Appendix D

# Technical Notes: EPA

## *Technical Note #D.1: Information Sources Under TSCA*

### Section 4: Testing Rules[1]

Section 4 of TSCA may be of great importance in developing information about a range of reproductive health hazards. It directs EPA to promulgate testing rules to develop data with respect to health effects of existing or new chemicals if a chemical may present an unreasonable risk of injury to health or the environment, is produced in substantial quantities and may reasonably be anticipated to enter the environment in substantial quantities, or may cause significant or substantial human exposure.

In such a testing rule, EPA can prescribe standards for the development of data by chemical manufacturers on mutagenicity, teratogenicity, behavioral disorders, and any other effects.[2]

To date, the only testing rule that has been finalized is for **1,** 1,-trichloroethane, which includes protocols for the development of data on fetal defects and abnormal development. Several other rules have been proposed.'

Critics of $4 claim that administrative delays and the inability of testing protocols to be designed through regulatory rulemakings have made 54 unworkable.[4] This criticism appears valid since scientific consensus on the types of studies needed and their specific design are difficult to reach through formal rulemakings. In response to these problems, EPA began to negotiate voluntary testing agreements for several chemicals for which the agency has made informal findings of an unreasonable risk. Under these negotiated testing protocols (which rely to a certain extent on testing screens), laboratory and subclinical testing of reproductive health hazards can be emphasized just as in $4 testing rules. In July 1984, however, a Federal trial court ruled that such voluntary testing agreements were illegal.[5]

One related issue is whether data reported to EPA under these testing agreements can be obtained by the public. Health data generated under testing rules are not subject to confidentiality claims by the manufacturer of an existing or new chemical under TSCA.[6] Therefore, information on reproductive health hazards can be obtained by the public.

Testing data reported under S 4 can also be used to provide a basis for regulatory action under other parts of TSCA to ban or control the production, use, or method of disposal of chemicals. Section 4(f) of the Act may be particularly important because it provides the basis for expedited agency regulatory review of substances suspected on the basis of testing or other data accumulated by the agency to pose a significant risk.

Under $ 4(f), if EPA receives test data or any other information "which indicates to the Administrator that there may be 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 mutations or birth defects,*** the Administrator shall 'initiate appropriate action under $$ 5, 6, or 7 to prevent or reduce to a sufficient extent such risk or publish in the Federal Register a finding that such risk is not unreasonable' "7 (emphasis added). Section 9 of the Act requires EPA to report findings under $ 4(f) to OSHA for appropriate action, but does not limit EPA's ability to act itself.[8] (See discussion of $9 below.) Should EPA publish findings under $ 4(f) that the risks of a substance are not unreasonable, those findings can be challenged in court.9

Section 4(e) of TSCA also directs EPA to establish an Interagency Testing Committee (ITC), to include members appointed by the Secretary of Labor and the Director of the National Institute of Occupational Safety and Health. The purpose of the ITC is to establish a list of chemical substances requiring testing rules under s 4(a). The Committee is directed to give priority to those substances "which are known to cause or contribute to or which are suspected of causing cancer, gene mutations, or birth defects. "]" EPA must publish a testing rule within **12** months of the listing of a substance bv the ITC. 11

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[1] 15 U s (: § 2603 (1982)

[2] Before prescribing epidemiological studies of workers in these testing rules, however, the Administrator must consult \\ ith the Director of NIOSH 15 US C. § 2603( (b)(2)(A)(1982)

[3] 49 Fed Reg. 39,810 (1984)

[4] See [' S EPA (() "1'S), Priorities and Progress, 28-29 (July 1 983) GAO has also endorsed negotiated test ing agreements as reasonable GAO EPA In) plementation of Selected Aspects of the Toxic Substances Control Art, Dec 7 1982 (GAO/RCED-8 -621.

