



Federal Register

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Part III

Environmental Protection Agency

40 CFR Part 63

**National Emission Standards for
Pharmaceuticals Production; Final Rule
and Proposed Rule**

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 63

[OAR–2004–0023; FRL–7911–3]

RIN 2060–AM52

National Emission Standards for Pharmaceuticals Production

AGENCY: Environmental Protection Agency (EPA).

ACTION: Direct final rule; amendments.

SUMMARY: EPA is taking direct final action to amend the national emission standards for pharmaceuticals production. The direct final rule amendments include provisions for planned routine maintenance of wastewater tanks, alternative monitoring provisions for caustic scrubbers and condensers, and references general standards for containers. We are making the amendments by direct final rule, without prior proposal, because we view the revisions as noncontroversial and anticipate no adverse comments.

DATES: The direct final rule amendments are effective on July 12, 2005, without further notice, unless EPA receives adverse written comment by June 13, 2005, or if a public hearing is requested by May 23, 2005. If EPA receives such comments, it will publish a timely withdrawal in the **Federal Register** indicating which provisions will become effective and which provisions are being withdrawn due to adverse comment.

ADDRESSES: Submit your comments, identified by Docket ID No. OAR–2004–0023, 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.

- E-mail: air-and-r-docket@epa.gov.
- Fax: (202) 566–1741.
- Mail: EPA Docket Center, Environmental Protection Agency, Mailcode: 6102T, 1200 Pennsylvania Avenue, NW., Washington, DC 20460. Please include a duplicate copy, if possible.
- Hand Delivery: Air and Radiation Docket, Environmental Protection Agency, 1301 Constitution Avenue, NW., Room B–108, Washington, DC 20460. Such deliveries are only accepted during the Docket’s normal hours of operation, and special arrangements should be made for deliveries of boxed information.

We request that a separate copy also be sent to the contact person listed below (*see* **FOR FURTHER INFORMATION CONTACT**).

Instructions: Direct your comments to Docket ID No. OAR–2004–0023. 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 websites 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. For additional information about EPA’s public docket visit EDOCKET on-line or see the **Federal Register** of May 31, 2002 (67 FR 38102).

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, *i.e.*, 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 and Radiation 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 the Air Docket is (202) 566–1742.

FOR FURTHER INFORMATION CONTACT: Mr. Randy McDonald, Organic Chemicals Group, Emission Standards Division (Mail Code C504–04), U.S. EPA, Research Triangle Park, North Carolina 27711, telephone number (919) 541–5402, electronic mail address mcdonald.randy@epa.gov.

SUPPLEMENTARY INFORMATION: *Regulated Entities.* The regulated category and entities affected by this action include:

Category	NAICS codes	SIC codes	Examples of regulated entities
Industry	325411 and 325412	2833 and 2834	<ul style="list-style-type: none"> • Producers of finished dosage forms of drugs (<i>e.g.</i>, tablets, capsules, and solutions), active ingredients, or precursors. • Producers of material whose primary use is as an active ingredient of precursor.
	Typically 325199	Typically 2869	

This table is not intended to be exhaustive, but rather provides a guide for readers likely to be interested in the revisions to the regulation affected by this action. To determine whether your facility, company, business, organization, etc., is regulated by this action, you should carefully examine all

of the applicability criteria in 40 CFR 63.1250. If you have questions regarding the applicability of the direct final rule amendments to a particular entity, consult the person listed in the preceding **FOR FURTHER INFORMATION CONTACT** section. *Worldwide Web (WWW)*. In addition to being available

in the docket, an electronic copy of the direct final rule amendments will also be available on the WWW through EPA’s Technology Transfer Network (TTN). Following signature by the EPA Administrator, a copy of the direct final rule amendments will be posted on the TTN’s policy and guidance page for

newly proposed or promulgated rules at <http://www.epa.gov/ttn/oarpg>. The TTN provides information and technology exchange in various areas of air pollution control.

Comments. We are publishing the direct final rule amendments without prior proposal because we view the amendments as noncontroversial and do not anticipate adverse comments. We consider the changes to be noncontroversial because the only effect is to provide alternative monitoring requirements and extend planned routine maintenance provisions for storage tanks to wastewater tanks. In the Proposed Rules section of this **Federal Register**, we are publishing a separate document that will serve as the proposal in the event that timely adverse comments are received.

