# Pesticides: Problems Facing the Industry in Submitting Proprietary Scientific Data to an International Organization

by

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# PESTICIDES: PROBLEMS FACING THE INDUSTRY IN SUBMITTING PROPRIETARY SCIENTIFIC DATA TO AN INTERNATIONAL ORGANIZATION

## I. INTRODUCTION

United States pesticide firms confront several troublesome problems with regard to scientific data, both domestically and internationally. Domestically, these firms face two main questions in this area: First, what is the scope of the Environmental Protection Agency's [hereinafter EPA] right to disclose to the public sensitive scientific data submitted to the EPA by these companies for the sole purpose of registering a pesticide?[1] Second, what is the proper method of calculating the compensation owed to a "data-generating" pesticide firm by another pesticide firm that uses that data to register a pesticide with the EPA?[2] On the international level, pesticide firms face the problem of preventing scientific data which the firms submit to international organizations from falling into the hands of a foreign competitor or a foreign government. The foreign competitor could use this data to register the pesticide in foreign countries.[3] A foreign

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[1] The Federal Insecticide Fungicide and Rodenticide Act (FIFRA), ch. 125, 61 Stat. 163 (1947) (current version at 7 U.S.C. §§ 136-136y (1988), covers the procedures for registering a pesticide for commercial use within the United States. According to FIFRA, the EPA shall make available to the public all safety tests relating to a pesticide now registered or previously registered, except information on manufacturing, quality control, methods used to measure any inert ingredient, or the identity or percentage of any deliberately added inert ingredient; but these excepted types of information also must be made available if the Administrator of the EPA deems that the public disclosure of such information is necessary to protect against unreasonable risk to health or environment. 7 U.S.C. 136h(d). The EPA, however, has not always been forthcoming with the disclosure of such information to the public. *See infra* text accompanying notes 68-69.

[2] Under FIFRA, an applicant must make an offer of reasonable compensation to the original data submitter. Failing agreement between the parties, the matter must be submitted to binding arbitration. 7 U.S.C. § 136a(c)(1)(D). However, neither FIFRA nor its legislative history makes clear what constitutes reasonable compensation. *See infra* text accompanying notes 77-79.

[3] *See* R. BOARDMAN, PESTICIDES IN WORLD AGRICULTURE 69 (1986) [hereinafter BOARDMAN]. *See also infra* text accompanying notes 90-92.

government, on the other hand, could use this data as a basis for blacklisting the compound or the pesticide company involved.

At the root of these controversies lies the following scenario. A large United States pesticide manufacturer may spend millions of dollars yearly on gathering the required data for registering a single pesticide and for other administrative purposes involving that pesticide. Not surprisingly, the manufacturer considers this data, whether trade secret or not, as its proprietary interest. As with any private property, the manufacturer insists it has the right to control the access of others to the data.

Under present federal law, each pesticide manufacturer that seeks to register a pesticide for commercial use must, among other things, submit adequate data to the EPA in support of registration of that pesticide.[4] The EPA is required to reveal to the public the results of safety studies performed on any pesticide that is currently, or was once, registered.[5] By enacting this legislation, Congress sought to provide the public with the means to assess for themselves the value of these studies.[6] However, the pesticide industry has attempted to effect the repeal of this legislation both in court and by lobbying pressure.[7] Pesticide manufacturers fear that commercial misuse of the safety data could occur if the data falls into the public's hands.[8] At present, the EPA will disclose health and safety data to a member of the public provided that the latter signs an affirmation to the effect that he or she will do nothing to pass the data on to a multinational or foreign firm. Yet public interest groups and industry groups have not reached agreement as to what are the limits for such an affirmation.[9] The future of this legislation, then, remains uncertain.

Also under U.S. law, a firm seeking to register a pesticide that has already been registered may be allowed to use the data submitted by the original registrant in support of the of the latter firm's application for registration.[10] The issue may then arise whether the so-

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[4] 7 U.S.C. § 136a(c)(1)(D) (1988).

[5] *Id.* at § 136h(d).

[6] Safir and Davis, *Disclosure of Pesticide Data: A Viable Compromise at Last?*, 12 ENVTL. L. REP. 15017 (1982) [hereinafter Safir].

[7] *Id.* at 15018-22.

[8] *Id.* at 15018.

[9] *See, e.g., NCAMP Objects to Data Release Plan; Roundup Data Probably First Out*, PESTICIDE & TOXIC CHEMICAL NEWS [hereinafter PESTICIDE NEWS], Aug. 8, 1984, at 22-23. *See also infra* text accompanying notes 71-72.

[10] 7 U.S.C. § 136a(c)(1)(D). *See infra* text accompanying notes 55-63 and 76-79.

called "follow-on registrant" should have to pay the original registrant for the opportunity costs that the follow-on registrant avoids by gaining immediate market access, for the actual costs of developing the test data[11], or according to a system based on market share of the pesticide ingredients in question.[12] This issue remains unsettled.

The success of international efforts to regulate pesticides hinges in large part on the willingness of individual pesticide firms to submit proprietary data in furtherance of such regulation.[13] The Codex Committee on Pesticide Residues [hereinafter CCPR] which is a subsidiary of the Codex Alimentarius Commission [hereinafter CODEX], a United Nations organization under the auspices of the World Health Organization [hereinafter WHO] and the Food and Agricultural Organization, is the main international forum on pesticide residues matters.[14] United States pesticide manufacturers are willing to participate in the work of the CCPR if for no other reason than to seek a harmonization of divergent pesticide laws so as to facilitate the international trade in pesticides.[15] Two groups of scientists, collectively known as the Joint Meeting on Pesticide Residues [hereinafter JMPR], have set acceptable levels of human intake of given pesticides and recommended maximum acceptable levels of pesticide residues on certain foods.[16] Member states of CODEX are obliged to make a good faith effort to incorporate the Codex-recommended levels into their national regulatory systems and at the very least to consider the Codex levels when setting their own levels.[17]

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[11] Coll, *Determining Compensation for Subsequent Use of Test Data Under FIFRA: A Value-Based or Cost-Based Standard?*, 11 COLUM. J. ENVTL. L. 193, 193-194 (1986) [hereinafter Coll]. *See infra* notes 77-79 and accompanying text.

