



The Layman's Guide to the Toxic Substances Control Act

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Office of
Toxic Substances
Washington DC 20460

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Introduction



Chemicals — those found in nature and those created in laboratories — are at the heart of our highly industrialized, technology-based society. They help to protect our health and to control pests. Chemicals help clothe, shelter, and feed us. They are found in innumerable products for our homes, businesses, and industry.

The chemical industry plays a vital role in the economy of the United States. The production of chemicals and allied products accounted for roughly 5 percent of the Gross National Product, and the industry employs about 1.1 million people. More than 60,000 chemical substances are presently manufactured or processed for commercial use in the United States, and almost one thousand more are introduced each year.

Although most chemicals present little or no danger to the environment or human health when used properly, in the past few decades some chemicals commonly used and widely dispersed have been found to be significantly harmful. An example is the family of chemicals called polychlorinated biphenyls, or PCBs. It was not until after tens of millions of pounds of PCBs were produced and released into the environment, however, that scientists realized how persistent and potentially toxic they were. Over the past few years, we have found PCBs in our bodies and even in the milk of nursing mothers.

In 1971, the President's Council on Environmental Quality developed a legislative proposal for coping with the increasing problems of toxic substances. After five years of public hearings and debate, Congress enacted the Toxic Substances Control Act (TSCA) in the fall of 1976.

By enacting TSCA, Congress established a number of new requirements and authorities for identifying and controlling toxic chemical hazards to human health and the environment. Programs now exist under TSCA to gather information about the toxicity of particular chemicals and the extent to which people and the environment are exposed to them, to assess whether they cause unreasonable risks to humans and the environment, and to institute appropriate control actions after weighing their potential risks against their benefits to the Nation's economic and social well-being.

The following sections briefly describe the major provisions of TSCA. The discussion is intended to familiarize the public with the provisions of the law, not to constitute an authoritative legal statement of it.

Scope of the Law

To ensure wise and informed decision-making by the government, TSCA gives the Environmental Protection Agency (EPA) authority to gather certain kinds of basic information on chemical risks from those who manufacture and process chemicals. The law also enables EPA to require companies to test selected existing chemicals for toxic effects, and requires the Agency to review most new chemicals before they are manufactured. To prevent unreasonable risks, EPA may select from a broad range of control actions under TSCA, from requiring hazard-warning labels to outright bans on the manufacture or use of especially hazardous chemicals. EPA may regulate a chemical's unreasonable risks at any stage in its life-cycle: the manufacturing, processing, distribution in commerce, use, or disposal.

Eight product categories are exempt from TSCA's regulatory authorities: pesticides, tobacco, nuclear material, firearms and ammunition, food, food additives, drugs, and cosmetics. Many of these product categories are regulated under other Federal laws.

Testing of Chemicals

TSCA gives EPA authority to require manufacturers or processors of certain existing chemicals (i.e., those already being distributed in commerce) to test their health and environmental effect. EPA exercises this authority only when it can make certain statutory findings about the

substance involved and when industry fails to develop the needed data on its own. These required findings are: (1) that there are insufficient data already available with which to perform a reasonable risk assessment; (2) that testing is necessary to provide such data; (3) that a chemical may present an unreasonable risk of injury to human health or the environment; or (4) that the chemical is produced in substantial quantities resulting in significant human exposure or environmental release.

Testing requirements are imposed only after a rulemaking proceeding which includes opportunities for both public comments and an oral presentation at a hearing.

An Interagency Testing Committee of government experts on chemical substances advises EPA on those that should be tested; however, actions are not limited to those recommended by the Committee. The eight Committee members represent the Departments of Labor, Commerce, Health and Human Services (including the National Cancer Institute, the National Institute for Occupational Safety and Health, and the National Institute of Environmental Health Sciences), the National Science Foundation, the Council on Environmental Quality, and EPA. The Committee designates priority chemicals for testing. Then, EPA either initiates rulemaking for testing requirements for designated chemicals or publishes the reasons why testing is not required.

Premanufacture and Significant New Use Notifications

The authors of TSCA recognized that health and environmental considerations are more easily addressed before, rather than after, a chemical is produced and introduced into commerce.

Thus, manufacturers or importers of new chemicals must give EPA a 90-day advance notification of their intent to manufacture or import a new chemical, except for those chemical categories specifically excluded by TSCA. Any chemical which is not listed on the inventory of existing chemicals

(discussed in "Recordkeeping and Reporting" section), published by the Agency, is considered "new" for purposes of this premanufacture notice requirement.

