

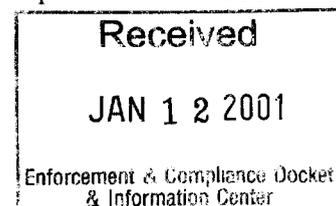
**Barriers and Opportunities to Electronic Reporting
under the Toxic Substances Control Act**

This memorandum analyzes provisions of the Toxic Substances Control Act (TSCA), 15 U.S.C. 2601-2692, that address reporting to the EPA by the regulated community and give EPA rulemaking authority to require data submission, reports, inspections, and recordkeeping. The potential barriers to electronic reporting and the opportunities to offer such reporting under TSCA are identified. It also analyzes some statutory provisions, which might affect electronic reporting, although it is not clear whether their impact would be positive or negative.

Very few statutory requirements of TSCA create any problems for electronic reporting. Most of the sections that require reports do not create any barriers to electronic reporting, and three sections are somewhat ambiguous so their impact on electronic reporting will depend upon how EPA's regulations have interpreted them. However, one provision – section 14 (c) – explicitly requires that writing and certified mail must be used for manufacturers or processors to designate certain data or information as being confidential and for EPA to notify affected parties if it intends to make a public release of inspection and other data submitted by them. Consequently, EPA must continue to require written submissions and use certified mail in these situations unless TSCA is amended.

A. *TSCA §4, Testing Requirements (15 USC 2603)*

Section 4 requires testing and the development of data related to the health and environmental effects of chemical substances or mixtures when the manufacture, distribution, processing, use or disposal of a chemical substance or mixture may present an unreasonable risk of injury to the health or the environment, and where such data does not already exist or is insufficient. As the general section authorizing rulemaking and testing requirements under TSCA, section 4 does not specifically address reporting or data submission requirements. However, subsection 4(b)(3)(A) does authorize EPA to issue rules for data submission, subsection 4(c) authorizes applications for exemptions from testing and data submission, and subsection 4(g) authorizes petitions for EPA



to adopt standards for the development of test data.

Under subsection 4(b)(1), EPA is authorized to issue rules regarding the time limits for testing toxic substances and for submitting to the Administrator data obtained from such testing, including the submission of preliminary data during the testing period. There is nothing in this section that creates a barrier to electronic submission of data for evaluation by EPA, and revisions of these testing rules could provide an opportunity for EPA to offer electronic reporting.

Section 4(b)(1): Testing requirements -- Rulemaking	No barrier
(...) Any such rule may require submission to the Administrator of preliminary data during the period prescribed under subparagraph (C).	

More generally, subsection 4(b)(3)(A) authorizes EPA to make rules requiring tests and submission of data for any substance or mixture affected by TSCA. No barriers exist in this subsection to adopt rules allowing for electronically reporting or storing such data.

Section 4(b)(3)(A): Tests and submissions of data - Rulemaking	No barrier
A rule (...) respecting a chemical substance or mixture shall require the persons described in subparagraph (B) to conduct tests and submit data to the Administrator on such substance or mixture (...).	

Subsection 4(c) provides for applications for exemptions from the testing requirements. Nothing in the language of the section prevents the EPA from receiving those applications electronically; the provision "in such form and manner as the Administrator shall prescribe" creates an opportunity for rules that would specifically offer potential applicants an electronic method to submit an application for exemption.

Section 4(c): Application for an Exemption -- Rulemaking	No barrier
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(1) Any person required (...) to conduct tests and submit data on a chemical substance or mixture shall apply to the Administrator (in such form and manner as the Administrator shall prescribe) for an exemption from such requirement.

Similarly, subsection 4(g) provides for manufacturers or processors to petition EPA for standards for the development of test data, and the language of the statute would allow EPA to offer petitioners the possibility of submitting their requests electronically.

Section 4(g): Petition for test data standards	No barrier
A person intending to manufacture or process a chemical substance for which notice is required (...) may petition the Administrator to prescribe standards for the development of test data for such substance.	