[5] NRDC and Industrial Union Department v. Ruckleshaus, No 83-8844 (S 1) N Y. Aug. 23, 1984) (Court order voids 16 testing agreements)

[6] 15 U ' s [: § 2613(b) ( 1 982)

[7] 15 U S C. § 2603(f) ( 1982)

[8] 15 U 's (: § 2608(a) (1 982)

[9] 15 U S (' § 2618 (1982) These rules were used for III stance, to challenge EPA's decision in early 1982 not to l st formaldehyde under § 4(f ) NRDC \ Ruckleshaus, No 83-2034 (D (' Cir tiled July 18, t 9831 The agency subsequently published an advanced notice of proposed rulemaking for formaldehyde, 48 Fed Reg 52,507 ( 1983)

[10] 15 U S C § 2603(e) ( 1982)

[11] 15 U S (' § 2603(e)( 1)(A)(v iii) (1982)

## Section 5: New Chemicals[12]

Section 5(a)(1) prohibits the manufacture of a new chemical without notification to EPA.[13] This provides another means for screening chemical substances for reproductive toxicity before the chemicals are manufactured commercially, since premanufacture notification (PMN) must be accompanied by a minimum set of health and environmental exposure and production data at least 90 days before the manufacture or processing of the substance begins. Unfortunately, according to studies prepared by OTA[14] and the General Accounting Office,[15] fewer than 50 percent of all PMNs that EPA receives include toxicity data and only about 20 percent of these contain information about a chemical's mutagenicity. Most critics assert that this is because EPA's PMN regulations allow manufacturers to avoid the submission of these kinds of data.[16]

EPA's review of PMNs involves an assessment of risks for each chemical based on a substance's toxicity and the nature and extent of human exposure, including occupational and environmental exposure. Health and exposure data in PMNs, subject to certain types of confidentiality claims, are available for public examination by interested persons.[17]

There are several ways in which EPA can regulate the production of a substance for which there may be human health hazards, but when there are insufficient data available to ban the chemical's production under the Act's regulatory mechanisms. Under § 5(a)(2), EPA may determine that certain future uses or exposures of a chemical or class of substances will constitute a "significant new use" for which the manufacturer must file a PMN under § 5(a)(1).[18] Such a determination can be made by publishing a significant new use rule (SNUR), so that if production volume, route of exposure, or use of the substance changes, a PMN including new exposure and production data must be submitted before the new use is authorized. Under § 5(e),[19] EPA may also issue a proposed order that limits production, distribution, and use of certain substances if the agency determines that insufficient information has been generated to evaluate the risk to human health or the environment. EPA can also promulgate a testing rule under §4, discussed above, in order to develop health and exposure data about a chemical or a particular use.

Section 5(f)[20] is also important with respect to potential reproductive health hazards. It provides that the Administrator can take immediate action to protect the public's health and welfare on the basis of information received through a PMN that the manufacture, processing, distribution in commerce, use, or disposal of a chemical substance presents or will present an unreasonable risk of injury to human health. The Administrator may propose an administrative order to limit the amount of the substance that can be manufactured, processed, or distributed in commerce, or he may petition a U.S. District Court to prohibit the manufacture, processing, or distribution in commerce until a regulatory action can be completed under § 6 of the Act.

## Section 8: Reporting and Recordkeeping Requirements[21]

This section enables EPA to acquire valuable information concerning significant adverse health reactions and other important exposure and health effects information about new and existing chemicals. Because health effects information cannot be claimed as confidential by manufacturers under TSCA's provisions,[22] §8 can also provide valuable information to workers who suspect they have been exposed to hazardous substances, including information about other workers exposed to similar substances or mixtures in their employment. While small businesses are generally exempt from § 8's reporting requirements,[23] they may also be required by EPA to maintain and submit reports concerning chemicals for which testing or regulatory actions are pending.[24] The following sections detail these provisions.

**Recordkeeping.**[25]—Section 8(a) authorizes EPA to require manufacturers of existing chemicals (i.e., those not subject to PMN requirements) to maintain records or submit reports on information that is "known to or reasonably ascertainable" to the extent this information is necessary to administer TSCA. Section 8(a) must be implemented by rulemaking for specific chemicals or classes of substances. Through the use of this provision, EPA can accumulate information about substances that are suspected of having reproductive effects associated with their manufacture, processing, use, disposal, or byproducts. The section also speci-

[12]15 U.S.C. § 2604.

[13]15 U.S.C. § 2604(a)(1).

[14]U.S. Congress, Office of Technology Assessment, The Information Content of Premanufacture Notices, 49-53 (OTA-BP-H-17, 1983).

[15]See, e.g., GAO, EPA Implementation of Selected Aspects of the Toxic Substances Control Act, Dec. 7, 1982 (GAO/RCED-83-62).

[16]For instance, see exemptions allowed under 15 U.S.C. § 2604(h) (1982). See also 47 Fed. Reg. 33,896 (1982) (site-limited and low volume chemicals intermediates); 47 Fed. Reg. 33, 896 (1982) (site-limited and low volume chemicals intermediates); 47 Fed. Reg. 33,924 (1982).

