The Commission's staff will then make a determination of whether the information is trade secret or proprietary information that cannot be released. That determination will be made in accordance with applicable provisions of the CPSA; the Freedom of Information Act (FOIA), 5 U.S.C. 552b; 18 U.S.C. 1905; the Commission's procedural regulations at 16 CFR part 1015 governing protection and disclosure of information under provisions of FOIA; and relevant judicial interpretations. If the Commission concludes that any part of the information that has been submitted with a claim that the information is a trade secret or proprietary is disclosable, it will notify the person submitting the material in writing and provide at least 10 calendar days from the receipt of the letter to allow for that person to seek judicial relief. 15 U.S.C. 2055(a)(5) and (6); 16 CFR 1015.19(b).

List of Subjects in 16 CFR Part 1700

Consumer protection, Drugs, Infants and children, Packaging and containers, Poison prevention, Toxic substances, Reporting and recordkeeping requirements.

For the reasons set forth above, the Commission proposes to amend 16 CFR part 1700 as follows:

PART 1700—POISON PREVENTION PACKAGING ACT OF 1970 REGULATIONS

1. The authority citation for part 1700 continues to read as follows:

Authority: 15 U.S.C. 1471–76. Secs. 1700.1 and 1700.14 also issued under 15 U.S.C. 2079(a).

2. Section 1700.14 is amended by republishing paragraph (a) introductory text and by adding new paragraph (a)(32) to read as follows:

§ 1700.14 Substances requiring special packaging.

(a) *Substances.* The Commission has determined that the degree or nature of the hazard to children in the availability of the following substances, by reason of their packaging, is such that special packaging meeting the requirements of § 1700.20(a) is required to protect children from serious personal injury or serious illness resulting from handling, using, or ingesting such substances, and the special packaging herein required is technically feasible, practicable, and appropriate for these substances:

* * * * *

(32) *Over-the-Counter Drug Products.* (i) Any over-the-counter drug product in a dosage form intended for oral administration that contains an active ingredient also contained in a drug product that is or was a prescription drug product required by paragraph (a)(10) of this section to be in special packaging shall be packaged in accordance with the provisions of § 1700.15 (a), (b), and (c). This requirement applies whether or not the amount of the active ingredient in the over-the-counter drug product is different from the amount of that active ingredient in the prescription drug product. This requirement does not apply to a drug product for which an application for over-the-counter marketing has been submitted to the FDA before [insert date 180 days after promulgation of final rule] or which has been granted over-the-counter status by the FDA before [insert date 180 days after promulgation of final rule]. Notwithstanding the foregoing, any special packaging requirement under this § 1700.14 otherwise applicable to an over-the-counter drug product remains in effect.

(ii) For purposes of this paragraph (a)(32), active ingredient means any component that is intended to furnish pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment, or prevention of disease or to affect the structure or any function of the body of humans; and drug product means a finished dosage form, for example, tablet, capsule, or solution, that contains a drug substance (active ingredient), generally, but not necessarily, in association with one or more other ingredients. (These terms are intended to have the meanings assigned to them in the regulations of the Food and Drug Administration appearing at 21 CFR 201.66 and 21 CFR 314.3, respectively.)

§ 1702.16 [Amended]

3. Section 1702.16 is amended by removing paragraph (b) thereof in its entirety.

Dated: August 23, 2000.

Sadye E. Dunn,

Secretary, Consumer Product Safety Commission.

List of Relevant Documents

1. Briefing memorandum from Suzanne Barone, Ph.D., EH, to the Commission, ''Proposed Rule to Require Special Packaging for Oral Prescription Drugs that are Granted Over-the-Counter Status by the Food and Drug Administration,'' May 16, 2000.

2. Letter from Debra L. Bowen, M.D., Acting Director, Division of Over-the-Counter Drug Products, Food and Drug Administration, to Jeffrey S. Bromme, Esq., General Counsel, Consumer Product Safety Commission, October 7, 1998.

3. Memorandum from Marcia P. Robins, EC, to Suzanne Barone, Ph.D., EH, ''Economic considerations: Proposal to Maintain Child-Resistant Packaging Requirements for Oral Prescription Drugs that Have Been Granted OTC Status by the FDA,'' April 7, 2000.

4. Memorandum from Suzanne Barone, Ph.D., Project manager for Poison prevention, Directorate for Health Sciences, to Sadye E. Dunn, Secretary, Consumer Product Safety Commission, ''Responses to Questions from Commissioner Moore on Over-the-Counter Switches,'' June 23, 2000.

[FR Doc. 00–21937 Filed 8–29–00; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 2

[FRL–6860–9]

RIN 2025–AA02

Elimination of Special Treatment for Category of Confidential Business Information: Reproposal

AGENCY: Environmental Protection Agency.