B. TSCA §5: Manufacturing and Processing Notices (15 USC 2604)

Section 5(a)(1) sets forth the general requirements for submitting notices and test data to the Administrator at least 90 days before the manufacture or processing of a new chemical substance, and it also provides an opportunity to apply for exemptions to the notice requirement.

Section 5(a)(1): Manufacturing and processing notices -- Reporting	No barrier
Except as provided in subsection (h) of this section, no person may - (A) Manufacture a new chemical substance (...)or (B) Manufacture or process any chemical substance for a use which the Administrator has determined (...) is a significant new use, unless such person submits to the Administrator, at least 90 days before such manufacture or processing, a notice...	

Subsection 5(b) requires that any persons, who are subject to the notice requirements of TSCA, must submit test data together with the notice to EPA prior to manufacturing or processing substances or mixtures. The language of the statute does not specify in what form the data must be submitted, except that the submission of data shall be "in accordance with the rule at the time the notice is submitted." EPA's rules for submitting test data could allow the regulated community the opportunity for electronic reporting of such data, provided that the rules also allow for any such submitted data to be available for inspection by interested persons, as

required by subsection 5(b)(3). The requirement that EPA make any submitted test data available for inspection, addressed in greater detail in the analysis of section 14 below, is not itself a barrier to electronic reporting. However, this requirement involves considerations of public access to submitted data from health and safety studies, and it also requires that EPA's system for electronic reporting would have to provide the special treatment accorded by TSCA to data that the submitter has designated as requiring confidential treatment.

Section 5(b): Submission of test data -- Reporting and Recordkeeping	No barrier
<p>(1)(A) If (i) a person is required (...) to submit a notice to the Administrator before beginning the manufacture or processing of a chemical substance, and (ii) such person is required to submit test data for such substance (...), such person shall submit to the Administrator such data in accordance with the rule at the time notice is submitted in accordance with subsection (a)(1) of this section.</p> <p>(2)(A) If a person (i) is required (...) to submit a notice to the Administrator before beginning the manufacture or processing of a chemical substance listed under paragraph (4), and (ii) is not required (...) to submit test data for such substance, such person shall submit to the Administrator data prescribed by subparagraph (B) (...).</p> <p>(3) Data submitted under paragraph (1) or (2) shall be made available, subject to section 2613 of this title, for examination by interested persons.</p>	

The content of the notices required under TSCA is specified in subsection 5(d)(1), which allows for test data to be submitted "in such form and manner as the Administrator may prescribe." Thus, it creates an opportunity for EPA to adopt a rule offering electronic reporting of test data. However, because the statutory language covers "any test data in the possession or control of the person giving notice," it is unlikely that electronic reporting could be the exclusive means of meeting the notice requirements, assuming that some of this pre-existing test data exists in paper form only.

Section 5(d)(1): Content of notice -- Rulemaking	No barrier
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The notice required by subsection (a) of this section shall include (...)

(B) in such form and manner as the Administrator may prescribe, any test data in the possession or control of the person giving such notice which are related to the effect of any manufacturing, processing, distribution in commerce, use, or disposal of such substance(...)

(C) a description of any other data concerning the environmental and health effects of such substance, insofar as known to the person making the notice(...)

As in the provisions for applications for exemptions from the requirement to submit testing data in subsection 4(c) above, subsection 5(h) provides that a person may apply to the EPA for an exemption from the notice and data requirements of section 5. Such exemptions would apply in cases of manufacturing or processing substances for test marketing, when the EPA determined that submission of data would be duplicative, or when the substance is equivalent to one for which data has already been submitted. EPA's procedures to apply for an exemption under this subsection could allow for electronic submissions of applications; the statutory language presents no barrier to doing so.

