

## Trade Secret Confidentiality and Toxic Substances Regulation: A Non-Tariff Trade Barrier in the Chemical Trade

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# TRADE SECRET CONFIDENTIALITY AND TOXIC SUBSTANCES REGULATION: A NON-TARIFF TRADE BARRIER IN THE CHEMICAL TRADE

The United States and the European Economic Community (EEC)<sup>1</sup> have enacted measures to control the use of hazardous chemical substances.<sup>2</sup> The United States passed the Toxic Substances Control Act (TSCA) in 1976.<sup>3</sup> TSCA was the legislative response to a governmental study conducted in 1970 on the dangers of toxic chemicals.<sup>4</sup> The EEC counterpart to TSCA, the Council of European Communities Directive on Classification, Packaging, and Labelling of Dangerous Substances (Directive), was enacted in 1967 and substantially amended in 1979.<sup>5</sup>

Both measures require chemical manufacturers and importers to submit extensive information about their chemical products to the respective regulatory authority.<sup>6</sup> Although both measures provide for the confidential treatment of some of this data, their approaches to confidentiality differ.<sup>7</sup> For the most part, the Directive offers greater protection against the disclosure of trade secrets than does TSCA. Because of the greater possibility that the U.S. regulatory authority will reveal a trade secret to competitors, a chemical manufacturer will, all other things equal, export his product to the EEC rather than to the United States. In this way, the differences in the confidentiality provisions of the two statutes create a non-tariff trade

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1. The EEC member states are Belgium, Denmark, France, Greece, Ireland, Italy, Luxembourg, the Netherlands, the United Kingdom, and West Germany.

2. For a discussion of potential chemical hazards, see Borasko, *The Pesticide Dilemma*, NAT'L GEOGRAPHIC 145-83 (Feb. 1980); THE TOXIC SUBSTANCES STRATEGY COMM., REPORT TO THE PRESIDENT I-1 to I-9 (Aug. 1979) (public review draft).

3. Pub. L. No. 94-469, 90 Stat. 2003 (1976) (codified at 15 U.S.C. §§ 2601-2629 (1976)).

4. COUNCIL ON ENV'T'L QUALITY, TOXIC SUBSTANCES (1971), *reprinted in* LEGISLATIVE HISTORY OF THE TOXIC SUBSTANCES CONTROL ACT 757-88 (1976) [hereinafter cited as LEGISLATIVE HISTORY].

5. Directive 67/548/EEC, J.O. COMM. EUR. (No. L 196) 13 (1967) [hereinafter cited as 1967 Directive], *as amended by* Directive 79/831/EEC, O.J. EUR. COMM. (No. L 259) 10 (1979) [hereinafter cited without cross reference as Directive]. All essential details of the 1967 Directive were replaced by the 1979 amendments.

6. 15 U.S.C. §§ 2603-2607 (1976); Directive art. 6, Annex VII & VIII. For a discussion of the data disclosure requirements, see notes 35-50, 69-78 *infra* and accompanying text.

7. 15 U.S.C. § 2613 (1976); Directive art. 11. For a comparative analysis of the two measures' approaches to confidentiality, see notes 79-151 *infra* and accompanying text.

barrier in the EEC-United States chemical trade. The trade barrier is the subject of this Note.

Sections I and II discuss the general approaches of TSCA and the Directive toward toxic substance legislation, focusing especially on their rules of confidentiality. Section III presents a comparative analysis of the confidentiality provisions, thereby setting forth the trade barrier problem. Finally, section IV suggests recommendations for reducing this trade barrier.

## I

### TOXIC SUBSTANCES CONTROL ACT

#### A. GENERAL APPROACH

Through TSCA, Congress hoped to effectively regulate toxic substances without unduly burdening technological innovation.<sup>8</sup> TSCA covers foreign importers as well as domestic manufacturers of chemical substances.<sup>9</sup> Congress charged the Environmental Protection Agency (EPA) with responsibility for the administration of the Act.<sup>10</sup> TSCA places the burden to supply data regarding all manufactured chemical substances on the chemical industry.<sup>11</sup> EPA bases its regulatory actions upon a consideration of this data.<sup>12</sup>

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8. 15 U.S.C. § 2601(b) (1976). For an extensive analysis of TSCA, see Druley & Ordway, *The Toxic Substances Control Act*, [1977] ENVIR. REP. (BNA) (Monograph No. 24); Gaynor, *The Toxic Substances Control Act: A Regulatory Morass*, 30 VAND. L. REV. 1149 (1977). See also LEGISLATIVE HISTORY, note 4 *supra*.

9. All operative provisions of TSCA expressly apply to the "manufacture" of chemical substances. TSCA defines the term "manufacture" to mean not only the production of chemical substances, but also their importation into the United States. 15 U.S.C. § 2602(7) (1976). Furthermore, TSCA expressly provides that Treasury may disallow the importation of chemical substances if the foreign manufacturer fails to comply with any provision of the Act. *Id.* § 2612(a).

The Act does not apply to chemical substances manufactured solely for export from the United States as long as the manufacturer satisfies certain conditions. *Id.* § 2611.

10. See *id.* §§ 2601(c), 2602(1). Scattered sections of TSCA specifically empower EPA to promulgate regulations. See, e.g., *id.* §§ 2607(a)(1), 2613(a)(1). Pursuant to this grant of power, EPA has issued regulations contained in scattered sections of 40 C.F.R. (1980).

11. *Id.* § 2601(b)(1). EPA may require the submission of reasonably ascertainable data under many sections of the Act. See *id.* §§ 2603-2607. This data may include, but is not limited to, the following: (1) the trade name, chemical identity, and molecular structure of the substance, *id.* § 2607(a)(2)(A); (2) the proposed categories of use, *id.* § 2607(a)(2)(B); (3) estimates of the amount to be manufactured and processed for particular uses, *id.* § 2607(a)(2)(C); (4) description of byproducts resulting from manufacturing, use, or disposal, *id.* § 2607(a)(2)(D); (5) all existing data regarding the substance's health and environmental effects, *id.* § 2607(a)(2)(E); (6) the expected level of exposure to human beings, *id.* § 2607(a)(2)(F); and (7) the method of disposal, *id.* § 2607(a)(2)(G).

12. In addition, EPA must base its regulatory actions upon a consideration of all the anticipated environmental, economic, and social consequences of its action. *Id.* § 2601(c).

TSCA controls existing as well as new chemical substances.<sup>13</sup> EPA is required to compile and keep current an inventory list of all chemical substances manufactured in the United States.<sup>14</sup> Any substance not included in this inventory list is considered to be a "new chemical substance,"<sup>15</sup> and is subject to the premarket notification requirement.<sup>16</sup> The producer intending to manufacture a new chemical substance must notify EPA at least 90 days prior to its manufacture.<sup>17</sup> Extensive data must accompany this notice, including the chemical's identity, its proposed uses, the estimated production quantities, and test data on environmental effects.<sup>18</sup> If, after a consideration of this data, EPA finds that the substance creates an unreasonable risk of harm, it may either prohibit<sup>19</sup> or regulate the manufacture of that substance.<sup>20</sup>

If EPA finds that any new or existing chemical substance may present an unreasonable risk of injury, and that insufficient data exist from which the effects of that substance can be determined, EPA must require the manufacturer to conduct tests to determine those effects.<sup>21</sup> If the tests indicate that production of the substance creates an "unreasonable risk of injury to health or the environment,"<sup>22</sup> TSCA allows EPA to invoke several remedies.<sup>23</sup> EPA may:

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13. A "chemical substance" is a substance either created by a chemical reaction or in elemental form. *Id.* § 2602(2)(A). It does not include mixtures, controlled pesticides, tobacco, nuclear material, special commercial items, or controlled food and drugs. *Id.* § 2602(2)(B). A "mixture" is a combination of chemical substances that is not the product of a chemical reaction. *Id.* § 2602(8). In this Note, "chemical" and "substance" will mean chemical substances or mixtures unless otherwise designated.

