocol's phaseout schedules in the United States. Those regulations are codified at 40 CFR part 82. As of January 1, 1996, production and import of most class I ODSs were

[1] ''Consumption'' is defined as the amount of a substance produced in the United States, plus the amount imported into the United States, minus the amount exported to Parties to the Montreal Protocol (*see* section 601(6) of the Clean Air Act). Stockpiles of class I ODSs produced or imported prior to the 1996 phase out may be used for purposes not expressly banned at 40 CFR part 82.

[2] Class I ozone depleting substances are listed at 40 CFR part 82, subpart A, appendix A.

phased out in developed countries, including the United States.

However, the Protocol provides exemptions that allow for the continued import and/or production of ODSs for specific uses. Under the Protocol, for most class I ODS, the Parties may collectively grant exemptions to the ban on production and import of ODSs for uses that they determine to be ''essential.'' For example, with respect to CFCs, Article 2A(4) provides that the phaseout will apply ''save to the extent that the Parties decide to permit the level of production or consumption that is necessary to satisfy uses agreed by them to be essential.'' Similar language appears in the control provisions for halons (Art. 2B), carbon tetrachloride (Art. 2D), methyl chloroform (Art. 2E), hydrobromochlorofluorocarbons (Art. 2G), and bromochloromethane (Art. 2I). As defined by Decision IV/25 of the Parties, use of a controlled substance is essential only if (1) it is necessary for the health, safety or is critical for the functioning of society (encompassing cultural and intellectual aspects), and (2) there are no available technically and economically feasible alternatives or substitutes that are acceptable from the standpoint of environment and health.

Decision X/19 under the Protocol (taken in 1998) allowed a general exemption for essential laboratory and analytical uses through December 31, 2005. EPA included this exemption in our regulations at 40 CFR part 82, subpart A. While the Clean Air Act does not specifically provide for this exemption, EPA determined that an exemption for essential laboratory and analytical uses was allowable under the Act as a *de minimis* exemption. EPA addressed the *de minimis* exemption in the final rule of March 13, 2001 (66 FR 14760–14770).

Decision X/19 also asked the Protocol's Technology and Economic Assessment Panel (TEAP), a group of technical experts from member countries, to report annually on procedures that could be performed without the use of controlled substances and stated that at future meetings the Parties would decide whether such procedures should no longer be eligible for exemptions. Based on the TEAP's recommendation, the Parties to the Protocol decided in 1999 (Decision XI/15) that the general exemption no longer applied to the following uses: Testing of oil and grease, and total petroleum hydrocarbons in water; testing of tar in road-paving materials; and forensic finger-printing. EPA incorporated this exclusion at appendix G to subpart A of 40 CFR part 82 on February 11, 2002 (67 FR 6352).

Subsequently, in its May 2003 progress report the TEAP noted, ''No new non-ODS methods have been forthcoming which would enable the TEAP to recommend the elimination of further uses of controlled substances for analytical and laboratory uses'' (p. 106, see Air Docket OAR–2004–0064). Based on this statement, and in consideration of the pending cessation of the laboratory use exemption in 2005, the European Community proposed an extension of the exemption that would allow further time for development of non-ODS methods. At their fifteenth Meeting in November 2003, the Parties adopted the proposal in Decision XV/8, which extended the global exemption for laboratory and analytical uses to December 31, 2007.

EPA's regulations regarding this exemption at 40 CFR 82.8(b) currently state, ''A global exemption for class I controlled substances for essential laboratory and analytical uses shall be in effect through December 31, 2005, subject to the restrictions in appendix G of this subpart, and subject to the record keeping and reporting requirements at § 82.13(u) through (x). There is no amount specified for this exemption.'' Because certain laboratory procedures continue to require the use of class I substances in the United States, and because non-ODS replacements for the class I substances have not been identified for all uses, EPA is proposing to revise 40 CFR 82.8(b) to reflect the extension of the exemption to 2007 consistent with Decision XV/8. For a more detailed discussion of the reasons for the exemption, refer to the March 13, 2001, **Federal Register** notice. As discussed in the March 2001 notice, the controls in place for laboratory and analytical uses provide adequate assurance that very little, if any, environmental damage will result from the handling and disposal of the small amounts of class I ODS used in such applications. In addition, the amount of phased-out class I substances being supplied to laboratories under this exemption decreased each year since 1997 to reach the level of eight metric tons in 2001 (approximately one-quarter the amount supplied in 1997), according to EPA's tracking system for ODSs.