Section 5(h): Exemptions -- Rulemaking	No barrier
<p>(1) The Administrator may, upon application, exempt any person from any requirement of subsection (a) or (b) of this section to permit such person to manufacture or process a chemical substance for test marketing purposes (...)</p> <p>(2) The Administrator may, upon application, exempt any person from any requirement of subsection (b) (2) of this section to submit data for a chemical substance. (...)</p> <p>(4) The Administrator may, upon application and by rule, exempt the manufacturer of any new chemical substance from all or part of the requirements of this section if the Administrator determines that the manufacture, processing, distribution... will not present an unreasonable risk of injury to health or the environment.</p>	

C. TSCA §6; Regulation of Hazardous Chemical Substances and Mixtures
(15 USC 2605)

Section 6 addresses the regulation of hazardous chemical substances and mixtures and provides rulemaking authority for the EPA to enact, in its discretion, one or more of the following regulatory options: entirely prohibiting the manufacture, processing, or distribution in commerce of certain hazardous substances or mixtures; prohibiting these activities for particular uses or in concentrations or levels in excess of specified levels; prohibiting or regulating the commercial use and disposal of substances or mixtures, and requiring the addition of certain markings,

the processes used for manufacturing or processing and to monitor and conduct tests in order to ascertain compliance with the applicable rules. These recordkeeping and monitoring requirements of section 6 (a)(4) could be affected by electronic data collection and reporting, but there is no barrier in this section to EPA offering electronic means of recordkeeping and monitoring.

Section 6 (a)(4): Records of Processes and Tests - Recordkeeping	No barrier
<p>A requirement that manufacturers and processors of such substance or mixture make and retain records of the processes used to manufacture or process such substance or mixture and monitor or conduct tests which are reasonable and necessary to assure compliance with the requirements of any rule applicable under this subsection.</p>	

Further, section 6 (a)(7) requires that manufacturers or processors give notice both to distributors in commerce and to other persons in possession or exposed to such substance or mixture, as well as to give public notice of such risk of injury. While these notice requirements do not specifically address reporting to EPA, this rulemaking authority could be used to adopt electronic means of issuing such public notices along with more traditional methods.

Section 6 (a)(7): Notice of Risk of Injury -- Reporting	No barrier
<p>A requirement directing manufacturers or processors of such substance or mixture (A) to give notice of such unreasonable risk of injury to distributors in commerce of such substance or mixture and, to the extent reasonably ascertainable, to other persons in possession of such substance or mixture or exposed to such substance or mixture, (B) to give public notice of such risk of injury (...)</p>	

Subsection 6(b)(1) specifies that EPA may order regulated parties to submit descriptions of the quality control procedures, where EPA has a reasonable basis to conclude that the manufacturing or processing could present a risk of injury to health or the environment. EPA could provide for the electronic submission of the descriptions of quality control procedures. A critical factor in effectively protecting against inadequate quality control procedures is for EPA to receive timely

warnings of risks to health and the environment. Electronic reporting of descriptions of quality control procedures could allow for more effective monitoring of quality control procedures in cases where EPA determined them to be inadequate.

Section 6 (b)(1): Quality control - Reporting	No barrier
The Administrator may by order require such manufacturer or processor to submit a description of the relevant quality control procedures followed in the manufacturing or processing of such chemical substance or mixture; (...)	

Section 6(c)(2) provides that EPA can use its rulemaking authority to allow interested parties to submit their views and data. The rules could be revised specifically to allow for the electronic submission of such information, provided these materials are then made publicly available.

Section 6(c) (2): Submission of public comments - Rulemaking	No barrier
When prescribing a rule under subsection (a) the Administrator shall (...) (A) publish a notice of proposed rulemaking stating with particularity the reason for the proposed rule; (B) allow interested persons to submit written data, views, and arguments, and make all such submissions publicly available;	

D. TSCA 8; Reporting and Retention of Information (15 USC 2607)

Section 8 concerns requirements for manufacturers or processors of hazardous chemical substances and mixtures to establish and maintain records and submit reports to the extent that EPA determines is necessary for effective enforcement of TSCA. Section 8 (a)(1) authorizes the promulgation of rules for recordkeeping and reporting to EPA of the common names, trade names, chemical identities, and molecular structures of each chemical substance or mixture for which reports are required, as well as reporting the categories of use, amounts to be processed, manufactured, descriptions of byproducts, all existing data concerning the environmental and health effects, estimates of the number of persons subject to being exposed and the duration of exposure, and the manner or method of disposal of the substances or mixtures. The rulemaking authority under this section, authorizing EPA to require recordkeeping and reporting "as [EPA]

may reasonably require," offers an opportunity to adopt electronic recordkeeping and reporting.