[17]See 15 U.S.C. §§ 2604(H), 2613(b).

[18]15 U.S.C. § 2604(a)(1).

[19]15 U.S.C. § 2604(e).

[20]15 U.S.C. § 2604(f).

[21]15 U.S.C. § 2607.

[22]15 U.S.C. § 2613(b).

[23]15 U.S.C. § 2607(a)(3)(A). See 40 C.F.R. § 710.2(X) (defining small manufacturer).

[24]49 Fed. Reg. 45,425 (codified at 40 C.F.R. pt. 704 (1984)).

[25]15 U.S.C. § 2607(a).

fies that the Administrator may require estimates of the number of people exposed to a substance in the workplace .[26]

EPA published final general information reporting rules and a final information assessment rule in June 1982.[27] The rules cover 250 chemicals, as opposed to the 2,226 substances listed in the earlier 1980 rules implementing this section for obtaining general information on these chemicals .28 Additional chemicals have been designated for reporting under 8(a).[28] In June 1983, EPA published a methodology for releasing data not subject to confidentiality protections it has received pursuant to 5 8(a).[30]

In addition to promulgating general reporting rules, EPA has used its authority under 5 8(a) to require reporting on specific chemicals. In 1980 it issued a rule requiring reporting of the manufacture or proposed manufacture or import of Tris (2, 3-dibromopropyl), phosphate, and polybrominated biphenyls (PBBs).[3'' Final asbestos reporting rules were issued in July 1982.32 The agency proposed reporting requirements for chlorinated terphenyls in April 1983.[33]

Inventory.–TSCA ~ 8(b) requires EPA to compile and maintain an inventory of chemicals in production and distributed in commerce. This inventory is to be regularly updated and can provide some structural activity information about chemicals that are suspected reproductive health hazards. Final reporting regulations for the submission of data for the compilation of the $ 8(b) inventory were issued in December 1977.[34]

Substances not listed in the inventory are subject to premanufacturing notice requirements under 5. Amended twice, the most recent supplement of the inventory was published in May 1982. Section 8(b) also requires persons who manufacture chemicals or mixtures solely for scientific experimentation to maintain and submit records on these chemicals' production volume and worker exposure to EPA.[35]

Significant Adverse Reactions.—Section 8(c) requires chemical manufacturers and processors to 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." Significant adverse reactions are reactions that may indicate a tendency of a chemical or mixture to cause long-lasting ***or irreversible damage*** to health or the environment .[36] This may not therefore include temporary illnesses such as nausea or headaches, but would probably include sterility, albeit temporary, although this is not clearly indicated in the regulation .[37] Section 8(c) requires companies to keep all employee allegations deemed by the company to be significant adverse reactions for 30 years and all other allegations for 5 years. These records, if obtainable from companies, may provide valuable information to substantiate effects for certain occupational uses of chemicals. EPA published final rules implementing $ 8(c) in August 1983.[38]

There are several important limiting factors on the use of this rule. "Already known human effects" discussed in medical and scientific literature do not have to be reported .39 All manufacturers and many processors are subject to the regulation, but distributors and retailers who do not manufacture or process chemicals are not. The rule contains no automatic reporting requirements once a notice is submitted, but EPA has stated that it may require reporting at a later time. (The proposed rule had required automatic reporting of allegations if three similar allegations were recorded within 1 year for a particular substance )[40] Thus, obtaining such reports may be limited, except when they are clearly identifiable and can be obtained by discovery in tort litigation.

Health and Safety Studies Reporting.—Section 8(d) of TSCA may also be a significant source of information about chemicals that are suspected of causing reproductive effects in occupational settings. It directs the Administrator to promulgate rules requiring chemical manufacturers and processors to submit to EPA copies of safety and health studies conducted by companies."