II. Applicability of the Global Laboratory and Analytical Use Exemption to Methyl Bromide

As of January 1, 2005, production and import of methyl bromide no longer will be allowed in the United States, except for limited exemptions (40 CFR 82.4(d)). Methyl bromide is a class I controlled substance used chiefly as a fumigant for soil treatment and pest control. EPA created a system of allowances to permit continued production and import of methyl bromide for critical uses after January 1, 2005 (see 69 FR 76981, December 23, 2004). This exemption does not include allowances for continued production of methyl bromide to supply laboratories. However, the phaseout of methyl bromide production and import does not restrict inventories of methyl bromide produced prior to January 1, 2005, from being used for laboratory applications.

Methyl bromide (also known as bromomethane) does have laboratory uses, for example, as a chemical intermediate and methylating agent. EPA regulations allow for methyl bromide to be produced after the January 1, 2005, phaseout date if production is covered by ''essential use allowances or exemptions.'' (40 CFR 82.4(b)(1)) The regulations list the laboratory and analytical use exemption as a ''global exemption for class I controlled substances,'' subject to the restrictions in appendix G (40 CFR 82.4(n)(1)(iii), 82.8(b)). However, EPA has not specifically addressed the issue of whether the exemption should apply to methyl bromide. In addition, it is not clear what the Parties to the Protocol intended. Previous Decisions by the Parties concerning essential uses have referred generally to ''ozone-depleting substances,'' not to specific, individual ozone-depleting substances (see, for example, Decisions VI/9, VII/11, and X/19, available in Air Docket OAR–2004–0064). As noted above, the Protocol's control measures for most of the class I ODS contain language stating that the phaseout shall not apply ''to the extent that the Parties decide to permit the level of production or consumption that is necessary to satisfy uses agreed by them to be essential.'' However, Article 2H of the Montreal Protocol, which states the control measures for methyl bromide, does not contain such language.

It is possible that the Parties will clarify the applicability of the laboratory and analytical use exemption to methyl bromide at a future Meeting of the Parties. In anticipation of such clarification, EPA is proposing that production and import of methyl bromide for essential laboratory and analytical uses, as defined in 40 CFR part 82, subpart A, appendix G, be allowed under the general laboratory use exemption (40 CFR 82.4(n)(1)(iii)) through December 31, 2007. EPA requests comment on the types of laboratory and analytical uses of methyl

bromide, and whether such uses may be considered essential under the terms identified in Decision IV/25(1)(a) by the Parties (see Docket OAR–2004–0064). We also request comment on the amount of newly produced or imported methyl bromide that would be needed by laboratories in the United States annually in order to satisfy essential uses. Last, we request comment on the level of purity that should be specified for laboratory and analytical use of methyl bromide (see Annex II to the report of the Sixth Meeting of the Parties, available in Air Docket OAR–2004–0064).

Because EPA cannot be certain when the Parties will clarify the matter described above, the Agency may decide to finalize, after consideration of comments received on this proposal, only the portion of this rule that extends the date of the essential laboratory and analytical use exemption for substances other than methyl bromide to December 31, 2007. EPA may finalize the proposal with a separate notice to apply this extension to methyl bromide or to remove methyl bromide from the exemption, if warranted based on action by the Parties.

III. Statutory and Executive Order Reviews

A. Executive Order 12866: Regulatory Planning and Review

Under Executive Order 12866 (58 FR 51735, October 4, 1993), the Agency must determine whether this regulatory action is ''significant'' and therefore subject to review by the Office of Management and Budget (OMB) and the requirements of the Executive Order. The Order defines ''significant regulatory action'' as one that is likely to result in a rule that may:

(1) Have an annual effect on the economy of $100 million or more, or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or tribal governments or communities;

(2) Create a serious inconsistency or otherwise interfere with an action taken or planned by another agency;

(3) Materially alter the budgetary impact of entitlements, grants, user fees, or loan programs or the rights and obligations of recipients thereof; or

(4) Raise novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in the Executive Order.

It has been determined that this action is not a ''significant regulatory action'' under the terms of Executive Order 12866 and is therefore not subject to OMB review.

B. Paperwork Reduction Act

This action does not add any information collection requirements or increase burden under the provisions of the Paperwork Reduction Act, 44 U.S.C. 3501 *et. seq*. OMB previously approved the information collection requirements contained in the final rule promulgated on May 10, 1995, and assigned OMB control number 2060–0170 (EPA ICR No. 1432.21).

Burden means the total time, effort, or financial resources expended by persons to generate, maintain, retain, or disclose or provide information to or for a Federal agency. This includes the time needed to review instruction; develop, acquire, install, and utilize technology and systems for the purposes of collecting, validating, and verifying information, processing and maintaining information, and disclosing and providing information; adjust the existing ways to comply with any previously applicable instructions and requirements; train personnel to be able to respond to a collection of information; search data sources; complete and review the collection of information; and transmit or otherwise disclose the information. An Agency may not conduct or sponsor, and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number. The OMB control numbers for EPA's regulations are listed in 40 CFR part 9 and 48 CFR chapter 1.