Section 8 (a) (1): Rulemaking, Reporting and Recordkeeping	No barrier
<p>(1) The Administrator shall promulgate rules under which (A) each person (...) who manufactures or processes or proposes to manufacture or process a chemical substance (other than a chemical substance described in subparagraph (B)(ii)) shall maintain such records and shall submit to the Administrator such reports, as the Administrator may reasonably require, and require the owner or operator of any point source to (i) establish and maintain such records, (ii) make such reports (...) as he may reasonably require; and</p>	

Subsection 8(a)(2) specifies the scope of the records and reporting required under TSCA and covers the commercial and scientific particulars of the chemical substances and mixtures, the uses, amounts, byproducts, data on health and environmental effects, number of persons exposed and the methods of disposal. The likelihood that such data already exist in, and are maintained by, manufacturers and processors in electronic form supports the adoption of electronic means for reporting. The statute authorizes EPA to require maintenance of such records and could allow for electronic reporting of any such data. Thus, no barrier exists to EPA offering electronic methods of recordkeeping or reporting.

Section 8 (a) (2): Chemical information--Reporting and Recordkeeping	No barrier
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The Administrator may require under paragraph (1) **maintenance of records and reporting with respect to the following** insofar as known to the person making the report or insofar as reasonably ascertainable:

- (A) The common or trade name, the chemical identity, and the molecular structure of each chemical substance or mixture for which such a report is required.
- (B) The **categories or proposed categories of use** of each such substance or mixture.
- (C) The **total amount of each such substance and mixture** manufactured or processed, **reasonable estimates** of the total amount to be manufactured or processed, the amount (...), and reasonable estimates of the amount (...) for each of its categories of use or proposed categories of use.
- (D) A **description of the byproducts** resulting from the manufacture, processing, use, or disposal of each such substance or mixture.
- (E) **All existing data concerning the environmental and health effects** of such substance or mixture.
- (F) The **number of individuals exposed, and reasonable estimates** of the number who will be exposed, to such substance or mixture in their places of employment and the duration of such exposure.
- (G) In the **initial report** under paragraph (1) on such substance or mixture, **the manner or method of its disposal**, and in **any subsequent report** on such substance or mixture, any change in such manner or method.

Additionally, subsection 8(a)(3)(A)(ii) provides for EPA to adopt special rules applicable to small manufacturers and processors. Such rules would require recordkeeping and reporting in instances where relief has been granted by EPA for actions brought under the provisions of sections 5 (manufacturing and processing notices) or 7 (imminent hazards).

Section 8 (a) (3)(A)(ii): Rulemaking, Recordkeeping, and Reporting	No barrier
The Administrator may by rule require a small manufacturer or processor of a chemical substance or mixture – (...) to maintain such records on such substance or mixture, and to submit to the Administrator such reports (...). A rule under this clause requiring reporting may require reporting with respect to the matters referred to in paragraph (2).	

Section 8 (c) authorizes EPA to issue rules to require recordkeeping for significant adverse health reactions alleged to have been caused by hazardous substances or mixtures. Records of adverse reactions to health of employees must be retained for 30 years following the date of the first reporting or discovery by the reporting party, and records of any other adverse reaction must be retained for five years. Upon request by a designated representative, each person required to maintain such records must permit EPA to inspect and copy such records. This section has an ambiguous effect on electronic reporting and recordkeeping of significant health reactions due to the challenges of electronically retrieving records that may have been created prior to implementation of electronic recordkeeping as well as the

Any person who manufactures, processes, or distributes in commerce any chemical substance or mixture **shall maintain records of significant adverse reactions to health or the environment, as determined by the Administrator by rule**, alleged to have been caused by the substance or mixture. **Records** of such adverse reactions to the health of employees **shall be retained for a period of 30 years** from the date such reactions were first reported to or known by the person maintaining such records. **Any other record** of such adverse reactions **shall be retained for a period of five years** from the date the information contained in the record was first reported to or known by the person maintaining the record. Records required to be maintained under this subsection shall include **records of consumer allegations** of personal injury or harm to health, **reports of occupational disease or injury, and reports or complaints of injury** to the environment submitted to the manufacturer, processor, or distributor in commerce from any source. Upon request of any duly designated representative of the Administrator, each person who is required to maintain records under this subsection **shall permit the inspection of such records and shall submit copies of such records.**