The term "health and safety" study is defined by TSCA as:

> . any study (including laboratory studies) of any effect of any chemical substance or mixture on health or the environment or on both, including underlying data and epidemiological studies, studies of occupational exposure to a chemical substance or mixture, and any test performed pursuant to this act .[42]

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[26] 15 U S C § 2607(a)(2)(F)

[27] 47 Fed Reg 26,992 ( 1 982)

[28] 45 Fed Reg 13,646 ( 1980) (used to obtain general exposure data on 2, 226 chemicals)

[29] 48 Fed Reg 22,697 (1 983)

[30] 48 Fed Reg 27,041 ( 1 983)

[31] 45 Fed Reg 70,728 ( 1 980)

[32] 46 Fed Reg 70,728 ( 1 982) (recodified at 48 Fed Reg 23,420 (1 983))

[33] 47 Fed Reg 33,298 ( 1 982)

[34] 48 Fed Reg 19,419 ( 1 983)

[35] 42 Fed Reg 64 ,572 (1 977) See Bronstein and Nunverberg, Section 8(b) of the Toxic Substances Act A Case Study of Government Regulation of the Chemical industry 13 Nat. Resources L J 706 (1981)

[36] 15 U.S (' § 2607c

[37] Environmental Law Institute, EPA Authority and Activities Relating to Occupational Reproductive Hazards (1 984) (unpublished report)

[38] 48 Fed Reg 38 178 (1 983)

[39] Id

[40] 45 Fed Reg 47,0()8 (1980)

[41] The term "processor" may cover "end-user" hilt this is not clear under the statute, and may be thrown into doubt because in other parts of the statute the word users" is employed However, as discussed later, EPA's regulations would cover anyone in possession of such studies

[42] Proposed rule at 45 Fed Reg 47 ,008 ( 1 980)

Section 8(d) includes two sets of requirements. First, under subpart 8(d)(1), manufacturers and processors must submit lists of health and safety studies conducted by them, known to them, or reasonably ascertainable to them. Second, subpart 8(d)(2) requires those in possession of a study to submit copies of any study contained on the list or otherwise known to the person. EPA first promulgated regulations implementing §8(d) in 1978 that required reporting of studies on chemicals listed in the first Interagency Testing Committee report.[43] The rule was challenged in the Third Circuit Court of Appeals, and though the rule was subsequently revoked by the agency,[44] the court upheld EPA's broad assertion of authority under the section to obtain health and safety data on chemical substances, even during the research and development of a product and even though a company did not manufacture, process, or distribute a particular substance.[45] This broad conferral of power on EPA to collect information about a chemical even though it was not yet commercialized by a particular company may yield important health reasons why a company chooses not to pursue production, although another company may decide otherwise.

In September 1982, EPA reissued a rule implementing § 8(d).[46] The health and safety data reporting rule has two basic requirements. It requires the submission of unpublished health and safety studies on specifically listed chemicals by manufacturers, processors, and others in possession of them. This exempts distributors from reporting studies on designated substances, and it also relieves manufacturers and processors from submitting information contained in research and development and in underlying data such as medical records and exposure monitoring data on chemicals not on the TSCA chemical inventory. The 1982 rule required unpublished health and safety data to be submitted to EPA for asbestos and 39 chemicals recommended for additional testing by the ITC. In a related action, EPA also proposed a rule requiring data submissions on 14 chemicals recommended for testing by the ITC since June 1981.[47]

Commercial manufacturers and processors of a listed chemical (and those who are proposing to do so) are required to submit copies of both studies in their possession at the time the chemical is listed and lists of studies known to the submitter but not in his possession. (This does not require these parties, however, to update the studies.) Persons no longer manufacturing or processing a chemical when it is listed, but who manufactured or processed it or proposed to do so at any time during the time it was listed, must only submit copies of studies in their possession.

**Substantial Risk Notices.**—Under § 8(e) of TSCA, a company is required to notify EPA within 15 days of obtaining information that reasonably supports the conclusion that the substance or mixture presents a "substantial risk of injury to health or the environment. . . ." Very often these substantial risk notices concern occupational exposures and hence may be a very important source of data concerning chemicals associated with reproductive effects. Guidance on the submission of substantial risk notices was published by the Agency in September 1977.[48] In March 1978, EPA issued a policy statement interpreting the section.[49]

These notices are evaluated by EPA's Office of Pesticide Programs and Office of Toxic Substances. Referrals to other agencies, or decisions to list the chemical under a § 8 reporting rule to gather additional toxicity or exposure data or to undertake a formal risk assessment on the substance, follow. Section 8(e) submissions and initial evaluations are available for public inspection and copying. The agency thus far has published three volumes of initial evaluations covering approximately 500 notices received through December 31, 1982. A number of these contain preliminary information on reproductive health hazards. This information could be valuable in a product liability case brought by a worker exposed to a reported substance.