[12] *See infra* note 79 and accompanying text.

[13] *See* BOARDMAN, *supra* note 3, at 8.

[14] *See* Frawley, *Codex Alimentarius - Food Safety - Pesticides*, 42 FOOD DRUG COSM. L.J. 168, 173 (1987) (The author describes the CCPR as "the international risk management team for pesticide residues").

[15] BOARDMAN, *supra* note 3, at 105.

[16] *See* WORKING WITH THE JMPR AND THE CCPR - A GIFAP MANUAL FOR THE AGROCHEMICAL INDUSTRY [hereinafter GIFAP MANUAL] 7-8 (1988) (available from GIFAP, Brussels, Belgium).

[17] The CODEX standards do not require government acceptance since CODEX is not a regulatory body. However, member states of CODEX are under a treaty obligation to make their best efforts to accept these standards. *See*, Kimbrell, *Codex Alimentarius Food Standards and Their Relevance to U.S. Standards*, FOOD TECHNOLOGY 93, 94 (June, 1982). As of mid-1988, CODEX had 134 member nations including the United States. GOVERNMENT/INDUSTRY CODEX MEETING, May 12-13, 1986 (Arlington, VA) (updated version) 6.

Usually, the manufacturer(s) of a pesticide must submit adequate data to CODEX before the JMPR can examine the pesticide.[18] For many years, pesticide manufacturers from the United States and elsewhere were very reluctant to submit data to any international body, including CODEX. These firms feared that this data would fall into the hands of foreign governments and/or foreign competitors, and that another company would use this data to register the pesticide abroad.[19]

As a result of an agreement [hereinafter Agreement] regarding data security reached in 1983 between the Groupement International des Associations Nationales de Fabricants de Produits Agrochimiques [hereinafter GIFAP], the pesticide industry group officially recognized by CODEX[20], and the International Programme on Chemical Safety [hereinafter IPCS], United States pesticide manufacturers seem assured of proper safeguarding of their data.[21] Yet a few problems remain. For instance, the JMPR makes annual reports which are published and widely read. Although a manufacturer is asked by the JMPR to indicate in advance what parts of its data constitute trade secrets, and trade secrets are not disclosed in these reports[22], a competitor could conceivably use the summary of the data published along with the reports to register the pesticide in another country[23].

This note will examine the interests of pesticide manufacturers vis á vis their proprietary data submitted to international organizations (specifically the CCPR) and how these interests are presently accommodated. Federal pesticide law will serve as background material for this inquiry.

## II. BACKGROUND

### *A. Federal Law on Pesticide Data Disclosure and Data Compensation.*

#### *1. Federal Insecticide, Fungicide and Rodenticide Act of 1947*

The Federal Insecticide, Fungicide and Rodenticide Act of 1947 (FIFRA) established the requirement that prospective licensees of a pesticide submit to the Secretary of Agriculture the product's chemical formula and data to support the licensing of that pesticide if the

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[18] BOARDMAN, *supra* note 3, at 59.
[19] *Id.* at 69.
[20] GIFAP MANUAL, *supra* note 16, at 36.
[21] *Id.* at 21.
[22] *Id.* at 30.
[23] *Id.* at 16.

Secretary should so require.[24] FIFRA has always forbidden the government from disclosing the chemical formula of a currently or previously registered pesticide to the public[25]. Yet, in its original version FIFRA did not prohibit the USDA from disclosing test data submitted by one applicant for registration to a later applicant. In fact, the USDA appears to have routinely considered submitted test data from one applicant in deciding whether to license another applicant for the same pesticide or for a different pesticide having the same active ingredient(s).[26]

*2. Federal Environmental Pesticide Control Act of 1972*

Not until the enactment in 1972 of the Federal Pesticide Control Act[27] (FEPCA) were the rules on data use tightened. Under this statute, registration of a pesticide became contingent upon the manufacturer showing that the pesticide would not cause unreasonable adverse effects on the environment.[28] Most importantly, FEPCA set up a data licensing scheme pursuant to which one of two conditions would have to be met before the EPA could release the data to another applicant for registration purposes. First, the original registrant would have to give its permission for the follow-on applicant to use the former's data. Alternatively, the applicant would have to provide reasonable compensation to the registrant before the data could be used, and such data could not contain trade secrets or commercial or financial information.[29] The Administrator of the EPA

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[24] Currently codified at 7 U.S.C. § 136-136y (1988). The United States Department of Agriculture [hereinafter USDA], was responsible for regulating pesticides until 1970. Upon its creation in 1970, the Environmental Protection Agency [EPA] was given this task. Reorg. Plan No. 3 of 1970, 3 C.F.R. 1072 (1966-1970 Compilation), *reprinted in* Appendix to 5 U.S.C. at § 609 (1970) *and in* 84 Stat. 2086 (1970). However, the task of regulating pesticide residues in meat and poultry products remains with the USDA. *Id.*

[25] Current version at 7 U.S.C. § 136h(b) (1988).

[26] The Supreme Court expressed this belief in Ruckelshaus v. Monsanto Co., 467 U.S. 986, 1009-10, n.14 (1984). An active ingredient (in the case of a pesticide) is defined as an ingredient which will prevent, destroy, repel, or mitigate any pest. 7 U.S.C. § 136(a)(1) (1982).

[27] Federal Environmental Pesticide Control Act, Pub. L. No. 92-516, 86 Stat. 979 (1972) (*codified as amended at* 7 U.S.C. §§ 136-136y (1988)) (FEPCA). Even though FEPCA represented a major amendment of FIFRA, FEPCA and its subsequent amendments are still referred to as FIFRA.

[28] 7 U.S.C. § 136a(c)(5)(C)(D), (1988). The applicant still must show that the composition of the pesticide warrants the proposed claims for it and that the labelling comply with FIFRA. *Id.* at (A), (B).

[29] 7 U.S.C. § 136a(c)(1)(D) (1988).