14. *Id.* § 2607(b)(1).

15. *Id.* § 2602(9).

16. *Id.* § 2604(a)(1)(A). The premarket notification requirement also applies to the processing of an existing chemical substance for a new use. *Id.* § 2604(a)(1)(B).

17. *Id.* § 2604(a)(1).

18. *Id.* § 2604(d)(1), *incorporating by reference id.* § 2607(a)(2). For a discussion of the data requirements of section 2607(a)(2), see note 11 *supra*. In addition to the data required by section 2607(a)(2), subsections 2604(d)(1)(B) and (C) set forth an additional data submission requirement regarding the health and environmental effects of a new chemical substance.

19. *Id.* § 2604(b)(3).

20. EPA may regulate the manufacture of the substance by limiting the amount that may be manufactured, *id.* § 2604(b)(2)(A), or by taking any remedial measure prescribed by sections 2605(a)(2)-2605(a)(7). *Id.* § 2604(b)(2)(B), *incorporating by reference id.* §§ 2607(a)(2)-(7). For a listing of these measures, see notes 24-34 *infra* and accompanying text.

21. *Id.* § 2603(a). If testing would merely duplicate data already submitted or currently being developed, the manufacturer may be exempt from the testing requirement. *Id.* § 2603(c).

22. The applicable standard is "a reasonable basis to conclude that a chemical substance or mixture presents or will present a significant risk of serious or widespread harm to human beings from cancer, gene mutation, or birth defects." *Id.* § 2603(f).

23. *Id.* Section 2603(f) incorporates by reference all remedies available under sections 2604-2606.

(1) prohibit manufacture;<sup>24</sup> (2) limit the amount manufactured;<sup>25</sup> (3) prohibit a particular use;<sup>26</sup> (4) limit the level of a particular use;<sup>27</sup> (5) require warnings to consumers and instructions for the substance's use;<sup>28</sup> (6) regulate commercial use;<sup>29</sup> (7) regulate disposal;<sup>30</sup> (8) require notice of unreasonable risk and the institution of a repurchase procedure;<sup>31</sup> (9) obtain injunctive relief;<sup>32</sup> or (10) any combination of the above.<sup>33</sup> Finally, if a substance presents an "imminent hazard," EPA may commence a civil action for seizure or other relief.<sup>34</sup>

## B. PROTECTION OF CONFIDENTIAL DATA

Often, the chemical producer must reveal trade secrets in order to satisfy TSCA's information disclosure provisions. To relieve the chemical producer's fear that EPA will reveal these trade secrets to competitors,<sup>35</sup> Congress included provisions that protect the confidentiality of certain information disclosed under the Act.<sup>36</sup> Rather than articulating a new rule for the confidential treatment of trade secrets, Congress incorporated into TSCA the confidentiality standard enunciated in section 552(b)(4) of the Freedom of Information Act (FOIA).<sup>37</sup> Congress incorporated FOIA so that future disputes arising under TSCA could be resolved by consulting the large body of case law interpreting the FOIA confidentiality provisions.<sup>38</sup>

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24. *Id.* § 2605(a)(1)(A).

25. *Id.* § 2605(a)(1)(B).

26. *Id.* § 2605(a)(2)(A).

27. *Id.* § 2605(a)(2)(B).

28. *Id.* § 2605(a)(3).

29. *Id.* § 2605(a)(5).

30. *Id.* § 2605(a)(6).

31. *Id.* § 2605(a)(7).

32. *Id.* § 2604(f)(3)(A)(ii).

33. *Id.* § 2605(a).

34. *Id.* § 2606(a). Under certain circumstances, a private citizen may commence a civil action to enforce the provisions of TSCA. *Id.* § 2619.

35. For discussion of the chemical industry's fear that EPA will reveal trade secrets, see Murray, *Proposed Chemical Rules Dismay Industry*, CHEMICAL & ENGINEERING NEWS, March 19, 1979, at 21; CHEMICAL & ENGINEERING NEWS, Sept. 5, 1977, at 17 ("EPA Jolts Industry with Revised TSCA Rules"); CHEMICAL WEEKLY, Feb. 1, 1978, at 41 ("EPA Plans to Keep it Confidential").

36. 15 U.S.C. § 2613 (1976). In addition, EPA has promulgated regulations regarding confidentiality. 40 C.F.R. §§ 2.306, 710.7 (1980).

37. 15 U.S.C. § 2613(a) (1976). The Freedom of Information Act, 5 U.S.C. § 552 (1976), provides that any person may obtain access to the records of a federal agency upon compliance with certain procedural formalities. FOIA, however, expressly exempts certain records that are not to be disclosed to the public. Section 552(b)(4) is one of these exemptions. For a discussion of the FOIA and its exemptions, see 12 R. MILGRIM, BUSINESS ORGANIZATIONS—TRADE SECRETS ¶ 6.02A (1979).

38. H.R. Rep. No. 94-1341, 94th Cong., 2d Sess. 50 (1976), reprinted in LEGISLATIVE HISTORY, *supra* note 4, at 457.

Section 552(b)(4) provides that "trade secrets and commercial or financial information" disclosed to federal agencies must be accorded confidential treatment.<sup>39</sup> Although federal courts have construed the meaning of the "trade secret" branch of the section 552(b)(4) exemption very narrowly,<sup>40</sup> they have interpreted the "commercial or financial information" branch very broadly.<sup>41</sup> As a general rule, any information "that would not ordinarily be disclosed to the public" qualifies for confidential treatment under this provision.<sup>42</sup> Even if a trade secret does not fit within the court's narrow interpretation of that term, it will fall within the broad interpretation of commercial or financial information.<sup>43</sup> Therefore, TSCA protects the confidentiality of a trade secret unless that secret falls within one of TSCA's specific exceptions to the FOIA confidentiality rule.<sup>44</sup>

The manufacturer may designate the data that he believes is entitled to confidential treatment and may submit that data separately from the other information disclosed to EPA.<sup>45</sup> Once designated as confidential by the manufacturer, EPA must notify the manufacturer in writing of its intent to disclose such data, even if the data does not qualify for confidential treatment under the FOIA rule.<sup>46</sup> EPA may not disclose the data until thirty days after the manufacturer receives the notice.<sup>47</sup> EPA, however, may disclose

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39. 5 U.S.C. § 552(b)(4) (1976).

40. Of the dozens of cases construing section 552(b)(4), only two have held information exempt from FOIA as a trade secret. See 12 R. MILGRIM, *supra* note 37, ¶ 6.02A(2)(c). For a collection of cases interpreting the FOIA exemption, see Annot., 21 A.L.R. Fed. 224 (1974).

41. See 12 R. MILGRIM, *supra* note 37, ¶ 6.02A(2)(a)-(b).

42. *Id.*

43. *Id.* ¶ 6.02A(2)(c).