ACTION: Proposed rule.

SUMMARY: The Environmental Protection Agency (EPA or Agency) published a document in the **Federal Register** on October 25, 1999 (64 FR 57421), proposing to amend its regulations to eliminate the special treatment of a category of confidential business information (CBI). This category of CBI includes comments received from businesses that substantiate their claims of confidentiality for previously submitted information. In response to requests from interested parties, EPA extended the comment period on the proposed rule from December 27, 1999, to January 26, 2000 (64 FR 71366, December 21, 1999). EPA is now reproposing the rule to address some of the comments that it received.

DATES: Comments on this proposed rule must be submitted by October 30, 2000.

ADDRESSES: Send written comments on this proposed rule to Docket Number EC–1999–015, Enforcement and Compliance Docket and Information Center (ECDIC), U.S. Environmental Protection Agency, 1200 Pennsylvania Ave., NW, Room 4033, Mail Code 2201A, Washington, DC 20460; Phone, 202–564–2614 or 202–564–2119; Fax, 202–501–1011; Email, *docket.oeca@epa.gov.* Documents related to this proposed rule are available for public inspection and viewing by contacting the ECDIC at this same address.

FOR FURTHER INFORMATION CONTACT: Rebecca Moser, Office of Information

Collection, Office of Environmental Information, U.S. Environmental Protection Agency, 1200 Pennsylvania Ave., NW, Mail Code 2822, Washington, DC 20460; Phone, 202–260–6780; Fax, 202–260–8550; Email, *moser.rebecca@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

In 1976, EPA first promulgated its comprehensive CBI regulations as part of its regulations in 40 CFR part 2 for implementing the Freedom of Information Act (FOIA). These regulations include special provisions addressing CBI under specific EPA statutes. For all business information submitted to EPA, the regulations allow businesses that submit information to EPA to claim that information is entitled to confidential treatment. If information is claimed as CBI, EPA generally will not disclose the information to the public, in response to a FOIA request or otherwise, unless EPA makes a determination that the information is not entitled to confidential treatment and notifies the affected business giving the business an opportunity to seek judicial review of EPA's action. The regulations set out procedures for EPA to make confidentiality determinations for information claimed as confidential.

At the time the 1976 regulations were issued, EPA concluded that when EPA received a FOIA request or otherwise needed to determine the confidentiality of particular information claimed as CBI, EPA would need to obtain comments from the business that made the CBI claim telling the Agency why the business believes its information is entitled to confidential treatment. Thus, the regulations provide that EPA will notify the business when information it has claimed as confidential is requested under FOIA or EPA has some other reason to make a determination whether it is entitled to confidential treatment, and the business is given an opportunity to submit comments supporting its confidentiality claim. EPA refers to these comments as ''CBI substantiations.''

Under the FOIA and other statutes, such CBI substantiations were not required. At the time the CBI regulations were written, the leading case in this area was *National Parks & Conservation Ass'n* v. *Morton*, 498 F.2d 765 (D.C. Cir. 1974), which held that information was deemed confidential if disclosure of such information was likely ''to impair the Government's ability to obtain necessary information in the future.'' Traditionally, the concept of impairment was applied when the information was voluntarily submitted and when the government believed that the submitter would not provide the information to the government if it were subject to disclosure. EPA believed that the public release of CBI substantiations would impair the Agency's ability to obtain necessary information substantiating CBI claims in the future.

At that time, EPA believed that affected businesses would be more likely to submit adequate substantiation information if such information were protected and that release of such information was likely to impair the Agency's ability to obtain it in the future. Therefore, based on EPA's reading of *National Parks*, the 1976 regulations encouraged the submission of CBI substantiations by granting such substantiations automatic confidential treatment by EPA if claimed by the business as confidential.

Currently, for business information other than substantiations, when EPA makes an initial determination that the information may be entitled to confidential treatment (*e.g.*, in response to a FOIA request), it notifies the business which asserted an applicable confidentiality claim, orally and in writing (40 CFR 2.204(e)). EPA's written notice provides the business with an opportunity to submit comments on the following:

(1) The portions of the information which are alleged to be entitled to confidential treatment;

(2) The period of time for which confidential treatment is desired by the business (*e.g.*, until a certain date, until the occurrence of a specified event, or permanently);

(3) The purpose for which the information was submitted to EPA and the approximate date of submission, if known;

(4) Whether a business confidentiality claim accompanied the information when it was received by EPA;

(5) Measures taken by the business to guard against undesired disclosure of the information to others;

(6) The extent to which the information has been disclosed to others and the precautions taken in connection therewith;

(7) Pertinent confidentiality determinations, if any, by EPA or other Federal agencies, and a copy of any such determination, or reference to it, if available;

(8) Whether the business asserts that disclosure of the information would be likely to result in substantial harmful effects on the business's competitive position, and if so, what those harmful effects would be, why they should be viewed as substantial, and an explanation of the causal relationship between disclosure and such harmful effects; and

(9) Whether the business asserts that the information is voluntarily submitted information, and if so, whether and why disclosure of the information would tend to lessen the availability to EPA of similar information in the future.