[hereinafter Administrator] was to determine what would be reasonable compensation under the circumstances after providing to both parties notice and an opportunity for hearing. Only the original registrant could appeal the Administrator's decision, and an appeal had to be brought in federal district court.[30]

Under FEPCA, the categories of registrant-supplied data that the EPA was prohibited from disclosing to an applicant or to the public were broadened. In addition to chemical formulas of pesticides, the EPA could not disclose trade secrets, commercial information and financial information.[31] At the heart of the EPA's right under FEPCA to disclose scientific data to others is the right of the original submitter of the data to mark those portions of the submitted data that constitute trade secrets or any other protected information.[32] Although the Administrator could under no circumstances make public a submitter's trade secrets, commercial information or financial information, it could release information relating to product formulas if necessary to carry out FEPCA.[33] Also, under FEPCA, for the EPA to release any data that it believes, contrary to the submitter's representations, to be unprotected, the EPA must notify the registrant of its intent to do so. The registrant may then seek a declaratory judgment from a district court as to whether such information is indeed protected.[34]

The FEPCA also addressed other new issues of information disclosure. For example, FEPCA mandated that pesticide manufacturers submit to the EPA certain information relating to the requirement that EPA registration be obtained for establishments where pesticides are produced.[35] This information included the types and amounts of pesticides currently produced, pesticides produced during the past

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[30] *Id.* at § 136a(c).

[31] FEPCA, Pub. L. No. 92-516 § 10(b), 86 Stat. 973, 989 (1972) (*codified as amended at* 7 U.S.C. § 136h (1988)).

[32] FEPCA, Pub. L. No. 92-516 § 10(a), 86 Stat. 973, 989 (1972) (*codified as amended at* 7 U.S.C. § 136h(a) (1988)).

[33] FEPCA, Pub. L. No. 92-516 § 10(b), 86 Stat. 973, 989 (1972) (*codified as amended at* 7 U.S.C. § 136h(b) (1988)). In addition, FEPCA requires that the Administrator upon registering a pesticide reveal to the public the data he relied on in making the registration statement and any other data he deems relevant to his decision. FEPCA, Pub. L. No. 92-516 § 3(c)(2), 86 Stat. 973, 979 (1972) (*codified as amended at* 7 U.S.C. § 136a(c)(2) (1988)).

[34] 7 U.S.C. § 136h(c) (1988).

[35] FEPCA, Pub. L. No. 92-516 § 7(c), 86 Stat. 973, 987 (1972) (*codified as amended at* 7 U.S.C. § 136e (1988)).

year, and those sold or distributed during the past year.[36] Such information was subject to the same restrictions on disclosure as trade secrets and commercial and financial information.[37] Also, FEPCA stipulated that the EPA may not require registrants to submit financial data, sales data other than shipment data, pricing data, personnel data, or research data (except that relating to registered pesticides or pesticides sought to be registered).[38]

*3. FIFRA Extension of 1975*

An extension to FIFRA, enacted in 1975[39], provided some further elaboration of the law on data use and compensation. Only data submitted to the EPA by a registrant on or after January 1, 1970 and which involves an application for registration or reregistration submitted after October 21, 1972 was covered by the Extension. Disclosure of such data would be subject to the condition that a future applicant must obtain permission for its use from the registrant or must offer to pay to the latter reasonable compensation for its use.[40] While under FEPCA only the original registrant could appeal a determination of the Administrator as to what constitutes to reasonable compensation for a given set of data,[41] under the 1975 Extension either the registrant or the new applicant could appeal the Administrator's decision.[42] Finally, whereas FEPCA provided that the district court could not find the amount of reasonable compensation to be *lower* than the Administrator's figure,[43] the 1975 Extension removed this limitation on the district court.[44]

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[36] *Id.*

[37] *Id.*

[38] FEPCA, Pub. L. No. 92-516 § 8(a), 86 Stat. 973, 987 (1972) (*codified as amended at* 7 U.S.C. § 136f(a) (1988)).

[39] Federal Insecticide, Fungicide and Rodenticide Act, extension, Pub. L. No. 84-140, 89 Stat. 751 (1975) (*codified as amended at* 7 U.S.C. §§ 136-136y (1982)) (1975 Extension).

[40] 1975 Extension, Pub. L. No. 84-140 § 12, 89 Stat. 751, 755 (1975) (*codified as amended at* 7 U.S.C. § 136a(c)(1)(D) (1988)).

[41] *See supra* note 30 and accompanying text.

[42] 1975 Extension, Pub. L. No. 84-140 § 12, 89 Stat. 751, 755 (1975 (*codified as amended at* 7 U.S.C. § 136a(c)(1)(D) (1988)).

[43] FEPCA, Pub. L. No. 92-516 § 3(c)(D), 86 Stat. 973, 979 (1972) (*codified as amended at* 7 U.S.C. § 136a(c)(1)(D) (1988)).

[44] 1975 Extension, Pub. L. No. 84-140 § 12, 89 Stat. 751, 755 (1975) (*codified as amended at* 7 U.S.C. § 136a(c)(1)(D) (1988)).

*4. Federal Pesticide Act of 1978*

The Federal Pesticide Act of 1978 (FPA)[45] rendered more complex the FIFRA provisions dealing with scientific data, and represents the present law in this area.[46]

First, the FPA amended the "trade secret" provisions so that the Administrator may disclose to the public safety studies on pesticides and their ingredients. Yet the Administrator may not reveal to the public information regarding manufacturing or quality control methods, the details of testing methods that gauge the quantity of any deliberately added inert ingredient of a pesticide, or the identity or percentage of any inert ingredient deliberately added to a pesticide.[47] Information on production, distribution, sale, or inventories of a pesticide may be disclosed to the public under certain circumstances.[48] The FPA provides a detailed scheme of notification to the data/information submitter, and judicial review, of any EPA decision to divulge the former's "trade secrets" to the public.[49]

Contractors, federal employees, and foreign and multinational pesticide firms are within the scope of certain subsections of the "trade secret" provision. Any trade secret information may be revealed to contractors if disclosure is necessary for the performance of work in connection with the FPA.[50] Criminal penalties are provided for federal employees who willfully disclose material the disclosure of which the

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[45] Federal Pesticide Act of 1978, Pub. L. No. 95-396, 92 Stat. 819 (*codified at as amended* 7 U.S.C. §§ 136-136y (1982)) (FPA).