44. TSCA provides several exceptions to the FOIA confidentiality rule. The data may be disclosed to U.S. employees in connection with their official duties for purposes of the protection of health or the environment, or for law enforcement. 15 U.S.C. § 2613(a)(1) (1976). Congress and U.S. contractors may also gain access to the information. *Id.* §§ 2613(a)(2), 2613(e). EPA may reveal health and safety data not related to the manufacturing process, *id.* § 2613(b), see note 103 *infra* and accompanying text, as well as information "necessary to protect health or the environment against an unreasonable risk of injury." *Id.* § 2613(a)(3), see notes 94-96 *infra* and accompanying text. Furthermore, EPA may disclose data relevant in a TSCA proceeding. *Id.* § 2613(a)(4), see notes 131-139 *infra* and accompanying text.

45. *Id.* § 2613(c)(1).

46. *Id.* § 2613(c)(2)(A).

47. *Id.* There are several exceptions to this thirty day notice rule. If information is given to U.S. employees, or revealed for law enforcement purposes, EPA is not required to give any notice. *Id.* § 2613(c)(2)(B)(i). If information is given to U.S. contractors, or released in a TSCA proceeding under sections 2613(a)(2) or (4), EPA need only give five days notice. 40 C.F.R. § 2.306(i)(2) (1980), *incorporating by reference id.* § 2.301(g)(2). Health and safety data releases are not noticed, 15 U.S.C. § 2613(c)(2)(B)(ii) (1976), but any health and safety information relating to manufacturing processes must be noticed under the general thirty day rule. *Id.* If EPA finds that a substance creates an unreason-

without notice any information not designated as confidential by the manufacturer.<sup>48</sup> In addition, if EPA decides to disclose data that the manufacturer believes to be protected by the Act, the manufacturer may bring an action in federal court to restrain EPA from disclosing the data.<sup>49</sup> Finally, TSCA imposes strict criminal penalties on persons who wrongfully disclose confidential data.<sup>50</sup>

## II

### EEC COUNCIL DIRECTIVE

#### A. GENERAL APPROACH

The Council of the European Communities promulgated the Directive on Classification, Packaging, and Labelling of Dangerous Substances on September 18, 1979.<sup>51</sup> The 1979 Directive constitutes the Sixth Amendment to the original 1967 Directive of the same title, which outlined in general terms the Council's strategy with regard to toxic substance control.<sup>52</sup> The Council issued the Directive under the Treaty of Rome, and in particular under Article 100, which calls for "approximation" of the laws of the member states in order to remove obstacles to the establishment of a Common Market.<sup>53</sup> Though a directive is "an essentially incomplete and indeterminate

able risk of injury to health or the environment, it must provide at least fifteen days written notice before disclosure. *Id.* § 2613(c)(2)(B)(i). When an "imminent, unreasonable risk of injury" exists, however, the manufacturer can receive as little as twenty-four hours oral notice. *Id.* In such a case, an exporter may find out by a mere phone call that one of his major trade secrets will be disclosed the next day. 40 C.F.R. § 2.306(k)(4) (1980).

48. 15 U.S.C. § 2613(c)(2)(A) (1976).

49. *Id.* § 2619(a). This injunction, however, may be of little utility to the manufacturer if EPA is disclosing the data under the unreasonable risk exception, *see* note 47 *supra* and accompanying text, because of the short applicable notice period. *Id.* § 2613(c)(2)(B)(i).

50. Any U.S. employee who, by virtue of his office, learns of confidential information and knowingly discloses such information, is guilty of a misdemeanor and may be fined up to \$5,000, imprisoned for up to one year, or both. *Id.* § 2613(d). *See* note 107 *infra*.

51. *See* note 5 *supra*. For a discussion of the Directive as it relates to TSCA, *see* Note, *Control of Toxic Substances: The Attempt to Harmonize the Notification Requirements of the U.S. Toxic Substances Control Act and the European Community Sixth Amendment*, 20 VA. J. INT'L L. 417 (1980).

52. *See* note 5 *supra*.

53. The Treaty of Rome provides that "[t]he Council shall . . . issue directives for the approximation of such provisions laid down by law, regulation or administrative action in Member States as directly affect the establishment . . . of the Common Market." Treaty Establishing the European Economic Community, art. 100 Mar. 25, 1957, 298 U.N.T.S. 11 (*in force* Jan. 1, 1958) [hereinafter cited as Treaty of Rome]. An authoritative English translation appears in [1973] Gr. Brit. T.S. No. 1, Part II (Cmd. 5179 II), at 1. One of the primary purposes of Article 100 is to permit removal of non-tariff trade barriers. *See* 3 H. SMIT & P. HERZOG, *THE LAW OF THE EUROPEAN COMMUNITY* 467-68 (1976).

act,"<sup>54</sup> it is immediately binding on Member States as to the result to be achieved.<sup>55</sup> Moreover, the European Court of Justice has held that directives have direct legal effect, even in the absence of formal domestic implementation.<sup>56</sup>

Two of the purposes of the Directive are protection of man and the environment from dangerous substances and reduction of intra-community barriers to the chemical trade.<sup>57</sup> Notification,<sup>58</sup> labeling, and packaging regulations are the means of controlling "substances" as defined in the Directive.<sup>59</sup> The notification procedure for newly marketed substances<sup>60</sup> requires premarket submission to the competent authority of a defined base set of information.<sup>61</sup> The competent authority initially determines whether the submitted

54. R. LAUWAARS, *LAWFULNESS AND LEGAL FORCE OF COMMUNITY DECISIONS* 28 (1973).

55. See 3 H. SMIT & P. HERZOG, *supra* note 53, at 467. Article 189 of the Treaty of Rome provides that "[a] directive shall be binding, as to the result to be achieved, upon each Member State to which it is addressed," while leaving to national authorities the choice of form and methods. Treaty of Rome, *supra* note 53, art. 189.

56. In *Public Prosecutor v. Ratti*, [1979] E. COMM. CT. J. REP. 1629, [1978-1979] COMMON MKT. REP. (Court Decisions) (CCH) ¶ 8266, [hereinafter cited as Court Decisions], the European Court of Justice interpreted the 1967 Directive, note 5 *supra*, prior to the promulgation of the Directive. The court stated:

[A]fter the expiration of the period fixed for the implementation of a directive a Member State may not apply its internal law—even if it is provided with penal sanctions—which has not yet been adapted in compliance with the directive, to a person who has complied with the requirements of the directive.

[1979] E. COMM. CT. J. REP. at 1642, Court Decisions, *supra*, at ¶ 8274. One commentator has noted:

It is the function of a directive to bring about, where this is necessary for the realization of the objectives of the Community, an adaptation of the national law of Member States. A directive may thus affect the national law of *all* Member States, as is the case, for instance, with the directives given by virtue of Article 100 . . . .

R. LAUWAARS, *supra* note 54, at 28 (footnotes omitted) (emphasis in original).

At least one Member State, Germany, has promulgated domestic legislation pursuant to the Directive. The German law in question should become effective in 1982. See [1980] COMMON MKT. REP. (CCH) ¶ 40,070.

57. Directive Preamble.

58. "[N]otification means the documents whereby the manufacturer or any other person established in the Community who places a substance on its own or in a preparation on the market presents the requisite information to the competent authority of a Member State." Directive art. 2(1)(d). Article 6 outlines the required contents of a "notification." See note 82 *infra*.

59. See *id.* art. 5. The Directive provides that "'substances' means chemical elements and their compounds as they occur in the natural state or as produced by industry, including any additives required for the purpose of placing them on the market." *Id.* art. 2(1)(a). The packaging provisions require safely designed and properly constructed containers for substances placed on the market. *Id.* art. 15. "[P]lacing on the market' means supplying or making available to third parties." *Id.* art. 2(1)(e).

60. Article 13 requires the Commission to keep a list of all substances notified under the Directive. *Id.* art. 13(2). If a substance is not on this list, it is considered a newly marketed substance.