Each business that is notified and invited to comment must submit comments to EPA by the date specified in the notice or, before the comments are due, request an extension of the comment period and receive approval from the EPA legal office (40 CFR 2.205(b)). If the business fails to submit comments by the due date (including any approved extension), the business waives its claim to confidentiality, and EPA may release the information without further notice.

If the business submits a CBI substantiation, the EPA legal office makes a final confidentiality determination. In making the final determination, the EPA legal office considers the business's claim, the CBI substantiation, any previously-issued confidentiality determinations which are pertinent, and other materials it finds appropriate (40 CFR 2.205(d)). EPA's current regulations list the following criteria for determining whether business information is entitled to confidential treatment (40 CFR 2.208):

(1) The business has asserted a business confidentiality claim which has not expired by its terms, nor been waived nor withdrawn;

(2) The business has satisfactorily shown that it has taken reasonable measures to protect the confidentiality of the information and that it intends to continue to take such measures;

(3) The information is not, and has not been, reasonably obtainable without the business's consent by other persons (other than governmental bodies) by use of legitimate means (other than discovery based on a showing of special need in a judicial or quasi-judicial proceeding);

(4) No statute specifically requires disclosure of the information; and

(5) Either—

(a) The business has satisfactorily shown that disclosure of the information is likely to cause substantial harm to the business's competitive position; or

(b) The information is voluntarily submitted information, and its disclosure would be likely to impair the Government's ability to obtain necessary information in the future. (See below for a discussion of a change in the concept of voluntarily-submitted information.)

If EPA determines that the information is entitled to confidential treatment for the full period requested by the business, EPA will maintain the information as CBI for that period and deny any FOIA requests for the information. If EPA determines that the information is not entitled to confidential treatment, then EPA notifies the affected business of its intention to release the information within 10 working days (or other applicable time period specified in subpart B), unless the business first seeks judicial review of the determination and seeks preliminary injunctive relief against disclosure (40 CFR 2.205(f)).

Under EPA's current regulations (40 CFR 2.205(c)), EPA will automatically treat a CBI substantiation marked as confidential as CBI (40 CFR 2.203(b)) if the information in the substantiation is not otherwise possessed by EPA. EPA does not request that the business submit comments substantiating why the information in its CBI substantiation should be treated as confidential. Thus, EPA does not make a substantive confidentiality determination for this information and treats it as confidential solely on the grounds that the business claims it as CBI. This means EPA will deny any FOIA request for the CBI substantiation. The result is that information submitted to EPA in a CBI substantiation and claimed as CBI is treated differently than all other business information submitted to EPA and claimed as CBI. This special treatment has been challenged in Federal Court (*Northwest Coalition for Alternatives to Pesticides (NCAP)* v. *EPA*, D.D.C., Civil Action No. 99–437) on the grounds that it violates FOIA.

EPA reviewed the provision granting automatic CBI treatment in response to the legal challenge by NCAP. After considering the validity of 40 CFR 2.205(c) in light of legal developments since 1976, EPA believes it is unlikely that EPA could defend its original basis for providing automatic protection of CBI substantiations. As part of a motion to stay the proceedings, EPA agreed to propose removing 40 CFR 2.205(c). (Orders granting a stay of the proceedings were filed on July 23, 1999, January 13, 2000, and April 18, 2000.)

On October 25, 1999, EPA published a notice in the **Federal Register** proposing to remove 40 CFR 2.205(c), eliminating the special treatment of CBI substantiations (64 FR 57421) and, thus, treating the information in CBI substantiations like all other business information submitted to EPA and claimed as CBI under 40 CFR part 2, subpart B. EPA proposed to eliminate the provision (1) because special treatment of substantiations is no longer necessary and (2) because elimination of the provision will bring EPA into conformity with other federal agencies. Comments to the proposed rule were due on December 27, 1999. In response to requests from interested parties, EPA extended the comment period from December 27, 1999, to January 26, 2000 (64 FR 71366, December 21, 1999).

EPA received comments on its proposed rule from nine entities: one in favor of the proposed rule [Northwest Coalition for Alternatives to Pesticides (NCAP)] and eight opposed (Chemical Specialities Manufacturers Association, Color Pigments Manufacturers Association, Inc., Edison Electric Institute, American Crop Protection Association, Utility Air Regulatory Group, Carolina Power & Light Company, FirstEnergy Corp., and Duke Energy Corporation).