[46] However, legislative development has since occured in one specific area of data compensation. The Federal Insecticide, Fungicide, and Rodenticide Act Amendments of 1988, Pub. L. No. 100-532, 102 Stat. 2654 (codified at 7 U.S.C. § 136 (1988)) (1988 Amendments) addressed certain problems facing the reregistration of pesticides. Reregistration involves the EPA's determination that an active ingredient of a registered pesticide lacks adequate data to support the continued registration of that pesticide. The pesticide manufacturer must then provide additional data according to the EPA's specifications so that the pesticide can remain registered. H.R. Rep. No. 100-939, 100th Cong., 2nd Sess. 28, *reprinted in* 1988 U.S. CODE CONG. & ADMIN. NEWS 3474, 3477. The 1988 Amendments provided mandatory fee schedules setting out amounts owed the original data submitter by follow-on registrants for pesticide active ingredients undergoing reregistration. 7 U.S.C. § 136a-1(h) (1988).

[47] 7 U.S.C. § 136h(d)(1) (1988). However, the Administrator may reveal such information to the public if he has determined that disclosure is necessary to protect against injury to health or environment. *Id.*

[48] *Id.* at § 136h(d)(2). Such information may be disclosed in relation to a public proceeding held to determine if the pesticide causes unreasonable adverse effects to man or the environment if the Administrator deems that disclosure is in the public interest. *Id.*

[49] *Id.* at § 136h(d)(3).

[50] *Id.* at § 136h(e).

employee knows to be prohibited by the FPA.[51] The Administrator may not knowingly reveal to foreign or multinational pesticide manufacturers, to any of their employees, or to any other person connected with such manufacturers information submitted by an applicant or registrant under the FPA.[52] Also, the Administrator must obtain an affirmation from any person intending to inspect data to the effect that the latter does not intend to deliver the data and will not negligently cause the data to be delivered to a foreign or multinational pesticide manufacturer.[53] Furthermore, the Administrator must inform the registrant or applicant of the names and affiliations of any persons to whom "trade secret" data are disclosed.[54]

Second, the FPA in effect divided submitted test data into three categories: 1) data submitted to support the application for the original registration or the new use of a pesticide which is registered after September 30, 1978 are protected by a 10-year "exclusive use" period from the date of such registration[55] (in other words, the original data submitter is protected against the use of his data by a follow-on applicant for a ten-year period; also, the data submitter is entitled to reasonable compensation for the use of his data for five more years[56]); 2) data submitted after December 31, 1969 and before September 30, 1978 may be considered by the Administrator in support of a follow-on application for the fifteen-year period following submission of the data only if the applicant obtains permission from or offers reasonably to compensate the data submitter[57]; and 3) data submitted to support the registration of a pesticide before January 1, 1970 may freely be considered by the Administrator in support of follow-on applications.[58] In a substantial departure from previous law, the FPA requires that disputes arising between parties concerning

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[51] *Id.* at § 136h(f).

[52] *Id.* at § 136h(g). Yet the Administrator may knowingly reveal such information if the applicant or registrant has consented to its disclosure. *Id.*

[53] *Id.*

[54] *Id.*

[55] *Id.* at § 136a(c)(1)(D)(i). The 10 year "exclusive use" period does not apply if the original data submitter gives his permission for follow-on registration. However, such permission is not necessary in regard to "defensive data". *Id.* The term "defensive data" refers to any additional data which the Administrator requires the registrant to produce in order to sustain the registration of a pesticide. Coll, *supra* note 11, at 200. *See also* FIFRA, 7 U.S.C. § 136(a)(c)(2)(B) (1982).

[56] *Id.* at § 136a(c)(1)(D)(ii).

[57] *Id.*

[58] *See id.*

compensation for data use be settled through binding arbitration by the Federal Mediation and Concilliation Service.[59]

Third, FPA addresses the issue of joint data development.[60] If a pesticide has more than one registrant and the Administrator determines that additional data is required to maintain the registration of that pesticide, the registrants may agree to jointly develop or to share the costs of developing such additional data.[61] The parties must notify the Administrator of their intent to agree. Yet, should the parties fail to agree on any detail of the agreement by a statutorily specified time,[62] any registrant may refer the matter to binding arbitration by the Federal Mediation and Concilliation Service.[63]

*5. Subsequent Developments*

Following the enactment of FPA, controversies emerged in two main areas regarding the FIFRA data provisions. The questions arose, first, as to the circumstances under which the EPA may disclose submitted health and safety test data to the public, and second, as to what is the proper method for calculating the compensation owed to the original data submitter by a follow-on applicant and by a joint data developer?

Regarding the health and safety data, the Third Circuit upheld the constitutionality of the public disclosure provisions of FIFRA.[64] The pesticide industry then resorted to other means to keep the EPA from disclosing the submitted health and safety data to the public, including injunctions and agreements with the EPA.[65] In early 1982, the National Agricultural Chemicals Association [hereinafter NACA] supported a bill to amend FIFRA by allowing the public access to the data only in a reading room and only in the form of summaries.[66] The pesticide

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[59] *Id.* FPA provides detailed instructions as to the procedure of such arbitration and the responsibilities of the Administrator following such arbitration. *Id.*

[60] *Id.* at § 136a(c)(2)(B).

[61] *Id.*

[62] Namely, sixty-one days after informing the Administrator of their intention to agree. *Id.*

[63] *Id.* In this situation, also, FPA provides elaborate instructions on the mode of arbitration and duties of the Administrator. *Id.*

[64] Mobay Chem. Corp. v. Gorsuch, 682 F.2d 419, 421-24 *cert. denied* 459 U.S. 988 (1982).

[65] Safir, *supra* note 6, at 15020-21.