61. For a discussion of the information to be included in this base set, see note 82 *infra*.



information satisfies the base set data requirements.<sup>62</sup> It may then request further information, conduct necessary sampling, or take other measures "[i]f it can be shown necessary for the evaluation of the hazard."<sup>63</sup> The competent authority must then transmit the notification dossier or a summary thereof to the Commission which, in turn, transmits the information to the competent authorities of all Member States.<sup>64</sup>

In the event of a disagreement between the manufacturer and a competent authority, or between two competent authorities, the parties may resort to the review procedures outlined in article 21.<sup>65</sup> Substances posing "a hazard for man or the environment" may be provisionally prohibited under certain circumstances.<sup>66</sup> Like TSCA, the Directive procedures apply to importers as well as to domestic manufacturers of chemical substances.<sup>67</sup> Member States are to adopt domestic legislative and administrative methods to effectuate the Directive's purposes.<sup>68</sup>

## B. CONFIDENTIALITY PROVISIONS

The Directive requires that secrecy be maintained for "confidential information."<sup>69</sup> Although the Directive does not expressly define "confidential information," article 11(1) requires that a "notifier"<sup>70</sup> regard such information as (1) that which is commercially sensitive, (2) the "disclosure of which might harm [the notifier] industrially or commercially," and (3) which the notifier "wishes to be kept secret."<sup>71</sup> A special provision requires that "Member States and the Commission shall ensure that *any* information concerning commercial exploitation or manufacturing be kept secret."<sup>72</sup> The latter provision appears to protect all trade secrets.<sup>73</sup>

The Directive exempts certain information from confidentiality protection.<sup>74</sup> Information not protected includes, *inter alia*, the sub-

62. *Id.* art. 7(1).

63. *Id.*

64. *Id.* arts. 9, 10.

65. *Id.* arts. 7(2), 10(2), 21.

66. *Id.* art. 23(1).

67. *Id.* art. 2(1)(e).

68. *Id.* art. 1. See notes 54-56 *supra* and accompanying text.

69. *Id.* art. 11(4).

70. A "notifier" is a person who makes a notification. *Id.* art. 2(1)(d).

71. *Id.* art. 11(1).

72. *Id.* art. 7(3) (emphasis added).

73. One commentator has noted that neither the Treaty of Rome, nor the pronouncements of the Court, the Commission, or the Council has defined "trade secrets." See 4 A. WISE, TRADE SECRETS AND KNOW-HOW THROUGHOUT THE WORLD § 7.02[1] (1974 & 1980 Supp.).

74. Directive art. 11(1).

stance's trade name, "possible ways of rendering the substance harmless," and other indications necessary to the safety of consumers.<sup>75</sup> More importantly, the Directive does not require that Member States divulge information merely because the Directive accords that information more protection than does domestic implementing legislation.<sup>76</sup> Responsibility for maintaining data secrecy rests with the Member States and the Commission.<sup>77</sup> In most cases, therefore, the regulating body of the Member State in question will decide whether submitted data satisfies the confidentiality tests.<sup>78</sup>

### III

#### COMPARATIVE ANALYSIS OF THE CONFIDENTIALITY PROVISIONS OF TSCA AND THE DIRECTIVE: THE CREATION OF A NON-TARIFF TRADE BARRIER

Governments, through legislation or administrative regulation, often interfere with free trade, thereby creating trade barriers.<sup>79</sup> Although the tariff is the most common form of trade barrier, governments also create significant non-tariff trade barriers through the use of import quotas, import deposits, limits on import licenses, and other stringent regulatory systems.<sup>80</sup>

Trade barriers operate as a disincentive to exportation in two ways. First, the barrier may increase the imported product's cost and, consequently, its selling price. If that increase makes his price higher than the price at which domestic producers sell the same product, the foreign producer will not be able to sell the product in the importing country, and hence, will not export it. Second, the barrier may create risks for the foreign producer that are too great relative to the potential benefits of exportation.

A comparison of the confidentiality provisions of TSCA with those of the Directive indicates that the Directive offers the chemical manufacturer greater protection against disclosure than does TSCA. In effect, the differences in the confidential treatment available under the two statutes operate as a non-tariff trade barrier. The foreign

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75. *Id.*

76. *Id.* art. 11(4).

77. Article 11(4) provides: "[The confidentiality provisions] shall not oblige a Member State whose legislation or administrative practices impose stricter limits for the protection of industrial and commercial secrecy than those laid down in these Articles to supply information, where the State concerned does not take steps to comply with these stricter limits." *Id.* art. 11(4).

78. *Id.* art. 11(2).

79. For a general discussion of trade barriers, see J. JACKSON, *WORLD TRADE AND THE LAW OF GATT* (1969).

80. *See generally id.*

chemical manufacturer's apprehension that EPA will reveal confidential information submitted to comply with TSCA data requirements discourages those producers from exporting to the United States.<sup>81</sup> The following comparative analysis sets forth the differences between the confidentiality provisions of TSCA and the Directive that create this non-tariff trade barrier.

#### A. COSTS OF COMPLIANCE

Both the Directive and TSCA require the submission of extensive data to the respective regulatory authority. The Directive requires manufacturers to develop and submit a broad, well-defined base set of information on the substance.<sup>82</sup> By consulting the Directive, the manufacturer knows precisely what information it must submit. Therefore, it can determine the cost of compliance with the Directive before taking any action with respect to the submission of data or the manufacture of the substance. In addition, the manufacturer knows precisely which trade secrets will be exposed to possible disclosure.

On the other hand, the range of information required to be submitted under TSCA is vague and poorly defined.<sup>83</sup> Rather than requiring submission of itemized types of data, the TSCA data requirement is couched in terms of general categories of information, leaving the manufacturer with little guidance as to what EPA may eventually require it to disclose.<sup>84</sup> Consequently, the manufac-

81. See Murray, *supra* note 35, at 21; CHEMICAL & ENGINEERING NEWS, Sept. 5, 1977, at 17 ("EPA Jolts Industry with Revised TSCA Rules"); CHEMICAL WEEK, Feb. 1, 1978, at 41 ("EPA Plans to Keep it Confidential").

82. Article 6 sets forth the Directive's base set data provision by precisely itemizing the types of data required. The manufacturer must declare the potential unfavorable effects of the substance, propose a classification and labelling scheme, recommend precautions for safe use of the substance, give notice of production quantity changes, submit new knowledge of the effects of an existing substance, inform the agency of new uses for existing substances, and describe any change in the properties of a notified substance. Directive art. 6. In addition, article 6 expressly incorporates the data requirements set forth in Annexes VII and VIII to the Directive. Both Annexes precisely itemize the data required. This data consists of the chemical name, trade name, chemical formula, composition, methods of detection, proposed uses, production estimate, recommended precautions on handling and storage, potential dangers, recommended procedures if a spill or personal injury occurs, physico-chemical data, toxicity, ecotoxicity, and methods for rendering the substance harmless in industrial and public settings. Directive Annexes VII & VIII.

83. TSCA's data submission requirements are scattered in various sections of the Act. See 15 U.S.C. §§ 2603-2607 (1976).

84. Some of the required data is precisely itemized. See note 11 *supra*. For the most part, however, the requirements are set forth in general language. For example, TSCA requires the submission of information regarding health and environmental effects to the extent necessary for EPA to ascertain whether the substance poses an unreasonable risk of harm. *Id.* § 2603(a). Although section 2603(b) suggests what this information should include, these suggestions are merely in the form of *guidelines*, not *requirements* such as

turer must always face the risk that, after incurring substantial testing costs, EPA will require more testing, thereby necessitating the incurrence of even greater costs. If the incurrence of these greater costs will make exporting to the United States economically unsound, the manufacturer may decide to withdraw the product from the U.S. market. Unfortunately, the manufacturer will not be able to recover the compliance costs already incurred. Furthermore, this uncertainty makes it impossible for the manufacturer to know precisely which trade secrets may be exposed to possible disclosure.