NCAP supported the proposed rule, stating that 40 CFR 2.205(c) should be removed since it currently allows EPA to exempt from disclosure an entire category of documents (*i.e.*, CBI substantiations that are claimed as confidential) that should not be entitled to exemption under FOIA. NCAP added that EPA's current regulations allow the Agency to withhold an entire CBI substantiation without segregation of non-exempt material based solely on the desire of the business that submitted the substantiation, and that under FOIA (USC 552(b)), EPA is required to disclose any reasonable segregable information that is not exempt.

Comments opposing the proposed rule included the following:

(1) EPA did not provide sufficient rationale for removing 40 CFR 2.205(c),

(2) Businesses would be reluctant to provide the detailed information needed to substantiate original CBI claims for fear that a substantiation might be released,

(3) The proposed rule could create an endless cycle of substantiations and place unnecessary burdens on EPA and industry, and

(4) The rule should not be applied retroactively.

Based on the comments received, EPA is reproposing the rule to provide a more thorough explanation for the proposed amendment which would change the CBI regulations to eliminate the automatic protection of CBI substantiations that are claimed as confidential and submitted to the Agency after the effective date of the final rule. EPA believes that the amendment to eliminate the special treatment in 40 CFR 2.205(c) is justified for the following reasons:

(1) *Change in Concept of ''Voluntarily-Submitted Information.''* When the CBI regulations were written in 1976, EPA believed that the public release of CBI substantiations would impair the Agency's ability to obtain necessary information in the future. Traditionally, the concept of impairment was applied when the information was voluntarily submitted and when the government believed that the submitter would not provide the information if it were subject to disclosure. The leading case at the time, *National Parks & Conservation Association* v. *Morton*, 448 F.2d 765 (D.C. Cir. 1974), concluded that information is confidential if disclosure of the information is likely ''to impair the Government's ability to obtain necessary information in the future.'' EPA, in issuing its 1976 regulations, believed substantiations should be considered as voluntarily-submitted information which, if released, would impair the Agency's ability to obtain such information in the future and, thus, granted substantiations automatic CBI status in the regulations.

The U.S. Court of Appeals for the D.C. Circuit ruled in *Critical Mass Energy Project* v. *NRC*, 975 F.2d 871 (D.C. Cir. 1992), that ''voluntarily'' submitted information should be categorically protected, provided it is not ''customarily'' disclosed to the public by the submitter. Subsequent judicial interpretation of the word ''voluntary'' suggests that if an industry must submit information to obtain a benefit—as in this case, the nondisclosure of CBI—then the submission is not voluntary.

In light of *Critical Mass* and subsequently decided cases, EPA believes it is unlikely that EPA could defend the position that CBI substantiations are voluntarily submitted and that they should therefore be automatically protected from disclosure without further finding that they are confidential. Thus, EPA believes it must have an independent rationale to determine whether any specific CBI substantiation submitted to the Agency is itself CBI. In response to the current litigation, EPA, in consultation with the Department of Justice, has determined that according to CBI substantiations the same treatment as other business information claimed as confidential under 40 CFR part 2, subpart B, is the appropriate legal position.

(2) *Comparison to Practices at Other Federal Agencies.* EPA contacted 12 other departments and agencies to determine how they handle CBI substantiations. These included the Department of Transportation, the Food

and Drug Administration, the Department of Energy, the Department of Commerce, the National Oceanic and Atmospheric Administration, the Department of Health and Human Services, the Department of the Interior, the Department of Education, the National Aeronautics and Space Administration, the Consumer Product Safety Commission, and the National Science Foundation. Although the specific procedures differ, none of these departments and agencies automatically protects CBI substantiations that are claimed as confidential from public disclosure. EPA's current practice of categorically protecting all CBI substantiations that are claimed as confidential, without examining the nature of these substantiations, appears to be unusual. The proposed rule would bring EPA into closer alignment with the practices of other departments and agencies.

(3) *Protecting Both Public Access and Confidentiality*. The amendment to eliminate the special treatment in 40 CFR 2.205(c) will help ensure that EPA honors both the public's right to obtain government-held information under FOIA and other laws and a submitter's right to the protection of CBI, as required under FOIA and other statutes. Under the proposed amendment, when EPA receives a FOIA request for a CBI substantiation that has been claimed as confidential and submitted after the effective date of the final rule, EPA will no longer automatically deny the request; rather, as with all other business information claimed as CBI, EPA will notify the affected business, provide the business the same opportunity to comment on its confidentiality claim that the business would have for any other information claimed as CBI, and then make an individual determination whether the information in the CBI substantiation is entitled to confidential treatment. The information would continue to be protected from disclosure if the business submitted comments, and the Agency determined that the information was entitled to confidential treatment.