In addition, EPA may designate a use of a chemical as a significant new use, based on consideration of several factors, including the anticipated extent and type of exposure to human beings or the environment. Anyone who intends to manufac-

The image shows a detailed view of the EPA Premanufacture Notice Form for New Chemical Substances. The form is titled "EPA PREMANUFACTURE NOTICE FOR NEW CHEMICAL SUBSTANCES" and is issued by the U.S. Environmental Protection Agency, Office of Toxic Substances, 401 M Street, S.W., Washington, D.C. 20460. It includes a section for "AGENCY USE ONLY" with fields for "Date of receipt" and "EPA Case Number". The form is divided into several parts: "GENERAL INFORMATION", "HUMAN EXPOSURE AND ENVIRONMENTAL RELEASE", "LIST OF ATTACHMENTS", and "OPTIONAL INFORMATION". It also contains "GENERAL INSTRUCTIONS" and "TEST DATA AND OTHER DATA" sections. The form is numbered "O 15 B No. 2010-2011, Approval Expires 3-2-06".

ture, import, or process a chemical for such a significant new use (even if the chemical is on the inventory and/or went through premanufacture notification review) must notify EPA 90 days before manufacturing, importing or processing the chemical for that use.

The 90-day review period for new chemicals and significant new uses can be extended by EPA for an additional 90 days for a good cause. Notices submitted for new chemicals, or significant new uses of chemicals, are to include: the identity of the chemical, its molecular structure, proposed categories of use, an estimate of the amount to be manufactured, imported or processed, the byproducts resulting from the manufacture, processing, use, and disposal of the chemical, estimates of exposure and any test data related to the health and environmental effects of the chemical. In addition, if a rule requiring testing of the chemical or its chemical class has been issued, the notice must include test data developed from that testing along with the other information.

Chemicals produced in small quantities solely for experimental or research and development purposes are automatically exempt from the premanufacture and significant new use notification requirements. In addition, any person may apply for an exemption for chemicals used solely for test marketing purposes or those determined by EPA not to present an unreasonable risk of injury to human health or the environment.

If EPA determines that insufficient information is in a notification to evaluate potential

risk, the Agency may order that the manufacture or importation of the chemical be prohibited until adequate data are developed. The company is under no time limit to submit the information, but until it does, EPA's ban remains in effect. After reviewing a premanufacture notification, containing sufficient data, if EPA determines that the new chemical presents or will present an unreasonable risk of injury to health or the environment, the Agency can during the review period prohibit the manufacturing, processing, or distribution in commerce of that chemical.

Control of Hazardous Chemicals

Under TSCA, EPA has the authority to prohibit or limit the manufacture, import, processing, distribution in commerce, use, or disposal* of a chemical when these activities are found to pose an unreasonable risk of injury to human health or the environment. A number of possible control options are available, ranging from total prohibition to labeling

**Distinction Between Disposal Authority of TSCA & RCRA.* TSCA has the authority to regulate the disposal stage of a chemical's life cycle on a chemical-by-chemical basis, that is, once a particular chemical is determined to be an unreasonable risk to human health and the environment (e.g., PCBs). The Resource Conservation and Recovery Act (RCRA) has the authority to establish regulations and programs to ensure safe waste treatment and disposal of any number of chemicals, and generally deals with waste streams rather than individual chemicals.

A manufacturer or processor may be required to make and keep records of the processes used in manufacturing a chemical and to conduct tests to assure compliance with any regulatory requirements. Further, the Agency may require a manufacturer or processor to give notice of any unreasonable risk of injury presented by his chemical to those who purchase or may be exposed to that substance. A manufacturer or processor may also be required to recall a substance which presents an unreasonable risk.

In proposing regulatory actions, EPA must provide an opportunity for comments by all interested parties.

A rule limiting, but not banning, a chemical may be made immediately effective when initially proposed in the *Federal Register* if the Agency determines that the chemical is likely to present an unreasonable risk of serious or widespread injury to health or the environment before normal rulemaking procedures could be completed. In the case of a rule prohibiting the manufacture of the chemical, EPA must first obtain a court injunction before the rule can be made immediately effective.

For those chemicals that present an imminent and unreasonable risk of serious or widespread injury to health or the environment, EPA may ask a court to require whatever action may be necessary to protect against such risk. (EPA also cooperates with other agencies in toxic chemical control. See *Relationship to Other Laws*, page 7.)