## B. INFORMATION COVERED BY CONFIDENTIALITY PROVISIONS

The Directive extends confidential treatment to more types of information than does TSCA. The chemical identity of a substance, often a trade secret, is expressly protected by both statutes. The Directive permits the manufacturer to encode the name of the chemical substance,<sup>85</sup> while the TSCA regulations allow the manufacturer to use a generic name.<sup>86</sup>

The statutes differ, however, in the availability of confidential treatment to non-chemical identity information. The Directive safeguards all non-chemical identity information that satisfies its general rule of confidentiality.<sup>87</sup> In other words, if the manufacturer desires to keep the data secret, regards the data as commercially sensitive,

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those set forth in the Annexes to the Directive. Furthermore, the manufacturer has no means of knowing whether a given amount of information is enough to support an EPA conclusion with respect to whether an unreasonable risk exists. The EPA may at any point determine the manufacturer has not submitted sufficient health and environmental data to support a conclusion.

85. Directive art. 11(3). The name of the substance is encoded on the list of notified substances maintained by the Commission. See note 60 *supra*. If the substance is classified as "dangerous" within the meaning of article 2, however, encoding is not permitted. For a discussion of the implications of this exception to the encoding rule, see notes 97-105 *infra* and accompanying text. For a comparison of the degree of protection accorded the chemical identity by both statutes, see note 86 *infra*.

86. 40 C.F.R. § 710.7(f)(1) (1980). The generic name is published in an appendix to the inventory list maintained by EPA. See note 14 *supra* and accompanying text. The Directive's encoding provision is more restrictive than the TSCA regulations' generic name provision. Under TSCA regulations, any chemical may use a generic name as long as the name is "only as generic as necessary." *Id.* § 710.7(e)(2)(ii) (1980). The Directive, however, restricts the use of encoding to non-dangerous substances. See note 85 *supra* and accompanying text. This "dangerous" exception is quite broad, excluding many chemicals from possible encoding. Furthermore, the EEC will encode the name only if the competent authority so agrees. Directive art. 11(3). On the other hand, EPA provides a generic name whenever one is desired. 40 C.F.R. § 710.7(e)(1) (1980). Consequently, if keeping the chemical identity secret is the manufacturer's only concern, the Directive creates a greater trade impediment to it than does TSCA.

87. Directive art. 11(1). This general rule is set forth in notes 69-72 *supra* and accompanying text. Any information that satisfies this test and does not fall within the list of items expressly denied confidentiality must be kept secret by the Commission. Directive art. 11(4).

and fears that disclosure might result in commercial harm, the Directive mandates confidential treatment.<sup>88</sup> Furthermore, if the data concerns the process used in the manufacturing of the substance, the Directive expressly protects it.<sup>89</sup> TSCA, on the other hand, does not expressly protect manufacturing data.<sup>90</sup> This data, like any non-chemical identification information, must satisfy the FOIA test in order to merit confidential treatment.<sup>91</sup> Although manufacturing data will satisfy this test in most cases, the manufacturer must risk the possibility that it will not.

TSCA's general confidentiality rule is subject to several exceptions.<sup>92</sup> Therefore, satisfaction of the FOIA test does not necessarily guarantee confidentiality. If information falls within the ambit of one of the exceptions, it will not receive confidential treatment even if the information consists of "trade secrets and confidential or financial information."<sup>93</sup> The most important exception provides that data "shall be disclosed if the Administrator determines it necessary to protect health or the environment against an unreasonable risk of injury to health or the environment."<sup>94</sup> This unreasonable risk standard can be easily satisfied by EPA.<sup>95</sup> When EPA finds an unreasonable risk and gives proper notice to the manufacturer, it may reveal the trade secret.<sup>96</sup>

The Directive includes a comparable exception to its confidentiality rule. Article 11(3) provides that if a substance is classified as "dangerous," the manufacturer will not be allowed to encode the substance's name.<sup>97</sup> In this way, one of the manufacturer's most important trade secrets—the chemical identity of the substance—will be revealed.

The absence of case law interpreting the TSCA exception makes it impossible to compare the Directive's "dangerous" standard with TSCA's "unreasonable risk" standard to determine which standard

88. *Id.* art. 11(1).

89. *Id.* art. 7(3).

90. Although TSCA exempts manufacturing data from the mandatory disclosure of health and safety studies requirement, *see* note 103 *infra* and accompanying text, such exemption does not require the confidential treatment of manufacturing data.

91. *See* notes 37-44 *supra* and accompanying text.

92. 15 U.S.C. §§ 2613(a)(1)-(4), 2613(b) (1976). These exceptions are discussed in note 44 *supra*.

93. 5 U.S.C. § 552(b)(4) (1976). *See* notes 37-44 *supra* and accompanying text.

94. 15 U.S.C. § 2613(a)(3) (1976).

95. *See* Gaynor, *supra* note 8, at 1152-55.

96. 15 U.S.C. § 2613(c)(2) (1976). For a discussion of TSCA's notice provisions, *see* note 47 *supra* and accompanying text.

97. Directive art. 11(3). *See* notes 85-86 *supra* and accompanying text.

is harder for the relevant authority to satisfy.<sup>98</sup> Therefore, any conclusion as to which standard, by itself, offers the manufacturer greater protection against disclosure is speculative. Nevertheless, two factors indicate that the manufacturer faces greater risk under the TSCA exception than under the Directive exception. First, a finding that a substance is dangerous under the Directive merely prevents the manufacturer from disguising the chemical identity of that substance.<sup>99</sup> Such a finding does not mandate the disclosure of sensitive non-chemical identity information. On the other hand, a finding of unreasonable risk under TSCA requires the disclosure of *any* information EPA deems necessary to protect health or the environment from the unreasonable risk.<sup>100</sup>

Second, article 2(2) of the Directive precisely defines the characteristics of a substance that make it "dangerous" within the meaning of the statute.<sup>101</sup> Consequently, before the manufacturer discloses any data to the EEC, it will know whether the exception will apply. If the harmful economic consequences of disclosure will exceed the potential for profits, the manufacturer can decide to refrain from exporting to the EEC *before* it incurs the costs involved in complying with the Directive. On the other hand, TSCA provides no guidance as to the meaning of "unreasonable risk." Therefore, the manufacturer faces the risk of incurring substantial compliance costs before EPA determines that it must disclose confidential information because the substance poses an unreasonable risk.

Finally, the differences in the confidential treatment accorded health and safety studies create another problem for the potential exporter to the United States. TSCA requires all chemical manufacturers to reveal to EPA "[a]ll existing data concerning the environmental or health effects of [a] substance or mixture."<sup>102</sup> TSCA then provides that EPA may disclose any of this data that does not pertain to "processes used in the manufacturing or processing of a chemical substance."<sup>103</sup> The Directive requires the manufacturer to submit all

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98. No judicial interpretation of the Directive's "dangerous" standard would be necessary to make such a comparison because this standard is statutorily defined. See note 101 *infra* and accompanying text.

99. See notes 85, 97 *supra* and accompanying text.

100. 15 U.S.C. § 2613(a)(3) (1976).