C. Regulatory Flexibility Act

The RFA generally requires an agency to prepare a regulatory flexibility analysis of any rule subject to notice and comment rulemaking requirements under the Administrative Procedure Act or any other statute unless the agency certifies that the rule will not have a significant economic impact on a substantial number of small entities. Small entities include small businesses, small organizations, and small governmental jurisdictions.

For purposes of assessing the impact of today's rule on small entities, the term small entities is defined as: (1) Pharmaceutical preparations manufacturing businesses (NAICS code 325412) that have less than 750 employees; (2) a small governmental jurisdiction that is a government of a city, county, town, school district or special district with a population of less than 50,000; and (3) a small organization that is any not-for-profit enterprise which is independently owned and operated and is not dominant in its field.

After considering the economic impacts of today's proposed rule on small entities, I certify that this action will not have a significant economic impact on a substantial number of small entities. In determining whether a rule has a significant economic impact on a substantial number of small entities, the impact of concern is any significant *adverse* economic impact on small entities, since the primary purpose of the regulatory flexibility analysis is to identify and address regulatory alternatives ''which minimize any significant economic impact of the rule on small entities.'' 4 U.S.C. 603 and 604. Thus, an agency may certify that a rule will not have a significant economic impact on a substantial number of small entities if the rule relieves regulatory burden, or otherwise has a positive economic effect on all of the small entities subject to the rule. This rule provides an otherwise unavailable benefit to those companies that obtain ozone-depleting substances under the essential laboratory and analytical use exemption. We have therefore concluded that today's proposed rule will relieve regulatory burden for all small entities.

Although this proposed rule will not have significant economic impact on a substantial number of small entities, we continue to be interested in the potential impact of the proposed rule on small entities and welcome comments related to these issues.

D. Unfunded Mandates Reform Act

Title II of the Unfunded Mandates Reform Act of 1995 (UMRA), Public Law 104–4, establishes requirements for Federal agencies to assess the effects of their regulatory actions on State, local, and tribal governments and the private sector. Under section 202 of the UMRA, EPA generally must prepare a written statement, including a cost-benefit analysis, for proposed and final rules with ''Federal mandates'' that may result in expenditures to State, local, and tribal governments, in the aggregate, or to the private sector, of $100 million or more in any one year.

Before promulgating an EPA rule for which a written statement is needed, section 205 of the UMRA generally requires EPA to identify and consider a reasonable number of regulatory alternatives and adopt the least costly, most cost-effective, or least burdensome alternative that achieves the objectives of the rule. The provisions of section 205 do not apply when they are inconsistent with applicable law. Moreover, section 205 allows EPA to

adopt an alternative other than the least costly, most cost-effective, or least burdensome alternative, if the Administrator publishes with the final rule an explanation why that alternative was not adopted.

Before EPA establishes any regulatory requirements that may significantly or uniquely affect small governments, including tribal governments, it must have developed a small government agency plan under section 203 of the UMRA. The plan must provide for notifying potentially affected small governments, enabling officials of affected small governments to have meaningful and timely input in the development of EPA regulatory proposals with significant Federal intergovernmental mandates, and informing, educating, and advising small governments on compliance with the regulatory requirements.

Today's rule contains no Federal mandates (under the regulatory provisions of Title II of the UMRA) for State, local, or tribal governments or the private sector, since it merely extends the availability of an already available exemption to the ban on production and import of class I ODSs. For the same reason, EPA has determined that this rule contains no regulatory requirements that might significantly or uniquely affect small governments.

E. Executive Order 13132: Federalism

Executive Order 13132, entitled ''Federalism'' (64 FR 43255, August 10, 1999), requires EPA to develop an accountable process to ensure ''meaningful and timely input by State and local officials in the development of regulatory policies that have federalism implications.'' ''Policies that have federalism implications'' is defined in the Executive Order to include regulations that have ''substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.''

This proposed rule does not have federalism implications. It will not have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 13132. Today's rule affects only the companies that produce or import class I ozone-depleting substances for laboratory or analytical uses. Thus, Executive Order 13132 does not apply to this rule.

F. Executive Order 13175: Consultation and Coordination With Indian Tribal Governments

Executive Order 13175, entitled ''Consultation and Coordination with Indian Tribal Governments'' (65 FR 67249, November 9, 2000), requires EPA to develop an accountable process to ensure ''meaningful and timely input by tribal officials in the development of regulatory policies that have tribal implications.'' This proposed rule does not have tribal implications, as specified in Executive Order 13175. Today's rule affects only the companies that produce or import class I ozone-depleting substances for laboratory or analytical uses. Thus, Executive Order 13175 does not apply to this rule.