If we receive such adverse comments on the amendments, we will publish a timely withdrawal in the **Federal Register** informing the public which provisions will become effective and which provisions are being withdrawn due to adverse comment. We will address all public comments in a subsequent final rule based on the proposed rule. Any of the distinct amendments in the direct final rule for which we do not receive adverse comment will become effective on the date set out above. We will not institute a second comment period on the direct final rule amendments. Any parties interested in commenting must do so at this time.

Judicial Review. Under section 307(b)(1) of the Clean Air Act (CAA), judicial review of the direct final rule amendments is available only by filing a petition for review in the U.S. Court of Appeals for the District of Columbia by July 12, 2005. Under section 307(d)(7)(B) of the CAA, only an objection to the direct final rule amendments that was raised with reasonable specificity during the period for public comment can be raised during judicial review. Moreover, under section 307(b)(2) of the CAA, the requirements established by the direct final rule amendments may not be challenged separately in any civil or criminal proceedings brought by EPA to enforce these requirements.

Outline. The information presented in this preamble is organized as follows:

- I. Why are we publishing the amendments as a direct final rule?
- II. What amendments are we making to the rule?
- 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 and Safety Risks
- H. Executive Order 13211: Actions that Significantly Affect Energy Supply, Distribution, or Use
- I. National Technology Transfer Advancement Act
- J. Congressional Review Act

I. Why Are We Publishing the Amendments as a Direct Final Rule?

We are publishing the amendments without prior proposal because we view the changes as noncontroversial and anticipate no adverse comment. The amendments to the final rule improve consistency with other standards by referencing generic type standards for containers; extending the planned routine maintenance provisions from storage tanks to wastewater tanks; and allowing alternative monitoring for scrubbers and condensers. The amendments do not alter the stringency of the standards, have no adverse health or environmental impacts, and will not increase costs.

II. What Amendments Are We Making to the Rule?

The direct final rule makes four amendments to the final rule. One amendment adds a reference to an existing generic standard as a compliance alternative for large wastewater containers. A second amendment applies the same planned routine maintenance provisions for storage tanks to wastewater tanks. A third amendment is to allow monitoring of the condenser product side temperature in lieu of the exit gas temperature. The fourth amendment is to allow monitoring of caustic strength of the scrubber effluent as an alternative to measuring pH. In addition to the amendments, we are correcting a citation error.

The National Emission Standards for Containers in subpart PP to 40 CFR part 63 were developed for administrative convenience and consistency and apply when other subparts reference subpart PP. The level of control required by subparts PP and GGG to 40 CFR part 63 are equivalent as both standards require vapor-tight containers. We are aware that there are some facilities subject to subpart GGG to 40 CFR part 63 that have containers subject to other maximum achievable control technology (MACT) standards that are permitted to meet subpart PP to 40 CFR part 63 with respect to those containers. Therefore,

we are amending the wastewater provisions in the final rule to reference subpart PP to 40 CFR part 63 as a compliance option for large containers to allow such sources the option of complying with a single subpart for containers otherwise subject to different MACT standards.

The final rule allows for 240 hours per year for use of storage tanks during periods of planned routine maintenance when the requirements for control devices do not apply. This provision allows for maintenance of the control device without emptying and cleaning the storage tank. During the initial implementation phase of the final rule, we became aware that the same problems of material management apply to wastewater tanks as well as storage tanks. Applying the planned routine maintenance provisions to storage of wastewater eliminates the need to empty and clean wastewater tanks with each downtime. This also eliminates emissions associated with cleaning and degassing the wastewater tank. Therefore, we are extending the planned routine maintenance provisions for storage tanks to wastewater tanks. The same issue of material management for stored wastewater was addressed in subpart FFFF to 40 CFR part 63 by providing the same planned routine maintenance provisions.

Also, we are including provisions for alternative monitoring for condensers and scrubbers. The new provisions allow for monitoring of the product side temperature for condensers and provisions for monitoring the caustic strength of the effluent for scrubbers. Again, in the initial implementation phase of the final rule, we were informed by several affected sources that alternative monitoring for condensers and scrubbers should be allowed. Those alternative monitoring provisions have been approved in precompliance reports for the final rule and are also included in subpart FFFF to 40 CFR part 63.

Finally, we are clarifying that for the final rule, a process change means the startup of a new process. As clarification in the preamble to the proposed national emission standards for hazardous air pollutants (NESHAP) for Pesticide Active Ingredient Production (PAI) (67 FR 17503), we stated that a process change means the startup of a new operating scenario associated with a new process. As in the proposed PAI rule, the final rule requires the owner or operator to prepare operating scenarios that describe the equipment, emissions, controls, and monitoring for each process. A new operating scenario must

be prepared each time the owner or operator makes a change to produce a new product. A new operating scenario must also be prepared for any change to an existing process that is not within the scope of a current operating scenario. As in the proposed PAI rule, we are clarifying that for the final rule, a process change means the startup of a new process.