EPA acknowledges that the proposed rule would create some additional burden for EPA and affected businesses when the Agency needs to make a final confidentiality determination for a particular CBI substantiation. EPA believes that only a portion of the CBI substantiations that are claimed as confidential would ever require such a determination (*e.g.*, in response to a FOIA request for the substantiation or if EPA needed to determine its confidentiality for other reasons). The Agency does not expect the proposed rule to impose a significant burden on affected businesses (see below, V. Paperwork Reduction Act).

II. Description of the Proposed Rule

EPA proposes to amend its general CBI regulations (40 CFR part 2, subpart B) to eliminate the special treatment of CBI substantiations. From the effective date of the rule forward, CBI substantiations would be treated in exactly the same manner as other business information that is claimed as confidential. Under the proposed rule, businesses would still be able to claim CBI substantiations as confidential as they can any other business information submitted to EPA (40 CFR 2.204(e)(6)) and would be entitled to all the other procedural rights in 40 CFR part 2, subpart B.

If EPA received a FOIA request for a CBI substantiation that had been marked as confidential and submitted to the Agency after the effective date of the final rule, EPA would make a preliminary determination of confidentiality, notify the affected business and request comments on its confidentiality claim, and then make a final confidentiality determination, in accordance with 40 CFR 2.204 and 2.205. If EPA then determined that the CBI substantiation was entitled to confidential treatment, EPA would continue to protect the information and deny any pending FOIA request. If EPA determined that the CBI substantiation was not entitled to confidential treatment, it would notify the affected business of its intention to release the information within 10 working days (or other applicable time period specified in subpart B) of the business's receipt of the notice, unless the appropriate EPA legal office was first notified that the business had sought judicial review and had sought preliminary injunctive relief against disclosure (40 CFR 2.205(f)).

This amendment would apply only to CBI substantiations submitted after the effective date of the final rule. Among the comments EPA received on the October 25, 1999, proposed rule were comments arguing that this proposed amendment, if adopted, should not be applied retroactively to CBI substantiations submitted to EPA before this change is made. Concerns were expressed about the fairness of applying the proposed rule to old substantiations which businesses claimed as confidential and submitted to EPA with the understanding that the substantiations would be protected. In response to these comments, EPA proposes to apply the rule only prospectively to CBI substantiations submitted after the change goes into effect.

As discussed above, EPA does not believe it can successfully defend its existing regulation at 40 CFR 2.205(c), in light of case law developments since 1976. Thus, if EPA were to continue to deny FOIA requests for CBI substantiations based on § 2.205(c), EPA could potentially be ordered by the courts to conduct a CBI determination or to disclose the information to FOIA requesters. EPA could also be potentially liable for attorneys' fees under FOIA. In addition, affected businesses would be at a disadvantage in protecting their CBI substantiations from disclosure in response to FOIA requests. Since the businesses would not have provided comments to EPA to substantiate why information in their CBI substantiations is entitled to confidential treatment, a court reviewing an EPA denial of a FOIA request for a substantiation would have only the issue of § 2.205(c) before it. There would be no substantive argument about why the information in a particular CBI substantiation is confidential. Thus, if the court decided that § 2.205(c) was not an appropriate basis for denying the FOIA request, EPA would be ordered to disclose the information.

On the other hand, if a CBI substantiation submitted after the effective date of the final rule were requested under FOIA, EPA would give the affected business an opportunity to comment on why the CBI substantiation is confidential, and EPA would be able to make a substantive final confidentiality determination. EPA believes it would be much more likely to prevail in defending such a substantive determination than in defending a denial based solely on § 2.205(c). EPA's purpose since 1976 has been to have CBI regulations that allow businesses to submit information to EPA while protecting its confidentiality and that allow EPA to make appropriate, defensible confidentiality determinations. We believe this proposed amendment is consistent with those goals and will allow businesses and EPA to have confidence that EPA can protect confidential CBI substantiations from public disclosure.

Generally, a CBI substantiation exists only because someone has requested access under FOIA to specific business information claimed as CBI, and EPA has given the affected business an opportunity to comment in support of its confidentiality claim. If EPA were to conclude that the underlying information is not entitled to confidential treatment, the FOIA

requester would get the information and would be unlikely to have any interest in the content of the CBI substantiation, since it had not proven persuasive with EPA.

If EPA were to conclude that the underlying information is entitled to confidential treatment, the FOIA requester would not get the information. Depending on the rationale in EPA's final confidentiality determination, the requester might subsequently ask to see the CBI substantiation since it had formed some or all of the basis for EPA's determination. The FOIA requester's interest in the CBI substantiation is contemporaneous with the final confidentiality determination. EPA believes that applying the rule prospectively will respond to the majority of future requests for CBI substantiations, and also avoid placing an undue burden on businesses that submitted CBI substantiations in the past.