G. Executive Order 13045: Protection of Children From Environmental Health Risks and Safety Risks

Executive Order 13045, ''Protection of Children from Environmental Health risks and Safety Risks'' (62 FR 19885, April 23, 1997), applies to any rule that (1) is determined to be ''economically significant'' as defined under Executive Order 12866, and (2) concerns an environmental health and safety risk that EPA has reason to believe may have a disproportionate effect on children. If the regulatory action meets both criteria, the Agency must evaluate the environmental health or safety effects of the planned rule on children, and explain why the planned regulation is preferable to other potentially effective and reasonably feasible alternatives considered by the Agency.

While this proposed rule is not subject to the Executive Order because it is not economically significant as defined in Executive Order 12866, we nonetheless have reason to believe that the environmental health or safety risk addressed by this action may have a disproportionate effect on children. Depletion of stratospheric ozone results in greater transmission of the sun's ultraviolet (UV) radiation to the earth's surface. The following studies describe the effects on children of excessive exposure to UV radiation: (1) Westerdahl J, Olsson H, Ingvar C. ''At what age do sunburn episodes play a crucial role for the development of malignant melanoma,'' Eur J Cancer 1994; 30A: 1647–54; (2) Elwood JM, Jopson J. ''Melanoma and sun exposure: an overview of published studies,'' Int J Cancer 1997; 73:198–203; (3) Armstrong BK. ''Melanoma: childhood or lifelong sun exposure'' In: Grobb JJ, Stern RS, Mackie RM, Weinstock WA, eds. ''Epidemiology, causes and prevention of skin diseases,'' 1st ed. London, England: Blackwell Science, 1997: 63–6; (4) Whiteman D., Green A. ''Melanoma and Sunburn,'' Cancer Causes Control, 1994: 5:564–72; (5) Kricker A, Armstrong, BK, English, DR, Heenan, PJ. ''Does intermittent sun exposure cause basal cell carcinoma? A case control study in Western Australia,'' Int J Cancer 1995; 60: 489–94; (6) Gallagher, RP, Hill, GB, Bajdik, CD, et. al. ''Sunlight exposure, pigmentary factors, and risk of nonmelanocytic skin cancer I, Basal cell carcinoma,'' Arch Dermatol 1995; 131: 157–63; (7) Armstrong, BK. ''How sun exposure causes skin cancer: an epidemiological perspective,'' Prevention of Skin Cancer. 2004. 89–116. The public is invited to submit or identify peer-reviewed studies and data, of which EPA may not be aware, that assessed results of early life sun exposure.

However, as discussed in the March 13, 2001, **Federal Register** notice, the laboratory and analytical applications addressed in today's proposed rule involve extremely controlled use and disposal of all chemicals, including any ODS. As a result, emissions of ODS into the atmosphere are negligible. In light of the conditions already applied to the global exemption by appendix G to subpart A of 40 CFR part 82, EPA believes that any additional controls on laboratory uses would provide little, if any, benefit.

H. Executive Order 13211: Actions That Significantly Affect Energy Supply, Distribution, or Use

This rule is not subject to Executive Order 13211, Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use (66 FR 28355, May 22, 2001) because it is not a significant regulatory action under Executive Order 12866.

I. National Technology Transfer and Advancement Act

Section 12(d) of the National Technology Transfer and Advancement Act of 1995 (''NTTAA), Public Law 104–113, section 12(d) (15 U.S.C. 272 note) directs EPA to use voluntary consensus standards in its regulatory activities unless to do so would be inconsistent with applicable law or otherwise impractical. Voluntary consensus standards are technical standards (*e.g.*, materials specifications, test methods, sampling procedures, and business practices) that are developed or adopted by voluntary consensus standards bodies. The NTTAA directs EPA to provide Congress, through OMB, explanations when the Agency decides not to use available and applicable

voluntary consensus standards. This proposed rule does not involve technical standards. Therefore, EPA is not considering the use of any voluntary consensus standards.

List of Subjects in 40 CFR Part 82

Environmental protection, Administrative practice and procedure, Air pollution control, Chemicals, Imports, Reporting and recordkeeping requirements.

Dated: May 6, 2005.

Stephen L. Johnson,

Administrator.

40 CFR Part 82 is proposed to be amended as follows:

PART 82—PROTECTION OF STRATOSPHERIC OZONE

1. The authority citation for part 82 continues to read as follows:

Authority: 42 U.S.C. 7414, 7601, 7671–7671q.

Subpart A—Production and Consumption Controls

2. Section 82.8 is amended by revising paragraph (b) to read as follows:

§ 82.8 Grant of essential use allowances and critical use allowances.

* * * * *

(b) A global exemption for class I controlled substances for essential laboratory and analytical uses shall be in effect through December 31, 2007, subject to the restrictions in appendix G of this subpart, and subject to the record keeping and reporting requirements at § 82.13(u) through (x). There is no amount specified for this exemption.

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[FR Doc. 05–9589 Filed 5–12–05; 8:45 am]

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