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 the regulatory action is "significant" and, therefore, subject to Office of Management and Budget (OMB) review and the requirements of the Executive Order. The Executive 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 the final rule amendments are not a "significant regulatory action" under the terms of Executive Order 12866 and are, therefore, not subject to OMB review.

B. Paperwork Reduction Act

This action does not impose any new information collection burden. This action gives a source owner or operator the option of using vapor balancing to comply with the standards. Since it is only an option, this action will not increase the information collection burden. The OMB has previously approved the information collection requirements contained in the existing regulations under the provisions of the Paperwork Reduction Act, 44 U.S.C. 3501 *et seq.*, and has assigned OMB control number 2060-0358 (EPA ICR No. 1781.01).

Copies of the Information Collection Request (ICR) document(s) may be

obtained from Susan Auby, by mail at the Office of Environmental Information, Collection Strategies Division; U.S. EPA (2822T); 1200 Pennsylvania Ave., NW., Washington, DC 20460, by e-mail at auby.susan@epa.gov, or by calling (202) 566-1672. A copy may also be downloaded off the Internet at <http://www.epa.gov/icr>. Include the ICR or OMB number in any correspondence.

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 instructions; 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 15.

C. Regulatory Flexibility Act

The EPA has determined that it is not necessary to prepare a regulatory flexibility analysis in connection with the final rule.

For purposes of assessing the impacts of today's amendments on small entities, a small entity is defined as: (1) A small business as defined by the Small Business Administration's regulations at 13 CFR 121.201; (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 direct final rule amendments on small entities, EPA has concluded 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 analyses is to identify and address regulatory alternatives "which minimize any significant economic impact of the proposed rule on small entities." 5 U.S.C. 603 and 604. Thus, an agency may conclude 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. The final rule amendments add several compliance options granting greater flexibility to small entities subject to the final rule that may result in a more efficient use of resources for them and, therefore, impose no additional regulatory costs or requirements on owners or operators of affected sources.

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, the 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 by State, local, and tribal governments, in the aggregate, or by the private sector, of \$100 million or more in any 1 year. Before promulgating an EPA rule for which a written statement is needed, section 205 of the UMRA generally requires the 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 the 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 the EPA establishes any regulatory requirements that may significantly or uniquely affect small governments, including tribal governments, it must have developed under section 203 of the UMRA a small government agency plan. The plan must provide for notifying potentially 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.

The EPA has determined that the final rule amendments do not contain a Federal mandate that may result in expenditures of \$100 million or more for State, local, and tribal governments, in the aggregate, or the private sector in any 1 year. The final rule amendments provide a source owner or operator with additional options to comply with the standards. Therefore, the final rule amendments are not subject to the requirements of sections 202 and 205 of the UMRA.

E. Executive Order 13132: Federalism

Executive Order 13132 (64 FR 43255, August 10, 1999) requires the 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.”

The final rule amendments do not have federalism implications. They 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. The final rule amendments provide a source owner or operator with another option to comply with the standards and, therefore, impose no additional burden on sources. Thus, Executive Order 13132 does not apply to the final rule amendments.

In the spirit of Executive Order 13132 and consistent with EPA policy to promote communications between the EPA and State and local governments, the EPA specifically solicits comment on the final rule amendments from State and local officials.

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

Executive Order 13175 (65 FR 67249, November 9, 2000) requires the 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.” The final rule amendments do not have tribal

implications, as specified in Executive Order 13175. The final rule amendments provide a source owner or operator with another option to comply with the standards and, therefore, impose no additional burden on sources. Thus, Executive Order 13175 does not apply to the final rule amendments.

The EPA specifically solicits additional comment on the final rule amendments from tribal officials.

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

Executive Order 13045 (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 or safety risk that the EPA has reason to believe may have a disproportionate effect on children. If the regulatory action meets both criteria, the EPA 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 EPA.

The EPA interprets Executive Order 13045 as applying only to those regulatory actions that are based on health or safety risks, such that the analysis required under section 5–501 of the Executive Order has the potential to influence the regulation. Today’s final rule amendments are not subject to Executive Order 13045 because they are based on technology performance, not health or safety risks. Furthermore, the final rule amendments have been determined not to be “economically significant” as defined under Executive Order 12866.