Section 8(d) also authorizes EPA to issue rules requiring the reporting of lists of health and safety studies on hazardous substances or mixtures and to obtain copies of such studies. This provision has an ambiguous effect on submission of such material by electronic means, however, because there may be a problem obtaining electronic copies of such lists or studies if they might have been published in paper form only and are not readily available in electronic format to the person or party who needs to submit them to EPA.

Section 8 (d): Health and Safety Studies - Rulemaking	Ambiguous
<p>The Administrator shall promulgate rules under which the Administrator shall require any person who manufactures, processes, or distributes in commerce or who proposes to manufacture, process, or distribute in commerce any chemical substance or mixture (or with respect to paragraph (2), any person who has possession of a study) to submit to the Administrator - (1) lists of health and safety studies (A) conducted or initiated by or for such person with respect to such substance or mixture at any time, (B) known to such person, or (C) reasonably ascertainable by such person (...)</p>	

Section 8(e) requires immediate notification of EPA by any party who obtains information showing the likelihood of substantial risk of injury to health or the environment from a chemical substance. There is no barrier to allowing electronic reporting of such information, and electronic reporting may make it easier to provide such immediate notice to EPA.

Section 8 (e): Notice to Administrator of substantial risks - Reporting	No barrier
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Section 10(b) mandates that EPA design and establish an “efficient and effective system” for data collection and dissemination, and for the use of data submitted under TSCA. EPA’s adoption of rules authorizing electronic submissions of reports, test data, and notices wherever possible would be consistent with establishing a more “efficient and effective system” for data retrieval and use. Consequently, this section may give EPA further authority to adopt electronic methods for many of the reporting, notice, and record keeping requirements under TSCA.

Section 10 (b): Establishing Data Systems – Reporting	No barrier
<p>(1) The Administrator shall establish, administer, and be responsible for the continuing activities of an interagency committee which shall design, establish, and coordinate an efficient and effective system, within the Environmental Protection Agency, for the collection, dissemination to other Federal departments and agencies, and use of data submitted to the Administrator under this chapter.</p> <p>(2) (A) The Administrator shall, (...) establish, and coordinate an efficient and effective system for the retrieval of toxicological and other scientific data which could be useful to the Administrator in carrying out the purposes of this chapter. Systematized retrieval shall be developed for use by all Federal and other departments and agencies with responsibilities in the area of regulation or study of chemical substances and mixtures and their effect on health or the environment.</p>	

F. *TSCA §11: Inspections and Subpoenas (15 USC 2610)*

Under section 11(b), EPA is authorized to carry out inspections and subpoenas to administer TSCA. This section is ambiguous about how the inspection or subpoenas of witnesses would apply to any electronic records or data because it seems to envision paper files and records, but it covers “all things within the premises” so it should include electronic records. Although inspection of electronic records is not explicitly authorized, the only explicit limitations relate to other types of financial, sales, pricing, personnel or research information. As a result, EPA could probably rely on this authority to inspect and subpoena electronic records as well.

Section 11(b): Inspections and subpoenas – Recordkeeping	Ambiguous
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Scope

(1) Except as provided in paragraph (2), **an inspection (...) shall extend to all things within the premises** or conveyance inspected (**including records, files, papers, processes, controls, and facilities**) bearing on whether the requirements of this chapter applicable to the chemical substances, mixtures, or products subject to subchapter IV of this chapter within such premises or conveyance have been complied with.

(2) No inspection under subsection (a) of this section shall extend to -

- (A) financial data,
- (B) sales data (other than shipment data),
- (C) pricing data,
- (D) personnel data, or
- (E) research data (other than data required by this chapter or under a rule promulgated thereunder),

unless the nature and extent of such data are described with reasonable specificity in the written notice required by subsection (a) of this section for such inspection.