[66] H.R. 566, 97th Cong., 2d Sess. (1982). Congress failed to act on this bill. NACA is an organization representing the interests of the United States pesticide industry and especially the large pesticide manufacturers. *See* BOARDMAN, *supra* note 3, at 45.

industry also sought administrative action from the EPA on this proposal. But the EPA refused to adopt the proposal on the ground that it lacked the authority to do so.[67] However, there is some evidence that in a move to protect the interests of large pesticide firms, the EPA then imposed a moratorium on all requests by the public for access to pesticides data.[68]

Because the EPA's alleged moratorium came under heavy fire from public interest groups, the EPA agreed to release health and safety data to the public, but on condition that the data requester sign a so-called "affirmation of non-multinational status" form.[69] In 1984, the United States Supreme Court upheld the FIFRA provisions regarding data disclosure to the public as constitutional,[70] and this decision put further pressure on the EPA to perform these duties in a fair manner. Both public interest groups and industry groups accepted, in principle, the EPA's use of the form but disagreed as to its contents.[71]

Interestingly, public interest groups and an industry group reached agreement in late 1985 on many of the EPA procedures for data disclosure to the public.[72] However, this agreement which was drafted as amendments to FIFRA died in Congress. As an indication of present efforts to resolve some of the controversies regarding public disclosure, a House bill entitled the FIFRA Amendments of 1987[73] provides the public with preregistration access to submitted data but on the condition that such data is not removed from an EPA office or the office of an appropriate state agency.[74] As an apparent concession to the public, the bill requires each pesticide manufacturer to compile fact sheets containing certain health and safety infor-

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[67] Letter from John A. Todhunter to Dr. Jack D. Early, President, NACA (June 8, 1982), at 1.

[68] Safir, *supra* note 6, at 15022 (citing LEGAL TIMES OF WASHINGTON, Feb. 22, 1982 at 11).

[69] PESTICIDE NEWS, *supra* note 9, Aug. 8, 1984 at 22-3.

[70] Ruckelhaus v. Monsanto Co., 467 U.S. 986, 1000-12 (1984)

[71] *See* PESTICIDE NEWS, *supra* note 9, Aug. 8, 1984 at 22-23. For example, industry groups favor a statement in the affirmation that the data receiver may not publish any information it has received from the EPA except for brief excerpts or summaries of that information. Public interest groups, on the other hand, want a statement that the data receiver may publish as much information as is necessary to enable public groups to engage in a meaningful evaluation of the pesticide concerned.

[72] *See* PESTICIDE NEWS, *supra* note 9, Nov. 20, 1985 at 31.

[73] H.R. 2463, 100th Cong., 1st Sess. (1987).

[74] H.R. 2463 § 101(a)(F)(i).

mation, to maintain fact sheets at its establishment, and to furnish a copy to any person upon request.[75]

The controversies regarding data compensation are still very much alive after the enactment of the FPA despite the existence of federal and arbitral decisions on the issue. One issue is settled beyond doubt. In two cases, the United States Supreme Court upheld the constitutionality of the FIFRA data compensation provisions, including the requirement of submission to binding arbitration of disagreements over the amount of compensation due.[76] Until recently, another issue appeared to be resolved. A decision of the Federal Mediation and Concilliation Service, *Stauffer Chemical Co. v. PPG Industries* which held that an original data submitter should receive value-based compensation as opposed to cost-based compensation from a follow-on applicant chose the more controversial of the two options.[77] Yet, in another arbitral decision, the question arose, whether market share, per capita share, or some other method of compensation should be used among joint data submitters under FIFRA, but the arbitral panel did not decide the question authoritatively, and instead merely provided certain factors to guide the parties in making a decision.[78] Most recently, and in an apparent about-face, an arbitral panel in *E.I. Du Pont de Nemours Co. v. Griffin Corp.* held that market-share com-

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[75] H.R. 2463, § 201(a). The bill requires each manufacturer to compile a fact sheet on each active ingredient of a pesticide. The fact sheet must contain the chemical name, common name, trade name of any ingredient, and a summary of pertinent health, safety, and environmental data on the ingredient. *Id.*

[76] Ruckelhaus v. Monsanto Co., 467 U.S. 986 (1984); Thomas v. Union Carbide Agricultural Prods., 473 U.S. 568 (1985). In *Ruckelhaus*, the Court held that the use of data by a "follow-on" applicant without compensation to the original data submitter does not violate the Fifth Amendment. 467 U.S. at 1000-20. In *Thomas*, the Court held that the requirement that parties to a dispute regarding data compensation resort to binding arbitration does not violate Article III of the Constitution. 473 U.S. at 582-84.

[77] No. 16 199 077 82 Federal Mediation and Concilliation Service (June 28, 1983) (Birch et al., Arb.). A value-based method of compensation takes into account the amount of money a follow-on registrant saves by avoiding the delays that the preparation of data for registration entails. On the other hand, a cost-based method involves the fair apportionment of the costs of developing the scientific data, and nothing more. One commentator estimates that the follow-on registrant in *Stauffer* had to pay the original data submitter around 15.5 million dollars under the value-based method as opposed to around 1.5 million dollars under the cost-based method. Coll, *supra* note 11, at 217-19.

[78] FMC Corp. v. Tricon Int'l, No 16 199 0033 84 G, American Arbitration Association (Jan. 10, 1985) (Foy et al., Arb.) See Coll, *supra* note 11, at 222 for a discussion of these factors.

pensation, with some modifications, is the appropriate method of data compensation.[79]

### *A. Agreement for the Security of Proprietary Scientific Data Submitted to the JMPR*

The Agreement is divided into a preamble and nine items.[80] According to the preamble, the Agreement will attempt to reconcile two competing goals. On the one hand, industry strives to protect its trade secrets and the products of its research, and to prevent any data made accessible to others from falling into the hands of competitors. On the other hand, the JMPR requires complete data in order to make its evaluations and publish summaries calculated to reveal its reasoning in the evaluation process. Following is a rundown of the more relevant portions of the Agreement.

ITEM 1

The pratice of the JMPR with regard to the evaluation of pesticides includes the examination of unpublished proprietary data supplied to the JMPR by pesticide manufacturers.