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

The final rule amendments are not subject to Executive Order 13211 (66 FR 28355, May 22, 2001) because they are 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, 12(d) (15 U.S.C. 272 note), directs the 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 the EPA to provide Congress, through OMB, explanations when the Agency decides not to use available and applicable voluntary consensus standards.

No new standard requirements are cited in the direct final rule amendments. Therefore, the EPA is not proposing or adopting any voluntary consensus standards in the direct final rule amendments.

J. Congressional Review Act

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. The EPA will submit a report containing the direct final rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the direct final rule in the **Federal Register**. The direct final rule is not a “major rule” as defined by 5 U.S.C. 804(2). The direct final rule amendments are effective on July 12, 2005.

List of Subjects in 40 CFR Part 63

Environmental protection, Administrative practice and procedure, Air pollution control, Hazardous substances, Intergovernmental relations, Reporting and recordkeeping requirements.

Dated: May 6, 2005.

Stephen L. Johnson,
Administrator.

■ For the reasons set out in the preamble, part 63 of title 40, chapter I of the Code of Federal Regulations is amended as follows:

PART 63—[AMENDED]

■ 1. The authority citation for part 63 continues to read as follows:

Authority: 42 U.S.C. 7401, *et seq.*

Subpart GGG—[Amended]

■ 1. Section 63.1253 is amended by adding two sentences to the end of paragraph (e) to read as follows:

§ 63.1253 Standards: Storage tanks.

* * * * *

(e) * * * The owner or operator may submit an application to the Administrator requesting an extension of this time limit to a total of 360 hours in any 365-day period. The application must explain why the extension is needed, it must specify that no material will be added to the storage tank between the time the 240-hour limit is exceeded and the control device is again operational, and it must be submitted at least 60 days before the 240-hour limit will be exceeded.

* * * * *

- 2. Section 63.1256 is amended by:
- a. Adding paragraph (b)(10); and
- b. Revising paragraph (d)(1)(i).

The revisions and addition read as follows:

§ 63.1256 Standards: Wastewater.

* * * * *

(b) * * *

(10) The emission limits specified in § 63.1256 (b)(2) and (h) for control devices used to control emissions from wastewater tanks do not apply during periods of planned routine maintenance of the control device(s) of no more than 240 hours in any 365-day period. The owner or operator may submit an application to the Administrator requesting an extension of this time limit to a total of 360 hours in any 365-day period. The application must explain why the extension is needed, it must specify that no affected wastewater

will be added to the tank between the time the 240-hour limit is exceeded and the control device is again operational, and it must be submitted at least 60 days before the 240-hour limit will be exceeded. Wastewater tanks shall not be sparged with air or other gases without an operational control device.

* * * * *

(d) * * *

(1) * * *

(i) Except as provided in paragraph (d)(3)(iv) of this section, if the capacity of the container is greater than 0.42 m³, the cover and all openings (e.g., bungs, hatches, sampling points, and pressure relief valves) shall be controlled in accordance with the requirements of either paragraph (d)(1)(i)(A) or (d)(1)(i)(B) of this section.

(A) The requirements specified in § 63.1258(h); or

(B) The requirements of subpart PP of this part for containers using level 2 controls that meet the definitions in § 63.923(b)(1) or (2).

* * * * *

- 3. Section 63.1258 is amended by:

- a. Amending paragraph (b)(1)(ii) introductory text to add a sentence before the last sentence; and
- b. Revising paragraph (b)(1)(iii) introductory text.

The revisions read as follows:

§ 63.1258 Monitoring requirements.

* * * * *

(b) * * *

(1) * * *

(ii) * * * As an alternative to measuring pH, you may elect to continuously monitor the caustic strength of the scrubber effluent. * * *

(iii) *Condensers.* For each condenser, the owner or operator shall establish the maximum condenser outlet gas temperature or product side temperature as a site specific operating parameter which must be measured and recorded at least every 15 minutes during the period in which the condenser is functioning in achieving the HAP removal required by this subpart.

* * * * *

- 4. Section 63.1259 is amended by revising the last two sentences in paragraph (a)(3) introductory text to read as follows:

§ 63.1259 Recordkeeping requirements.

(a) * * *

(3) * * * The owner or operator shall keep the startup, shutdown, and malfunction records specified in paragraphs (a)(3)(i) through (iii) of this section. Reports related to the plan shall be submitted as specified in § 63.1260(i).

* * * * *

[FR Doc. 05-9477 Filed 5-12-05; 8:45 am]

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