EPA proposes to apply the rule prospectively, without changing the procedures for handling substantiations that were submitted prior to the effective date of the final rule. At the same time, EPA would like to solicit public comments on two alternative approaches: (1) Applying the rule prospectively, but notifying affected businesses when old substantiations are requested under FOIA; and (2) applying the rule retroactively.

(1) Under the first alternative approach, EPA would notify the affected business if a FOIA request were received for an old substantiation (*i.e.*, a substantiation submitted prior to the effective date of the final rule) and provide the business with an opportunity to comment. In cases involving old substantiations, EPA would not treat the failure to comment as a waiver of the confidentiality claim. Any comments submitted by the affected business could provide EPA with an additional basis for defending its denial of a related FOIA request (in addition to § 2.205(c)), if such a denial were ever challenged in court.

If EPA were to take this approach, it might amend § 2.205(c) to read as follows:

• If information submitted to EPA by a business as part of its comments under this section prior to [Insert effective date of final rule] pertains to the business's claim, is not otherwise possessed by EPA, and is marked when received in accordance with § 2.203(b), it will be regarded by EPA as entitled to confidential treatment. This subsection does not apply to comments received after [Insert effective date of final rule].

• If EPA receives a request for comments submitted by an affected business under this section prior to [Insert effective date of final rule] which are entitled to confidential treatment, EPA will notify the affected business in accordance with § 2.204(e) and provide the business with an opportunity to comment. However, notwithstanding § 2.203(a)(2), failure to comment will not constitute a waiver of the confidentiality claim.

(2) Under the second alternative approach, EPA could apply the rule retroactively. This approach would mean that all CBI substantiations, regardless of when they were submitted to EPA, would be treated in exactly the same manner as other types of CBI. If the rule were applied retroactively and EPA received a FOIA request for an old substantiation, the Agency would notify the affected business and provide it with an opportunity to submit comments. As described above, comments submitted by the affected business could be useful to EPA in defending the denial of a FOIA request if it were ever challenged in court. If the rule were applied retroactively, failure by the affected business to submit comments would constitute a waiver of its confidentiality claim.

III. Statutory Authority

EPA is proposing this rule under the authority of 5 U.S.C. 301, 552 (as amended), and 553.

IV. Economic Impact

This proposed rule is not expected to have a significant economic impact on the parties affected by EPA's general CBI regulations (40 CFR part 2, subpart B). Any additional costs would be associated with preparing and submitting comments that explain why a CBI substantiation should be confidential. Based on best professional judgment, EPA estimates that of the approximately 360 substantiations it receives each year that are claimed as confidential, no more than about one-fourth (*i.e.*, 90) would be requested under FOIA or require final confidentiality determinations for other purposes. The total labor cost to businesses to submit comments defending the confidentiality of these 90 CBI substantiations would be approximately $41,798.70 (see below, V. Paperwork Reduction Act). No capital costs or operation and maintenance costs would be incurred as a result of removing 40 CFR 2.205(c).

V. Paperwork Reduction Act

The information collection requirements in this proposed rule have been submitted for approval to the Office of Management and Budget (OMB) under the Paperwork Reduction Act, 44 U.S.C. 3501 *et seq.* An Information Collection Request (ICR) document has been prepared by EPA (ICR No. 1665.04) and a copy may be obtained from Sandy Farmer by mail at Collection Strategies Division, U.S. Environmental Protection Agency Mail Code 2822, 1200 Pennsylvania Ave., NW, Washington, DC 20460; by email at *farmer.sandy@epamail.epa.gov*; or by calling (202) 260–2740. A copy may also be downloaded from the Internet at *http://www.epa.gov/icr*.

This ICR deals with the information collection process that would occur under the proposed rule if EPA found it necessary to determine the confidentiality of a CBI substantiation received from a submitter and claimed as CBI (*e.g.*, in response to a FOIA request or for some other purpose). EPA expects that it would need to make final confidentiality determinations for only some of the CBI substantiations that are claimed as confidential.

Under the proposed rule, CBI substantiations that are claimed as CBI and submitted after the effective date of the final rule would be treated in the same manner as any other business information that is claimed as CBI. Thus, under 40 CFR 2.205(d), if EPA requests comments from a business related to a CBI substantiation submitted after the effective date of the proposed rule, and the business fails to furnish comments by the specified due date, the business waives its claim to confidentiality.