101. A substance is "dangerous" if it is explosive, oxidizing, extremely flammable, highly flammable, flammable, very toxic, toxic, harmful, corrosive, irritating, dangerous for the environment, carcinogenic, teratogenic, or mutagenic. Directive art. 2(2). Article 2 precisely defines each of these characteristics.

102. 15 U.S.C. § 2607(a)(2)(E) (1976).

103. *Id.* § 2613(b). Manufacturing data, however, must still meet the FOIA confidentiality test before it merits confidential treatment. See notes 90-91 *supra* and accompanying text. Furthermore, confidentiality will not be accorded manufacturing data if it fits

data obtained through toxicological and ecotoxicological studies.<sup>104</sup> The Directive, however, only permits the disclosure of the manufacturer's interpretation of this data.<sup>105</sup> All underlying data generated by a health and safety study clearly consists of more information than does the mere interpretation of such a study. Therefore, the Directive protects more data generated through health and safety studies than does TSCA.

### C. ACCESS TO CONFIDENTIAL DATA

A primary concern of the potential exporter is who will have access to confidential data submitted to the regulating body. The greater the number of persons with access to confidential information, the greater is the likelihood that a damaging disclosure of such information will occur. If a large enough number of people will have access to the information in a given country, a chemical producer may be reluctant or unwilling to export to that country. Hence, permitting broad access to confidential information may aggravate the non-tariff trade barrier.<sup>106</sup> The availability of criminal sanctions against governmental officials who wrongfully divulge confidential data may deter disclosure, but such sanctions offer little solace to the manufacturer who has just lost a trade secret worth millions.<sup>107</sup>

One of the four groups given access to the Directive's confidential data is the competent authority of the country of manufacture.<sup>108</sup> The competent authority, appointed by the Member State,<sup>109</sup> examines data to ensure it conforms with the Directive and takes appropriate action if a potential hazard is found.<sup>110</sup> The competent

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within the unreasonable risk exception, *see* notes 93-96 *supra* and accompanying text, or any of the other exceptions to the FOIA rule, *see* note 44 *supra* and accompanying text.

104. Directive Annexes VII & VIII.

105. *Id.* art. 11(1).

106. *See* notes 79-81 *supra* and accompanying text.

107. Criminal sanctions are desirable from the exporter's standpoint to deter damaging disclosures. The Directive does not provide for such sanctions, but its silence in this regard may indicate that Member States themselves bear the responsibility for providing criminal penalties. *Cf.* Directive art. 7(3) ("Member States and the Commission shall ensure that any information concerning commercial exploration or manufacturing is kept secret"). TSCA, however, provides criminal penalties for employees of the United States or agency contractors who wrongfully disclose confidential information. The elements of the crime are: (1) a person who is an employee of the United States or of an agency contractor, (2) having access to data because of his employment, (3) and who knows disclosure is prohibited, (4) willfully discloses such data (5) to a person not entitled to receive it. *See* 15 U.S.C. § 2613(d) (1976). Penalties upon conviction include fines up to \$5,000, imprisonment for up to one year, or both. *Id.* § 2613(d)(1).

108. *See* Directive art. 6(1).

109. *Id.* art. 7(1).

110. The competent authority may ask for more information, order special tests, "carry out sampling," or take other "appropriate measures." *Id.*

authority sends the data to the Commission,<sup>111</sup> which, in turn, transmits the information to the other Member States' competent authorities.<sup>112</sup> If made necessary because of legal proceedings involving controlled substances, the Commission or competent authority may reveal secret information "to persons directly involved in such proceedings."<sup>113</sup> Member States have a duty to ensure that all parties receiving the information preserve its confidentiality.<sup>114</sup> The potential exporter generally knows its data will be in the hands of the Commission and ten competent authorities. The safety of the data will depend only on the discretion the Member States use in appointing the competent authorities.<sup>115</sup>

Unlike the Directive, TSCA and EPA regulations allow a potentially large number of persons access to confidential information. Within EPA, the regulations call for disclosure to any "office, officer, or employee with an official need for the information."<sup>116</sup> Furthermore, contractors working for EPA can obtain the information under certain circumstances.<sup>117</sup> The distinct possibility that an exporter's competition will one day be an EPA contractor may be a factor in the decision whether to export to the United States.<sup>118</sup>

Any non-EPA employee of the United States who needs confidential data in the course of his official duties protecting health or the environment or for specific law enforcement reasons shall have access to the information.<sup>119</sup> Furthermore, any congressional com-

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111. *Id.* art. 9.

112. *Id.* art. 10(1). The competent authority of one Member State may ask the Commission for further details about or tests conducted on the substance. If the second competent authority refuses to comply with such a request, the Commission is to resolve the dispute by making a decision pursuant to Article 21. *Id.* art. 10(2).

113. *Id.* art. 11(4).

114. *Id.* art. 7(3). This provision apparently requires each Member State to take steps, such as the imposition of criminal sanctions for unlawful disclosure, to maintain confidentiality of commercial and industrial secrets. See note 107 *supra* and accompanying text.

115. The precise number of persons with access will depend on the particular size of the competent authority appointed. The Directive does not specify how large the authority should be, but administrative costs impose a practical ceiling on the number of members a given competent authority will have.

116. 40 C.F.R. § 2.306(h) (1980), *incorporating by reference id.* § 2.209(e).

117. 15 U.S.C. § 2613(a)(2) (1976). Such disclosure must be "necessary for the satisfactory performance by the contractor of a contract with the United States." *Id.* The provision applies to contracts "entered into on or after the date of enactment" of TSCA. *Id.*

118. Such an event could occur if EPA contracted with a competitor to verify test results or even if the contractor merely expanded its operations after it had completed the EPA contract. The exporter is protected by the contract and remedy rules of 40 C.F.R. § 2.306(j) (1980), *incorporating by reference id.* § 2.301(h)(2)(ii). These protections, however, may be of little consolation once the secret has been lost. See 15 U.S.C. § 2626(a) (1976).

119. *Id.* § 2613(a)(1). For special administrative regulations governing interagency disclosure, see 40 C.F.R. § 2.306(h) (1980), *incorporating by reference id.* § 2.209(c).



mittee has a statutory right to any data EPA obtains under TSCA.<sup>120</sup> As under the Directive, TSCA data may be disclosed when relevant to proceedings under the Act.<sup>121</sup> EPA may disclose confidential information if the submitter consents.<sup>122</sup> When an exporter desires a generic name for his substance he must consent to disclosure to a *bona fide* manufacturer.<sup>123</sup> Finally, pursuant to a memorandum of understanding between EPA and the Occupational Safety and Health Administration,<sup>124</sup> OSHA may gain access to certain confidential data submitted under TSCA.<sup>125</sup>

Given the numerous and varied groups with potential access to confidential information submitted under TSCA, a chemical exporter to the United States could reasonably doubt the safety of its trade secrets. Even when data is initially protected under TSCA and limited to the parties specified by TSCA, the information can nonetheless be revealed later, if some other regulatory rule gives the public a greater right to access than do the TSCA rules and regulations.<sup>126</sup> A potential exporter, therefore, would be quite justified in concluding that information submitted stands a significant possibility of eventual disclosure.

#### D. THE PROCEEDINGS EXCEPTION

Both TSCA and the Directive permit revelation of confidential data in certain legal and administrative proceedings. The Directive allows disclosure when the proceeding "involv[es] sanctions . . . [and is] undertaken for the purpose of controlling substances placed on the market."<sup>127</sup> A person in any proceeding that does not involve sanctions or does not concern control of "substances placed on the market" will not have access to confidential information.<sup>128</sup> These

120. See 15 U.S.C. § 2613(e) (1976).

121. *Id.* § 2613(a)(4). See notes 127-140 *infra* and accompanying text.