In addition to using various control options, EPA warns the public about chemical hazards through its chemical advisory program. Chemical advisories encourage individuals or organizations to voluntarily reduce the risks associated with a chemical, such as the risk of continual contact with used motor oil. Chemical advisories discuss toxic effects of chemicals of concern, routes of exposure, and alternative methods of reducing risks.

Polychlorinated Biphenyls (PCBs). In TSCA, Congress singled out PCBs for both immediate regulation and phased withdrawal from the market. EPA may authorize certain uses of PCBs and may exempt, pursuant to certain TSCA criteria, specific activities involving the manufactur-



ing, processing, or distribution in commerce of PCBs. PCBs are of concern because tests on laboratory animals show that chronic exposure to PCBs may cause reproductive failures, gastric disorders, skin lesions, and tumors. Moreover, PCBs persist and when released into the environment tend to accumulate in tissues of living organisms. This means that, as PCBs move up in the food chain toward humans, their concentration, and thus their potential for harm, increases.

Recordkeeping and Reporting

A major challenge for the TSCA program was to develop a mechanism for identifying those chemicals likely to damage human health or the environment so that appropriate action could be taken by industry or EPA.

In fact, Congress recognized during its discussion on TSCA that very little was known about chemicals in the environment.

When the law was passed, it was not even known how many chemicals there were, in what quantities they were produced and where, what their byproducts were, who was exposed to them and under what conditions. This information was available only for a handful of existing chemicals. Therefore, Congress gave EPA the authority to compile an inventory of existing chemical substances, and to develop additional information on these basic questions.

The first inventory was published in 1979, based on information reported to EPA by chemical manufacturers, importers, and processors. The inventory — to which new chemicals are added when they go into production — shows now that nearly 58,000 commercial chemical substances are, or have been, manufactured or imported into the United States since January 1, 1975. (There are well over 5 million known chemical compounds, but most are research and development chemicals that are not used commercially.)

It is important to note that the chemical inventory is not a list of toxic or hazardous chemicals. Rather, it lists existing chemicals by their specific chemical name (e.g., acetonitrile, bromobenzene, chloromethane, etc.), giving for the first time an overall picture of the chemicals used for commercial purposes in the United States. In addition to being unprecedented, this list is of major importance because chemicals not on the inventory must be reviewed by EPA under the premanufacture notification program before they are allowed into U.S. commerce. In addition to compiling the inventory, EPA has used its TSCA reporting authority to obtain production, use, release, and exposure data on a number of chemicals — including asbestos and chemicals recommended by the Interagency Testing Committee for test rule consideration.

TSCA also requires any person who manufactures, processes, or distributes in commerce any chemical substance or mixture to keep records of significant adverse reac-

tions to health or the environment that allegedly were caused by the chemical. Records concerning health effects on employees must be kept for 30 years; other records must be retained for 5 years.

The Agency may require the submission of health and safety studies which are known or available to those who manufacture, process, or distribute in commerce specified chemicals.

In addition, if the chemical industry has information which indicates that a chemical presents a substantial risk of injury to health or the environment, EPA must be notified. Substantial-risk reporting has heightened industry's awareness of potential chemical risks, often resulting in manufacturers, processors, and distributors taking action on their own to minimize exposure to hazardous substances.

Relationship to Other Federal Laws

TSCA explicitly requires EPA to coordinate its activities with those of other Federal programs involved in toxic chemical control administered by organizations such as: The Consumer Product Safety Commission, The Food and Drug Administration, The Department of Agriculture, The Occupational Safety and Health Administration, The Department of Transportation, The Department of Health and Human Services, and others.

EPA may determine that an unreasonable risk presented by a chemical may be pre-

vented or sufficiently reduced by action under a Federal law it does not administer. If so, a request to the agency administering the other law is made to determine whether the risk exists and if the other agency's action would sufficiently reduce the risk. If the agency finds no risk or takes action directed to the risk, EPA may then not take any regulatory action directed to that same risk.

TSCA also directs EPA to use other laws it administers — such as the Resource Conservation and Recovery Act or the Clean Water Act — to protect against unreasonable risks unless a determination is made that it is in the public interest to protect against such risks under TSCA.

The following major laws are administered by EPA.