EPA receives approximately 443 substantiations per year, 360 of which are claimed as confidential. Based on best professional judgment, the Agency estimates that under the proposed rule, EPA might be required to make final confidentiality determinations for about one-fourth (*i.e.*, 90) of the substantiations that are claimed as confidential. In each case, EPA estimates that it would take affected businesses approximately 14 hours (2 attorney hrs., 4 manager hrs., 7 technical hrs., and 1 clerical hr.) at a cost of approximately $464.43 in labor ($50.00/attorney hr., $33.42/manager hr., $30.66/technical hr., and $16.13/clerical hr.) to prepare and submit comments. Affected businesses would spend a total of approximately 1,260 hours and $41,798.70 in labor costs to submit 90 such substantiations to EPA. No capital costs or operation and maintenance costs would be incurred in response to this information collection request.

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.

Comments are requested on the Agency's need for this information, the accuracy of the provided burden estimates, and any suggested methods for minimizing respondent burden, including through the use of automated collection techniques. Send comments on the ICR to the Director, Collection Strategies Division U.S. Environmental Protection Agency, Mail Code 2822, 1200 Pennsylvania Ave., NW, Washington, DC 20460; and to the Office of Information and Regulatory Affairs, Office of Management and Budget, 725 17th St., NW, Washington, DC 20503, marked ''Attention: Desk Officer for EPA.'' Include the ICR number (ICR No. 1665.04) in any correspondence. Since OMB is required to make a decision concerning the ICR between 30 and 60 days after August 30, 2000, a comment to OMB is best assured of having its full effect if OMB receives it by September 29, 2000. The final rule will respond to any OMB or public comments on the information collection requirements contained in this proposal.

VI. Regulatory Flexibility Act, as Amended

The Regulatory Flexibility Act, as amended by the Small Business Regulatory Enforcement Fairness Act of 1996, 5 U.S.C. 601 *et seq.*, generally requires an agency to conduct a regulatory flexibility analysis of any rule subject to notice and comment rulemaking requirements 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 not-for-profit enterprises, and small governmental jurisdictions. As indicated above, EPA expects that under the proposed rule, only a portion of the CBI substantiations that are submitted to EPA after the effective date of the final rule and marked as confidential would ever be requested under FOIA or require a confidentiality determination for some other reason. Based on best professional judgment, the Agency expects that about one-fourth of the substantiations that are claimed as confidential might be requested under FOIA; about 90 businesses would be affected (some of which might be small) and the total labor costs to these businesses would be approximately $41,798.70. No capital costs or operation and maintenance costs would be incurred. Therefore, under 5 U.S.C. 605(b), I certify that this proposed rule will not have a significant economic impact on a substantial number of small entities.

VII. Environmental Impact

This proposed rule is expected to have no environmental impact. It pertains solely to the collection and dissemination of information.

VIII. Executive Order 12866

Under Executive Order 12866 [48 FR 51735 (October 4, 1993)], EPA must determine whether the regulatory action is ''significant'' and therefore subject to 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.

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

IX. Executive Order 13132 on 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.''

Under Section 6 of Executive Order 13132, EPA may not issue a regulation that has federalism implications, that imposes substantial direct compliance costs, and that is not required by statute, unless the Federal government provides the funds necessary to pay the direct compliance costs incurred by State and local governments, or EPA consults with State and local officials early in the process of developing the proposed regulation. EPA also may not issue a regulation that has federalism implications and that preempts State law, unless the Agency consults with State and local officials early in the process of developing the proposed regulation.

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. This proposed rule eliminates the special treatment of a category of confidential business information. Thus, the requirements of section 6 of the Executive Order do not apply to this proposed rule.

X. Executive Order 13084 on Consultation With Indian Tribal Governments

Under Executive Order 13084, EPA may not issue a regulation that is not required by statute, that significantly or uniquely affects the communities of Indian tribal governments, and that imposes substantial direct compliance costs on those communities, unless the Federal government provides the funds necessary to pay the direct compliance costs incurred by the tribal governments, or EPA consults with those governments. If EPA complies by consulting, Executive Order 13084 requires EPA to provide to OMB, in a separately identified section of the preamble to the rule, a description of the extent of EPA's prior consultation with representatives of affected tribal governments, a summary of the nature

of their concerns, and a statement supporting the need to issue the regulation. In addition, Executive Order 13084 requires EPA to develop an effective process permitting elected officials and other representatives of Indian tribal governments ''to provide meaningful and timely input in the development of regulatory policies on matters that significantly or uniquely affect their communities.''

This proposed rule does not significantly or uniquely affect the communities of Indian tribal governments. This proposed rule applies to businesses, not government entities, submitting comments to substantiate CBI claims. Accordingly, the requirements of section 3(b) of Executive Order 13084 do not apply to this proposed rule.