122. 40 C.F.R. § 2.306(h) (1980), *incorporating by reference id.* § 2.209(f).

123. *Id.* § 710.7(e)(2)(iv). To determine whether a manufacturer is *bona fide*, EPA regulations require that the manufacturer submit various data and samples of the substance. *Id.* § 710.7(g)(2). EPA compares these with data supplied by the original claimant of confidentiality. *Id.* § 710.7(g)(3)-(4). If the submitted information corresponds with the original data to a significant degree, the manufacturer is relieved of the premanufacture notice testing. *Id.* § 710.7(g)(5). Otherwise, he must perform the tests. *Id.* § 710.7(g)(6).

124. See [1981] INT'L ENVIR. REP. (BNA) (Current Rep.) 673-74.

125. The agreement permits OSHA to obtain premanufacture notification submissions, substantial risk notices, and other confidential information. *Id.*

126. 40 C.F.R. § 2.306(h) (1980), *incorporating by reference id.* § 2.202(d).

127. Directive art. 11(4).

128. "Sanction" is not defined in the Directive, but a reasonable person could conclude any action to require different packaging or labelling than that proposed would be a sanction. Furthermore, any proceeding to elicit more information from the manufacturer, *id.* art. 7(1), could be viewed as involving a sanction in the sense that it requires the manufacturer to do something he otherwise would have no obligation to do.

requirements effectively limit the risk of disclosure under the exception. Because of the market control requirement in the test,<sup>129</sup> most proceedings will involve the manufacturer and a regulatory body. In these cases, the possibility of damaging disclosure will be slight, because both parties generally will already have access to the relevant confidential data.<sup>130</sup> Consequently, an exporter might reasonably conclude that his data will not be exposed to potentially damaging disclosure because of the proceedings exception to the Directive's rule of confidentiality.

Unlike the Directive, TSCA broadly defines the proceedings exception, thus exposing sensitive data to disclosure in a variety of proceedings. TSCA provides that data "may be disclosed when relevant in any proceeding under [TSCA], except that disclosure in such a proceeding shall be made in such manner as to preserve confidentiality to the extent practicable without impairing the proceeding."<sup>131</sup> Because Congress did not define "relevant," its meaning depends upon the particular procedural setting of the proceeding. Generally, the litigant seeking disclosure will easily meet the relevance test and thereby obtain the desired information.<sup>132</sup>

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129. *Id.* art. 11(4).

130. If the dispute is over revelation of data to the competent authority, the manufacturer will know that the authority's duty of secrecy will protect the data. *Id.* art. 7(3).

131. 15 U.S.C. § 2613(a)(4) (1976). In its Conference Report on TSCA, Congress stated: "[i]t is intended that the Administrator exercise due care to prevent the release of confidential information to competitors of persons submitting data merely because the competitors have joined the proceeding." LEGISLATIVE HISTORY, *supra* note 4, at 703.

132. If the proceeding is in federal court, a reasonable conclusion would be that the Federal Rules of Evidence definition will control. Under those rules, "relevant" data would be any information "tend[ing] to make the existence of any fact that is of consequence to the determination of the action more probable or less probable than it would be without the [data]." FED. R. EVID. 401. Because the "more probable" standard is easily met, disclosure by EPA will probably result in most proceedings.

Should the exporter find himself in an administrative proceeding involving EPA, the regulations at least set forth the matter to which the data must be relevant. 40 C.F.R. § 2.306(i) (1980). In cases where EPA acts without a record or an opportunity for a hearing, the standard is that the data must be relevant to the subject of the proceeding and the public interest must be served by disclosure. *Id.* § 2.306(i)(2), *incorporating by reference id.* § 2.301(g)(2). When the decision is to be made on the record, the standard varies, depending on who wants the information. When EPA desires to release data to the public, the data must be relevant to a matter in controversy, a higher standard than "subject of the proceeding," and the public interest must be served by disclosure. *Id.* § 2.306(i)(3), *incorporating by reference id.* § 2.301(g)(3).

Finally, should a private party to the proceeding request the data, he must show significant impairment of the presentation of a significant matter in the case, as well as greater benefit to the public than harm to the business from disclosure to obtain the data. *Id.* § 2.306(i)(4), *incorporating by reference id.* § 2.301(g)(4).

One result of these four standards is to prevent an exporter's competitors from receiving confidential data in some administrative actions because of the significant harm standard. Nevertheless, EPA can easily obtain disclosure in the administrative setting because of the low standard of relevance. In federal court, *anyone* meeting the "more probable" standard can probably gain access to the data. Consequently, a potential

TSCA outlines numerous different types of proceedings, in addition to rulemaking, in which relevant data may be revealed.<sup>133</sup> The greatest threat of disclosure to the potential exporter probably lies in the citizen's enforcement action, which permits any person to commence an action to enforce TSCA or to compel the EPA Administrator to act.<sup>134</sup> Thus, for example, in an environmental group's action to force the administrator to regulate a chemical, the exporter's confidential information may be revealed if relevant.<sup>135</sup> Another provision allows any person to petition EPA to initiate proceedings under TSCA.<sup>136</sup> Again, third parties attempting to force the Administrator to act may gain access to sensitive data.

Another troubling aspect for the potential exporter stems from TSCA's expressed goal of preserving the integrity of a proceeding regardless of the potential harm from release of confidential information.<sup>137</sup> If maintaining strict confidentiality will impair the proceeding, the data will be released.<sup>138</sup> An exporter may protect some data by challenging its relevance but, once a tribunal finds data relevant, it will preserve confidentiality only to the extent it does not result in impairment of the proceeding.<sup>139</sup>

Compared with the Directive's proceedings exception, the TSCA provision is complex. Exporters to the EEC know their data will be safe unless a proceeding arises that both involves sanctions and is for the purpose of controlling substances in the market. Exporters to the United States, however, must worry whether their data will be found relevant in one of the enumerated types of proceedings.<sup>140</sup> Moreover, exporters to the United States will be uncer-

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exporter can reasonably conclude his data will be found relevant in most proceedings in which the party requesting the data is not a competitor.

133. They are a criminal prosecution for unauthorized disclosure of data, 15 U.S.C. § 2613(d) (1976), an action for specific enforcement of TSCA, *id.* § 2616(a), an action for judicial review of rulemaking, *id.* § 2616(a), a citizen's petition, *id.* § 2620(a), and a proceeding to restore a wrongfully discharged employee, *id.* § 2622(b). Also, EPA must disclose data if so ordered by a court. 40 C.F.R. § 2.306(h) (1980), *incorporating by reference* § 2.209(d).

All of the proceedings pose a danger of disclosure of confidential data, but to varying degrees. The criminal prosecution will involve data that has already lost its confidentiality because of unauthorized disclosure. In proving the case, however, the prosecutor may need access to confidential data that was not revealed. The specific enforcement action, the seizure, review of rulemaking, and the employee discharge action generally involve the manufacturer and the government. Thus, most of the parties in these proceedings will likely have access to the data independently of the proceedings.

134. 15 U.S.C. § 2619(a) (1976). *See also* 40 C.F.R. § 2.306(e)(2) (1980).

135. *See* note 132 *supra*.

136. *See* 15 U.S.C. § 2620(a) (1976).

137. *See id.* § 2613(a)(4).

138. 40 C.F.R. § 2.306(i) (1980).