G. TSCA §12: Notice of Exports (15 USC 2611)

Section 12(b) stipulates that exporters or potential exporters of hazardous chemicals or mixtures, whether subject to the requirements of sections 4 or 5(b) or to an order issued under section 5, must notify EPA of their export or intention to export the substance or mixture. The statute's requirements pose no barrier to providing electronic notification of such actions. In fact, electronic reporting could facilitate both the reporting of data by exporters, as well as the consultation and access to such data electronically, once the EPA has notified the government of the foreign country where the export or intended export is destined.

Section 12 (b): Export Notices -- Reporting	No barrier
<p>(1) If any person exports or intends to export to a foreign country a chemical substance or mixture (...), such person shall notify the Administrator of such exportation or intent to export and the Administrator shall furnish to the government of such country notice of the availability of the data submitted to the Administrator under such section for such substance or mixture.</p>	

F.TSCA §14: Confidential Data (15 USC 2613)

Section 14 concerns situations when it is permissible to disclose information reported to EPA under TSCA, as well as the process for designating data to be treated as confidential and not disclosed. Subsection 14(c) specifically provides that a party subject to TSCA's reporting or data submission requirements who designates data to be treated as confidential should (1) submit such data separately from the other data and (2) designate the different categories of data, "in writing" and "in such manner as the Administrator may prescribe." Given the explicit language of the statute requiring that such designations be sent "in writing" and "by certified mail," EPA probably cannot offer electronic methods for manufacturers or processors to submit a designation of confidential data or information. Additionally, this section requires the Administrator to give notice "in writing" and "by certified mail" to the affected parties of the intended release of data. Thus, EPA could not provide electronic notification of such actions without having this statutory requirement modified. The provision of section 14(c)(1) for designations "in any manner as the Administrator may prescribe" would, however, possibly authorize EPA to amend its rules to interpret "in writing" as including electronic designations of confidential data and electronic notices of EPA's intent to release data.

Section 14 (c): Designation and release of confidential data	Potential barrier
<p>(1) In submitting data under this chapter, a manufacturer, processor, or distributor in commerce may (A) designate the data which such person believes is entitled to confidential treatment under subsection (a) of this section, and (B) submit such designated data separately from other data submitted under this chapter. A designation under this paragraph shall be made in writing and in such manner as the Administrator may prescribe.</p> <p>(2)(A) Except as provided by subparagraph (B), if the Administrator proposes to release for inspection data which has been designated under paragraph (1)(A), the Administrator shall notify, in writing and by certified mail, the manufacturer, processor, or distributor in commerce who submitted such data of the intent to release such data. (...)</p> <p>(B)(...) except that the Administrator may not release data [once he has determined doing so is necessary to protect health or the environment against unreasonable risk of injury] unless the Administrator has notified each manufacturer, processor, and distributor in commerce who submitted such data of such release. Such notice shall be made in writing by certified mail at least 15 days before the release of such data (...).</p>	

H. TSCA §15: Prohibited Acts (15 USC 2614)

Section 15 spells out the actions prohibited by TSCA and stipulates that it is a violation to fail or refuse to submit reports or maintain records as required by the Act. This provision is ambiguous because it is not clear how EPA would permit access, copying, or inspection of records when the records in question exist solely in electronic form. A manufacturer or processor might want to protect proprietary data from being accessed, copied or inspected, and the statute could be implemented by electronic means of recordkeeping and reporting. But EPA would need to satisfy the requirements for protecting confidential data through explicit rules regarding access to electronically archived data and records and requiring use of electronic technologies that will ensure the protection of confidential data.

Section 15: Prohibited acts - Recordkeeping and Reporting	Ambiguous
It shall be unlawful for any person to (...) (3) fail or refuse to (A) establish or maintain records , (B) submit reports, notices, or other information , or (C) permit access to or copying of records , as required by this chapter or a rule thereunder; or (4) fail or refuse to permit entry or inspection as required by section 2610 of this title.	