- **Clean Water Act**, as amended, is the basic authority for water pollution control programs. The goal of the act is to make national waters fishable and swimmable.
- **Safe Drinking Water Act**, as amended in 1977, permits EPA to regulate the quality of water in public drinking water systems and the disposal of wastes into injection wells.
- **Resource Conservation and Recovery Act** of 1976 ("RCRA") authorizes EPA to establish regulations and programs to ensure safe waste treatment and disposal.
- **Federal Insecticide, Fungicide, and Rodenticide Act** ("FIFRA"), as amended, directs EPA to regulate the manufacture, distribution and use of pesticides and con-

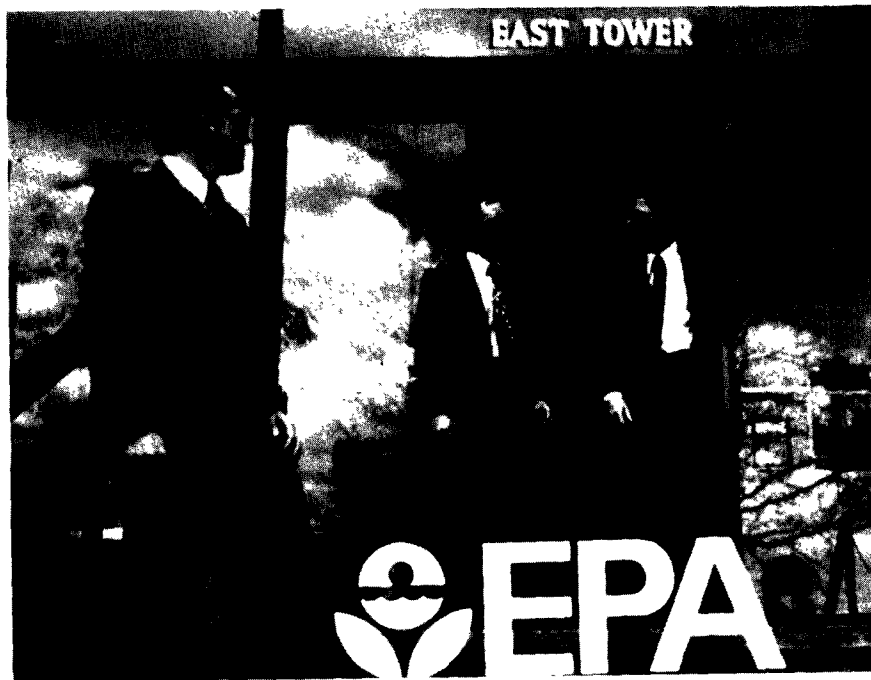
duct research into their health and environmental effects.

- **Toxic Substances Control Act** of 1976 ("TSCA"), provides authority to regulate the manufacture, distribution and use of chemical substances.

- **Clean Air Act**, as amended in 1977, provides the basic legal authority for the nation's air pollution control programs, and is designed to enhance the quality of air resources.

- **Comprehensive Environmental Response Compensation and Liability Act** of 1980 ("Superfund") establishes a program to deal with release of hazardous substances in spills and from inactive and abandoned disposal sites.

- **Marine Protection, Research, and Sanctuaries Act** of 1972 permits EPA to protect the oceans from the indiscriminate dumping of waste.



Research, Monitoring, and Data Systems

In order to fully meet statutory requirements, EPA and other Federal agencies have expanded research and related activities.

The EPA Research Committee system has been established to serve as a cornerstone for program planning in the Office of Research and Development (ORD) and to effect a formal liaison between ORD and the other program offices within EPA. The Chemical Testing and Assessment Research Committee (CTARC) plans research activities relevant to TSCA.

In addition to establishing a data system within EPA for information submitted under TSCA, the Agency is designing and establishing a system for toxicological and other scientific data accessible to all Federal agencies.

EPA has developed the Chemicals-in-Commerce Information System (CICIS) to store and retrieve TSCA data. This system contains TSCA confidential business information and state-of-the-art computer security techniques. The computerized TSCA Inventory became operational in late 1979, and several information services have derived from it, including subsystems for Freedom of Information Act requests, inventory profiles for EPA Regional Offices, support for the TSCA premanufacture review process, and health and safety study submissions.

The Interagency Toxic Substances Data Committee (ITSDC), formed in February 1978 by EPA and the Council on Environmental Quality, is continuing its work to construct a comprehensive Chemical Substances Information Network (CSIN).

CSIN enables toxic substances information users to have access to a number of independent and autonomous data banks in the public and private sectors. Users can make use of one computer to manage the logging-in, accessing, and processing of their queries for relevant records in and among many data and information systems — one simple access point to a "library of systems."