ITEM 2

Industry is requested to provide all of the relevant data required for a full evaluation. Only the JMPR will use this data. Manufacturers should clearly identify all highly confidential data so as to ensure

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[79] No 16 171 0080 86, American Arbitration Association (Dec. 22, 1988) (Foy et al., Arb.) This decision grants a market-share compensation to the original data submitter based on the follow-on registrant's highest year of market share in the first five years of the active ingredient in question. *Drexel, Griffin Favored Over Du Pont in Data Arbitration Decision*, PESTICIDE NEWS, *supra* note 9, Dec. 28, 1988 at 24. Also, the arbitrators provide rules as to different types of data and their eligibility for compensation. *See id.* Interestingly, a lawyer representing DuPont in this action asserts that the principle of substantial compensation advocated by *Stauffer* was upheld. He points out that the arbitrators rejected the follow-on registrants' figure of $127,315 (based on cost-based compensation) and that the market share approach which they adopted will yield at least $1.5 million of compensation to the original data submitter. *Du Pont to Get About $1.5 Million from Drexel, Griffin for Data*, PESTICIDE NEWS, *supra* note 9, Jan. 4, 1989.

[80] GIFAP MANUAL, *supra* note 16, at 55-56. *See supra* notes 20-21 and accompanying text. This agreement, as it appears in the GIFAP Manual, is titled "Policy Statement by the Central Unit of the International Programme on Chemical Safety (IPCS) on Procedures for The WHO Secretariat on Handling Unpublished Proprietary Data Submitted from Manufacturers to the World Health Organization for Toxicological Evaluation to Be Undertaken by The Joint FAO/WHO Meeting on Pesticide Residues (JMPR)". Since the agreement appears in its entirety on pages 55 and 56 of the GIFAP Manual, no citations to specific provisions will be made in this note.

that this data will not be published in a report. Any confidential information that is not submitted but is necessary for a full evaluation will be treated according to item 7.

ITEM 3

IPCS, on behalf of the JMPR, will ensure that data, once submitted, will be protected from unauthorized disclosure and that the proper facilities for safeguarding the data will be in place. ITEM 4

So-called "temporary advisors" will be used prior to and during JMPR sessions.[81] Temporary advisors work in their individual capacities as scientists, rather than as members of governments or institutions.

ITEM 5

During the meetings of the JMPR, only the temporary advisors who reviewed the data and the JMPR experts can make use of the data.

ITEM 6

The temporary advisor will be instructed not to copy all or portions of the unpublished proprietary data, and not to share or use the data for any purposes other than his JMPR assignment. When he finishes his assignment, the temporary advisor must return the data to the Secretariat of the WHO [hereinafter Secretariat]. The temporary advisor must agree in writing to these conditions, and any evidence of misconduct on the temporary advisor's part is grounds for his permanent dismissal from the JMPR program.

ITEM 7

Individual representatives of pesticide manufacturers will meet with the Chairman of the WHO [hereinafter Chairman] during the JMPR meeting to discuss certain issues relating to their specific pesticides. At such a meetings, the representative is expected to answer questions regarding the data submitted and, if required, provide oral information on trade secrets regarding the firm's manufacturing process. Information that is gathered in this process and that pertains to a certain pesticide will not be discussed with others.

ITEM 8

After the JMPR meeting, the unpublished proprietary data will be held under security for much time as is necessary to complete all JMPR tasks relating to that data. Then, the Secretariat will contact the original data submitter to determine whether the latter would like

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[81] Temporary advisors, among their other tasks, review the data and draft a toxicological report on the pesticide. *Id.*

to have the data destroyed (by shredding or burning) or returned to him.

ITEM 9

If the Secretariat receives either questions on information in the reports which require references to any unpublished proprietary data, or requests for copies of any unpublished proprietary data, he must discuss the matter with the original data submitter.

## III. ANALYSIS

Large United States pesticide manufacturers have strong reasons to demand that their proprietary scientific data be subject to stringent security measures when submitted to international organizations. The present United States laws on pesticide data disclosure and compensation favor the interests of large pesticide manufacturers over those of smaller pesticide manufacturers in some respects.[82] Original data submitters benefit from periods of exclusive use and from mandatory compensation for registration data submitted to the EPA after 1969.[83] Also, follow-on registrants must pay the original data submitter either value-based compensation or market share compensation, depending on whether *Stauffer*[84] or *Du Pont*[85] is followed in the future. But cost-based compensation which favors smaller pesticide firms has so far been rejected.[86] Under U.S. law, large manufacturers also enjoy safeguards in public access to their data. According to current actions of the EPA, the interests of pesticide manufacturers, especially those manufacturers generating extensive data, are favored over the public's right to know about the hazards of specific pesticides. That is, while the EPA will disclose certain health and safety data to the public as it is obligated to do under FIFRA,[87] it requires that the data requester

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[82] Large pesticide manufacturers have the resources to invent new pesticides and develop the expensive data needed to register a pesticide. Smaller manufacturers, on the other hand, typically lack these resources and so must register pesticides as follow-on registrants. *See* Coll, *supra* note 11, at 193-94.

[83] *See supra* notes 55-59 and 76-79 and accompanying text.

[84] No. 16 199 077 82 (Federal Mediation and Concilliation Service (June 28, 1983) (Birch et al., Arb.).

[85] No 16 171 0080 86 American Arbitration Association (Dec. 22, 1988) (Foy et al., Arb.).

[86] *See supra* notes 77-79 and accompanying text. "[W]hile arbitrators [look to] previous arbitration findings in making their decisions, they are not bound by earlier rulings." BNA, Inc., Chem. Reg. Rep., Jan. 6, 1989, at 1475 (statement of Stanley Landfair, attorney for Du Pont). However, an attorney for Drexel, claims that the arbitrators made clear that their findings should have precedential value. *Id.*

[87] *See supra* notes 47-49 and accompanying text.

sign an affirmation that restricts the uses that the requester may make of this data.[88] Finally, large pesticide firms are well protected against the willful impermissible disclosure by federal employees of submitted data, a protection that is enhanced by the availability of criminal penalties for violations. And the Administrator is expressly prohibited from disclosing protected data to any multinational or foreign firm or to any person connected with such a firm.[89]

Apart from the favorable security protections of data submitted by large United States pesticide manufacturers under FIFRA, a few practical concerns warrant the insistence of these companies on strong protections against unauthorized disclosure of their data submitted to international organizations. These concerns of the pesticide industry stem from the fact that the data that these firms submit to international pesticide authorities may come into the hands of foreign governments that are members of the organizations. Such foreign governments may then use the data in one of two ways that run counter to the interests of the data submitter. First, the foreign government may release the data to a competitor of the data submitter and the competitor may use the data as a basis for registering the pesticide in countries other than the United States.[90] The competitor may even receive this data directly from the international organization, for example, through a report published by the organization.[91] Second, the foreign government may use the data as a basis for banning the pesticide to which it relates or banning the manufacturer itself.[92]

The remainder of this analysis will address one facet of the problems facing United States pesticide manufacturers internationally with regard to their proprietary product data, namely, the problems they face in submitting data to the CCPR.[93] Furthermore, the Agreement will serve as a focal point of the discussion.