139. *See* note 132 *supra* and accompanying text.

140. *See* notes 133-36 *supra* and accompanying text.

tain as to the extent of disclosure, in view of the broad statutory requirement that proceedings not be impaired because of secrecy preservation.

#### E. CONFIDENTIALITY CLAIMS

Unless a person requests the release of information submitted under TSCA, EPA cannot disclose any data.<sup>141</sup> Once such a request is made, however, EPA must determine whether the FOIA confidentiality test has been satisfied.<sup>142</sup> If so, EPA cannot disclose the data to the requesting party.<sup>143</sup> EPA regulations provide that EPA need not make such determination, however, unless the manufacturer has asserted a confidentiality claim at the time he submitted the data.<sup>144</sup> Rather, in such a case, EPA may disclose the data to the requesting party regardless of whether the FOIA test would mandate confidentiality.<sup>145</sup> In effect, a failure to make such a claim will deprive the manufacturer of confidential treatment. To make a satisfactory confidentiality claim under TSCA, the manufacturer must show that: (1) the information will be protected by the business;<sup>146</sup> (2) the data is not reasonably obtainable through use of legal means;<sup>147</sup> (3) no statute requires disclosure;<sup>148</sup> and, most importantly, (4) "disclosure . . . is likely to cause substantial harm to the business' competitive position."<sup>149</sup>

The Directive's confidentiality test similarly requires the manufacturer to make a confidentiality claim before being entitled to confidential treatment.<sup>150</sup> The manufacturer must (1) regard the data as commercially sensitive; (2) show that disclosure might result in commercial harm; and (3) desire to keep the data secret.<sup>151</sup> Clearly, the Directive's requirement is easier to fulfill than that of TSCA. While under TSCA the manufacturer must show that disclosure is *likely* to cause *substantial* harm, it must only show that such disclosure *might* cause harm under the Directive. "Might" connotes a lesser

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141. The FOIA only permits disclosure of data to requesting parties. 5 U.S.C. § 552 (1976).

142. 40 C.F.R. §§ 2.204(b)-2.204(d) (1980). EPA may also make such a determination if, absent a request, it desires to ascertain whether information is entitled to confidential treatment, *id.* § 2.204(a)(2), or if it believes that a request is likely to be made in the future, *id.* § 2.204(a)(3).

143. *Id.* § 2.204(d)(1)(ii).

144. *Id.* §§ 2.203(c), 2.204(c)(2)(i)(A).

145. *Id.* § 2.204(c)(3).

146. *Id.* §§ 2.204(d), 2.306(g), *incorporating by reference id.* § 2.208(b).

147. *Id.* §§ 2.204(d), 2.306(g), *incorporating by reference id.* § 2.208(c).

148. *Id.* §§ 2.204(d), 2.306(g), *incorporating by reference id.* § 2.208(d).

149. *Id.* §§ 2.204, 2.306(g), *incorporating by reference id.* § 2.208(e).

150. *See* notes 69-73 *supra* and accompanying text.

151. Directive art. 11(1).

probability than "likely." Furthermore, a showing of substantial harm is clearly more demanding than a showing of mere harm. By placing a heavier burden on the manufacturer, TSCA permits disclosure in many cases where the Directive does not.

#### IV

### ELIMINATING THE TRADE BARRIER THROUGH REGIONAL OR UNILATERAL ACTION

The ideal solution to the trade barrier problem created by conflicting chemical regulation laws would require global cooperation. Because of practical considerations and political differences, however, achievement of a global solution in the near future is improbable.<sup>152</sup> As an alternative, a regional approach to the problem offers the most promise. Regional negotiations might not only eliminate the EEC-U.S. chemical trade barrier, but might also permit elimination of duplicative data requirements and reduction of requirements for non-essential data.<sup>153</sup> The responsible U.S. and European authorities, therefore, should consider the possibility of formulating a regional agreement in the area of toxic substance regulation.<sup>154</sup>

In the absence of a regional diplomatic solution, the United States could remove the trade barrier unilaterally, by simply defining more precisely the data required by TSCA.<sup>155</sup> The adoption of a

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152. See CHEMICAL WEEK, April 25, 1979, at 46. A global approach would permit meeting both goals of regulation and certainty. Trade barriers would cease to exist because all companies would be subject to the same rules. Reduction of costs might also result because each manufacturer would generate a single set of data instead of a different set for each country of export.

Unfortunately, the impediments to global regulation are great. As evidenced by the conflicts between TSCA and the Directive, different countries currently take different approaches to regulation. Political difficulties prevent nations from solving even their most pressing problems. Bringing the nations of the world together to negotiate a global regulatory scheme, therefore, appears unlikely in the near future.

153. Reducing non-essential data sent to a regulatory body should also improve that body's efficiency.

154. The industrial nations initiated regional measures to regulate toxic substances at a recent Organization for Economic Cooperation and Development (OECD) Conference. The OECD Conference resulted in significant progress on testing guidelines, updating mechanisms, good laboratory practices, premarketing data and acceptance of data. The problem of confidentiality was referred to a Group of Experts for further consideration. See Developments at OECD High Level Chemicals Group Meeting, Paris, 19-21 May 1980 (on file at *Cornell International Law Journal*). Any proposals by the Group of Experts will have to take the TSCA/Directive differences into account. See [1979] COMMON MKT. REP. (CCH) ¶ 10,179.

155. The EEC could contribute to the effort by specifying in the Directive the type of notice a manufacturer will receive of an impending disclosure. Presently, the authority to prescribe notice requirements is in the hands of the Member States. Consequently, the manufacturer may face ten different notice provisions. Imposition of criminal penalties by the EEC or the Member States for violation of the Directive's secrecy provisions would have a beneficial deterrent effect. Finally, the EEC could expand the encoding

base set data requirement would result in substantial improvement over the present substance by substance approach.<sup>156</sup> Such a system would permit the use of standard tests for *all* chemicals, with special tests required only for especially hazardous substances. The system would better afford the manufacturer an opportunity to foresee testing costs.

Another appropriate unilateral measure would involve an amendment to TSCA providing a more stringent standard for releasing confidential data.<sup>157</sup> Such an amendment would not seriously impair effective regulation, because the responsible agencies will already have access to the data. Additional unilateral amendments might provide for further limitations on the number of persons with access to data,<sup>158</sup> and the imposition of criminal penalties for knowing *receipt* of confidential data. Unilateral steps of this type would effectively eliminate the EEC-U.S. chemical trade barrier.

### CONCLUSION

Effective regulation of chemical substances requires balancing the needs of the public and the environment against the cost of such regulation to government and industry. Regulation, however, may also interfere with international trade. Sound policy decisions must take into account these international effects.

TSCA and the Directive currently create a non-tariff barrier to the international chemical trade. Global or regional solutions to the problem may be desirable, but such solutions may not be possible at the present time. Unilateral action by the United States, however, through the use of amendments to, or regulations under TSCA, might alleviate the trade barrier problem, without significant detriment to the overall goals of regulation.

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provision beyond non-dangerous substances. This would afford the manufacturer greater protection, but would not diminish the regulatory function because the agency knows whether a substance is dangerous or not.

156. Within the current TSCA framework, such a system could be imposed by issuing a regulation providing that any TSCA testing rule will require certain specific tests.

157. See notes 37-44 *supra* and accompanying text.

158. The United States should also define the terms "relevant" and "impairing" in the proceedings exception provisions discussed in note 132 *supra* and accompanying text. These definitions would permit the manufacturer to predict with greater clarity the evidentiary burden it will bear when challenging a pending release of data.