## Section 10: Data Collection[50]

Section 10 requires the Administrator to conduct such research, development, and monitoring as is necessary to carry out the purposes of TSCA. Pursuant to this section, EPA has designed laboratory protocols and carried out some limited basic research on reproductive health hazards associated with chemicals. It also authorizes EPA to establish the Interagency Toxic Substances Data Committee (ITSDC), which is responsible for the development and coordination of a Federal chemical information system.[51] The goal of the ITSDC is systemized retrieval of toxicological and other scientific data that can be used for research, risk analysis, and decisionmaking under § 25(b). The Council on Environmental Quality (CEQ) and the Office of Toxic Integration are responsible for the day-to-day management of the Chemical Substances Information Network (CSIN).

[43] 43 Fed. Reg. 30,984 (1978).
[44] 44 Fed. Reg. 77,470 (1979).
[45] Dow Chemical Co. v. EPA, 605 F.2d 673 (3rd Cir. 1979).
[46] 47 Fed. Reg. 38,780 (1982).
[47] 47 Fed. Reg. 38,800 (1982).
[48] 42 Fed Reg 45,362 (1977).
[49] 43 Fed Reg 11,010 (1978).
[50] U.S.C. §§ 2609 2624 (1982).
[51] This committee, assumed some of the data (('(ilk'('tllll capabilities (1 1 the now defunct ILRG

## *Technical Note 4'D.2: Cancellation of Pesticides Under FIFRA*

### Section 6(a): Automatic Cancellation[52]

FIFRA directs EPA to automatically cancel a pesticide registration 5 years after the registration date unless the registrant requests the continuance of the registration and EPA determines that the continued use of the product "will not have unreasonable effects on the environment. " In order for EPA to make this determination, the registrant must submit data on the use, exposure, and health effects of the active ingredients in the pesticide, pursuant to 40 C.F.R. Part 158, and specific data requests by EPA (referred to as "calling"). The re-registration process, according to EPA officials, should eventually provide more health data on which to determine the health and environmental effects of pesticides that hate been registered under FIFRA in prior decades. Under re-registration procedures initiated in **1984,** EPA is specifically requesting teratolo~v and multigenerational studies to determine reproductik'e effects.

### Section 6(b): Cancellation Based on Findings of Unreasonable Adverse Effects[53]

EPA may initiate procedures to cancel a pesticide's registration or change its classification from general to restricted use if it appears that the pesticide, its labeling, or other material required to be submitted does not comply with the statute, or when used in accordance \\'ith widespread and commonly recognized practice, generally causes unreasonable adverse effects on the eni'ironment .[54] J'arious economic aspects are to be balanced by the Administrator against findings of adlrerse risk.[55] A decision to cancel must be made if reclassification of the pesticide to restricted use(s) will not adequately protect against those risks. The notice of the cancellation or reclassification must be mailed to the registrant and published in the ***Federal Register*** along with the regulatory impact analysis of the decision through the RPAR process. While this notice is generally geared to inform those who depend on the use of the particular pesticide of the Administrator's intent, it may also serve to alert the public to hazards associated with the substance. Unless the pesticide is designated as an imminent hazard (discussed below), the cancellation procedures may take several years to complete.

### Section 6(d): Suspension[56]

FIFRA defines the term "imminent hazard" as "a situation that exists when the continued use of a pesticide during the time required for cancellation proceeding(s) would be likely to result in unreasonable adverse effects on the environment or will involve an unrea - sonable hazard, to the survival of a species declared endangered or threatened by the Secretary pursuant to the Endangered Species Act of 1973. "5[7] Such unreasonable adverse effects; on the environrnent, as discussed above, include hazards to human health,

On finding that action is necessary to prevent an imminent hazard during the time required for cancellation or change in classification proceedings, EPA may issue an order to suspend the registration of a pesticide immediately. (This recently happened when EPA suspended the registration of EDB due to groundwater contamination. ) Concurrently, EPA must issue a notice of its intention to change the classification of a pesticide or cancel a registration. This notice must inform the registrant of the order and contain the Administrator's findings pertinent to the issue of imminent hazard.

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[52] 7 U.S.C. § 136d(a) (1982).
[53] 7 U.S.C. § 136d(b) (1982)
[54] Id.
[55] Id.
[56] 7 U.S.C. § 136d(c) (1982).
[57] 7 U.S.C. § 136d(b) (1982).