Unlike the situtation under national regulatory schemes in which a pesticide manufacturer may at any time during the registration process withdraw its application without prejudice, a request for the evaluation of a pesticide by the JMPR, if withdrawn, may result in prejudice to the company involved.[94] Hence, before a pesticide man-

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[88] *See supra* text accompanying note 69.
[89] *See supra* text accompanying notes 50-53.
[90] *See* BOARDMAN, *supra* note 3, at 8.
[91] *See Id.* at 69.
[92] *Id.* at 70.
[93] *See supra* text accompanying note 14.
[94] GIFAP MANUAL, *supra* note 16, at 16. For example, the JMPR may proceed

ufacturer decides to submit a pesticide to JMPR review, he should make certain that the benefits of JMPR review outweigh the risks.

As for the matter of proprietary data, the manufacturer should consider several factors. Perhaps the most important consideration is that regardless of whether or not a company wants to undergo a JMPR review of one of its pesticides, such a review might take place anyway. Proprietary data submitted by a competing firm or data appearing in scientific publications may provide the basis for such a review. A company should at all times be prepared to submit data on any of its pesticides that have not already undergone a JMPR review. Otherwise, the JMPR might conduct a full evaluation of a pesticide without all the available data, and the results of such a review might therefore be less advantageous to the company.[95] Another important consideration is that the quality of the JMPR decision depends on the quantity and quality of the data submitted to that body.[96]

Two of the main tasks of the JMPR are to recommend a "maximum residue limit" [hereinafter MRL] and to recommend an "acceptable daily intake" [hereinafter ADI] for each pesticide it reviews.[97] However, the JMPR must have access to adequate data before it can assign an ADI and an MRL for a pesticide. Because the JMPR expects the data submitter to provide additional data if required to complete a particular evaluation,[98] it may be better for the manufacturer not to submit a pesticide for JMPR review unless the manufacturer is confident that it can produce adequate data within a

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to evaluate a pesticide even if a company seeks to withdraw its request for a JMPR evaluation. Prejudice could then result if, for instance, a country delays the registration of a pesticide because of passages in reports of the JMPR which the country deems require further clarification. Any waste of time in the registration of a pesticide could prove expensive for a manufacturer. *Id.*

[95] *Id.* at 15.

[96] *See* G. VETTORAZZI, HANDBOOK OF INTERNATIONAL FOOD REGULATORY TOXICOLOGY 118 (1980) [hereinafter VETTORAZZI].

[97] *See* GIFAP MANUAL, *supra* note 16, at 7. An ADI of a chemical is defined as the daily intake which, during an entire lifetime, appears to be without appreciable risk to the health of the consumer on the basis of all the known facts at the time of the evaluation of the chemical by the JMPR. *Id.* at 2 (citing GUIDE TO CODEX RECOMMENDATIONS CONCERNING PESTICIDE RESIDUES, Part 1, 1984). An MRL is defined as the maximum concentration of a pesticide residue resulting from the use of a pesticide according to good agricultural practice that is recommended by CODEX to be legally permitted or acceptable in or on a food, agricultural commodity, or animal feed. *Id.* at 1 (citing GUIDE TO CODEX RECOMMENDATIONS CONCERNING PESTICIDE RESIDUES, PART 1, 1984).

[98] According to Item 7 of the Agreement.

reasonable time.[99] If the amount of data submitted is inadequate, but more appears to be forthcoming and there is no concern about the safety of daily intakes of small amounts of the compound for a limited period of time, a temporary ADI may be assigned to the pesticide.[100] A manufacturer with inadequate data should inquire as to what consequences a temporary-ADI or no-ADI result may have on its national registration plans.[101]

Another factor that has kept some manufacturers from submitting data in support of a JMPR evaluation of a pesticide, and also one that does not involve consideration of the Agreement, is the fear that CODEX has opened its doors to Eastern Bloc countries. The presence of Eastern Bloc countries in CODEX raises the possibility that political issues could enter the data-submitting process.[102] That is to say, blacklisting could occur with certain compounds and/or pesticide companies.[103] Also, should the submitted data fall into the hands of these governments, they may not accord it the protection it deserves.[104]

Finally, a pesticide firm should consider the Agreement, how the Agreement fits into the CODEX regime, and whether or not the agreement provides satisfactory data security.

Because the Preamble to the Agreement states explicitly that the Agreement recognizes the need for complete data to be accessible for the evaluation and for summaries to be published that explain the reasoning process used in the evaluations, the manufacturer should assess the effect of these matters on the security of data submitted to the JMPR.[105]

Item 1 of the Agreement recognizes that the JMPR considers data and information from all sources, including unpublished proprietary data, in making its evaluations. All things being equal, the JMPR gives greater weight to published scientific data than to unpublished scientific data.[106] The reasoning is that data which appears in scientific journals has been scrutinized by editors and referees and has been

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[99] GIFAP MANUAL, *supra* note 16, at 20.

[100] *See* VETTORAZZI, *supra* note 96, at 119-20.

[101] GIFAP MANUAL, *supra* note 16, at 20.

[102] BOARDMAN, *supra* note 3, at 69-70. Among Eastern Bloc countries, Czechoslovakia, Poland, and Romania are members. In addition, East Germany attends CODEX sessions as an observer. *Id.* at 70.

[103] *Id.* at 70.

[104] *Id.*

[105] *See infra* text accompanying notes 114-117.