XI. Unfunded Mandates Reform Act of 1995

Under Section 202 of the Unfunded Mandates Reform Act of 1995 (UMRA), Public Law 104–4, EPA must prepare a budgetary impact statement to accompany any general notice of proposed rulemaking or final rule that includes a federal mandate which may result in estimated costs to State, local, or tribal governments in the aggregate, or to the private sector, of $100 million or more. Under Section 205, for any rule subject to Section 202, EPA generally must select the least costly, most cost-effective, or least burdensome alternative that achieves the objectives of the rule and is consistent with statutory requirements. Under Section 203, before establishing any regulatory requirements that may significantly or uniquely affect small governments, EPA must take steps to inform and advise small governments of the requirements and enable them to provide input.

EPA has determined that this proposed rule does not include a federal mandate as defined in UMRA. The proposed rule does not include a federal mandate that may result in estimated annual costs to State, local or tribal governments in the aggregate, or to the private sector, of $100 million or more, and does not establish regulatory requirements that may significantly or uniquely affect small governments.

XII. Executive Order 13045

Executive Order 13045, entitled ''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 or safety risk that EPA has reason to believe may have a disproportionate effect on children. If the regulatory action meets both criteria, EPA must evaluate the environmental health or safety effects of the planned rule on children, and explain why the planned rule is preferable to other potentially effective and reasonably feasible alternatives considered by EPA.

EPA believes Executive Order 13045 applies 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. This proposed rule is not subject to Executive Order 13045 because it does not establish an environmental standard intended to mitigate health or safety risks.

XIII. 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 EPA decides not to use available and applicable voluntary consensus standards.

This proposed rule does not involve any technical standards, and EPA is not considering the use of any voluntary consensus standards. EPA welcomes comments and specifically invites the public to identify any potentially-applicable voluntary consensus standards and explain why such standards should be used in this rule.

List of Subjects in 40 CFR Part 2

Environmental protection, Administrative practice and procedure, Confidential business information, Freedom of information, Government employees.

Dated: August 24, 2000.

Carol M. Browner,

Administrator.

For the reasons set out above, EPA proposes to amend 40 CFR part 2 as follows:

PART 2—PUBLIC INFORMATION

1. The authority citation for part 2 continues to read as follows:

Authority: 5 U.S.C. 301, 552 (as amended), 553; secs. 114, 205, 208, 301, and 307, Clean Air Act, as amended (42 U.S.C. 7414, 7525, 7542, 7601, 7607); secs. 308, 501, and 509(a), Clean Water Act, as amended (33 U.S.C. 1318, 1361, 1369(a); sec. 13, Noise Control Act of 1972 (42 U.S.C. 4912); secs. 1445 and 1450, Safe Drinking Water Act (42 U.S.C. 300j–4, 300j–9); secs. 2002, 3007, and 9005, Solid Waste Disposal Act, as amended (42 U.S.C. 6912, 6927, 6995); secs. 8(c), 11, and 14, Toxic Substances Control Act (15 U.S.C. 2607(c), 2610, 2613); secs. 10, 12, and 25, Federal Insecticide, Fungicide, and Rodenticide Act, as amended (7 U.S.C. 136h, 136j, 136w); sec. 408(f), Federal Food, Drug and Cosmetic Act, as amended (21 U.S.C. 346(f); secs. 104(f) and 108, Marine Protection Research and Sanctuaries Act of 1972 (33 U.S.C. 1414(f), 1418); secs. 104 and 115, Comprehensive Environmental Response, Compensation, and Liability Act of 1980, as amended (42 U.S.C. 9604 and 9615); sec. 505, Motor Vehicle Information and Cost Savings Act, as amended (15 U.S.C. 2005).

2. Section 2.205 is amended by revising paragraph (c) to read as follows:

§ 2.205 Final confidentiality determination by EPA legal office.

* * * * *

(c) *Confidential treatment of some comments from business.* If information submitted to EPA by a business as part of its comments under this section prior to [effective date of final rule] pertains to the business's claim, is not otherwise possessed by EPA, and is marked when received in accordance with § 2.203(b), it will be regarded by EPA as entitled to confidential treatment. This paragraph (c) does not apply to comments received after [effective date of final rule].

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[FR Doc. 00–22158 Filed 8–29–00; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Parts 52 and 81

[MI42–7823; FRL–6851–4]

Approval and Promulgation of State Implementation Plans; Michigan

AGENCY: Environmental Protection Agency.

ACTION: Notice of proposed rulemaking.

SUMMARY: The United States Environmental Protection Agency (EPA) is proposing to adjust the applicability date for the reinstating the 1-hour ozone National Ambient Air Quality Standard (NAAQS) in Muskegon County, Michigan and is proposing to determine that the area has attained the 1-hour ozone NAAQS. This proposal is based on 3 consecutive years of complete,