[106] VETTORAZZI, *supra* note 96, at 120.

called into question by the data submitter's peers.[107] If unpublished data is submitted, an expert must have supervised the tests and his name must be disclosed to the JMPR.[108] The procedures of experiments conducted to produce the data must be identified in sufficient detail to enable the JMPR to recreate the test conditions and check the results if necessary.[109] Finally, the method in which the unpublished scientific data was obtained must, under normal circumstances, comply with proper laboratory practices and the current standards of scientific precision before the data will be acceptable.[110]

According to Item 2, the manufacturer should mark any submitted data which constitutes a trade secret so that this portion will not be published in any report.[111] As an added safeguard for pesticide firms, very sensitive information may be submitted directly to the Chairman of the WHO. The Chairman will discuss this data with the JMPR only in a general manner and only to clarify certain items. He will then immediately destroy the data.[112] Further reasonable protection for trade secret information is provided in Item 7. In short, if the Chairman meets with an individual pesticide manufacturer and the manufacturer gives to the Chairman oral reports on any trade secret matter, the Chairman will not discuss this information with anyone else.

The conduct of temporary advisors in relation to the unpublished proprietary data is the main concern of Items 4, 5, and 6. This part of the Agreement may well be the part most in need of reconsideration in the eyes of United States pesticide firms. Although Item 4 declares that temporary advisors work as individuals rather than as industry or government representatives, no assurance is given that such individuals could not in fact have ties to industry or the government. Moreover, under Item 6, a temporary advisor who abuses the confidentiality of the data under his control is simply dismissed from the JMPR program. Civil and/or criminal penalties would provide an additional and reasonable deterrent for such abuse, given the potential gravity of the consequences to pesticide firms; none are presently provided for.

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[107] *Id.*

[108] *Id.*

[109] *Id.*

[110] *See id.* at 121.

[111] Under these circumstances, a published report by the JMPR would probably state that information on, for instance, the manufacturing process (a trade secret) was available to the JMPR. No further information would be supplied. GIFAP MANUAL, *supra* note 16, at 30.

[112] *Id.*

Finally, the Secretariat's duty under Item 9 to discuss with the manufacturer any requests received for copies of the manufacturer's unpublished proprietary data or for information from reports which would entail references to this data provides an additional and welcome assurance that such data will not fall into the wrong hands. As a further security measure, the Agreement should require that the Secretariat inform the manufacturer *before* he releases such information to the requesting party and then *only* with the manufacturer's permission, preferably in writing.[113]

Other considerations as to whether a manufacturer should submit data to the JMPR in support of an evaluation stem from the reports published by the JMPR.[114] Obviously, the data presented in these reports could be used as the basis for a competitor to register a pesticide in a foreign country or for a government to blacklist the pesticide or the company that submitted the data.[115] These reports could also provide a competitor with some knowledge of how the data submitting firm handled a problem specific to the pesticide industry.[116] The competitor could then attain the same competitive advantage enjoyed by the data submitter. Yet this problem is to some extent illusory in that many governments, supposedly including the United States, make much of the registration data submitted by a firm available to the public anyway.[117]

## IV. CONCLUSION

All things considered, the work of the JMPR deserves the continued support of the pesticide industry. The JMPR evaluations of pesticides

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[113] As an illustration of how the disclosure of unpublished proprietary data to others by CODEX has been tightened over the years, one could examine the disclosure of such data to bona fide scientists. CODEX has always given bona fide scientists, upon request, copies of unpublished reports which the JMPR considered in its evaluations. Yet in 1975, while reaffirming the right of scientists to receive this information, CODEX prohibited access to confidential information. VETTORAZZI, *supra* note 96, at 118-19.

[114] For instance, see *supra* note 94.

[115] Publications known as the JMPR Report and Evaluations are published after each JMPR Meeting. GIFAP MANUAL, *supra* note 16, at 16. The 1979 JMPR Report specifically states that if an Evaluation relies on unpublished proprietary data, the Evaluation should not form the basis of the registration of that pesticide if the so-called "me-too" registrant does not have proper authority to use such data. *Id.*

[116] *Id.*

[117] *Id.* For a discussion of the duties of the EPA in this regard, see *supra* notes 47-49 and accompanying text.

provide the basis for pesticide registrations in many countries and the acceptance by countries of the recommended ADIs and MRLs can only lead to greater harmonization of pesticide standards. Pesticide manufacturers should welcome such harmonization, because their costs of manufacturing a pesticide so as to comply with many different national standards would be lessened, and harmonization of pesticide laws would tend to increase the areas where a given pesticide may be sold. In short, pesticide firms should continue to submit the required data to the JMPR to enable that body to carry out its evaluations.

While lending its support to CODEX and the JMPR, however, the industry (as represented by GIFAP) should forge stronger alliances with the CODEX bodies and member governments in an effort to exact further guarantees that the proprietary data submitted to the JMPR will not be used for improper purposes. For instance, GIFAP should seek an agreement with member governments to the effect that these governments will cancel any registration of a pesticide that is based on raw data submitted to the JMPR, or information contained in the JMPR Reports and Evaluations when that data or information is being used without the permission of the data submitter. Such an agreement should also prohibit a member government from blacklisting a compound or company involved with the JMPR process unless good cause is shown therefore.

The Agreement itself represents a big step towards proper security for proprietary data submitted to the JMPR. Although there are no known instances in which proprietary data submitted to the JMPR has fallen into the hands of an unauthorized party because of a security lapse at CODEX,[118] the Agreement helps to assure that such an incident will not occur in the future. Yet from an industry standpoint GIFAP should press the ICPS for a redrafting of the Agreement on a few points. First, a new Agreement should provide a mechanism for selecting temporary advisors that would ensure that they are in no way partial to industry or government and provide more stringent penalties for a temporary advisor's negligent or willful disclosure of data to an unauthorized party. Also, the Chairman should be required to obtain the permission of the data submitter before releasing unpublished data or references to such data to a third party. More precise security measures afforded to proprietary data should spawn a greater will-

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[118] GIFAP MANUAL, *supra* note 16, at 21.

ingness on the industry's part to cooperate with CODEX and the JMPR.

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