Through the ITSDC, EPA is responsible for the day-to-day administration of CSIN, which became operational in November of 1981. CSIN significantly advances the availability of chemical data to both governmental and private sector organizations to efficiently resolve and manage issues concerning chemical substances.

Exports and Imports

If a person intends to export a chemical which is subject to certain requirements under TSCA, he must notify EPA. The Agency is responsible for notifying the importing country's government of the export and of EPA's regulatory action or the availability of information.

With respect to imports, no chemical substance, mixture, or article containing a chemical substance or mixture will be al-

lowed into the customs territory of the United States if it fails to comply with any TSCA rule or otherwise violates TSCA.

TSCA requirements generally relate to substances that are produced and distributed in U.S. commerce. However, chemical substances produced in the United States but for export only, can be covered by TSCA if EPA finds that the chemical substance will present an unreasonable risk within the U.S. EPA may require that the chemical substance be tested, and may further regulate it.

Disclosure of Data

Confidential data, such as trade secrets and privileged financial data, will be protected from disclosure by EPA. All health and safety information, submitted under TSCA, on chemicals in commerce is subject to disclosure. A person submitting other types of data to EPA may designate any part of them as confidential. EPA will treat such information as confidential until the Agency determines that the information is not entitled to such protection. If the release of confidential business information is essential for the protection of health or the environment, EPA may disclose it after notifying the person who submitted the data in advance of any contemplated release.

Effect on State Laws

With certain exceptions, TSCA will not affect the authority of any State or political subdivision to establish regulations con-

cerning chemicals. If EPA issues a testing requirement for a chemical, a State may not establish a similar one for the same purposes. If EPA restricts the manufacture or otherwise regulates a chemical under TSCA, a State may only issue requirements which are identical, are mandated by other Federal laws, or prohibit the use of the chemical. In response to a request by a State, EPA may grant an exemption to allow the State to regulate differently from TSCA regulatory actions under certain conditions. Specifically, EPA can grant exemptions if the State requirement (1) would not cause a person or activity to be in violation of a requirement under TSCA and (2) would provide a greater degree of protection and not unduly burden interstate commerce.

EPA is actively committed to a policy of delegating more authority and decision-making power to the States to implement TSCA.

State Programs

TSCA authorizes grants to be awarded to States to help establish programs to prevent or eliminate unreasonable risks associated with toxic substances. Seven States and Puerto Rico were recipients of such grants in 1979, 1980, and 1981. The projects funded, which will be completed and evaluated in 1983 and 1984, ranged in scope from developing toxic substances data bases to establishing State strategies to investigate and, if necessary, control unreasonable risks.

In addition, a Regional and State Relations Program to promote cooperative ap-

proaches to dealing with toxic substances problems was begun. The program's design and initial efforts came from recommendations made in a 1981 report submitted by the National Governors' Association (NGA), which studied, with the help of an EPA grant, how States manage toxics problems. Subsequently, grants to NGA were awarded to coordinate the States' access to EPA's Chemical Substances Information Network (CSIN), to act as a clearinghouse to publicize State toxic substances management practices and to allow experts from one State to advise their counterparts in another. In addition, a conference attended by twenty-six State representatives was held.

During the 1982 State legislative sessions, issues concerning integrated toxics management were monitored and a report on trends was issued. The toxics management activities were reviewed and assessed yielding profiles of eighteen States' programs from which needs analyses are being drawn.

These activities and others will further develop EPA's cooperative relationship with States and an integrated approach to dealing with toxic substances

Judicial Review

Not later than sixty days after a rule is promulgated under certain TSCA provisions, a person may file a petition for judicial review of such rule with the U.S. Court of Appeals for the District of Columbia Circuit or with the U.S. Court of Appeals for the circuit of his residence or business

Actions by Citizens

Any person may bring a civil suit to restrain a violation of TSCA by any party or to compel the Agency to perform any nondiscretionary duty required by this law.

In addition, any person may petition EPA to issue, amend, or repeal a rule under the testing, reporting, or restriction sections of TSCA. The Agency has 90 days to respond to a petition. If no action is taken or a petition is denied, the party has the opportunity for judicial review in a U.S. District Court. In both civil suits and citizens' petitions, the court may award reasonable legal costs and attorneys' fees, if appropriate.

Employee Protection



If an employee believes that his employer has discriminated against him because of the employee's participation in carrying out TSCA, he may file a complaint with the Secretary of Labor. The Secretary shall investigate the alleged discrimination and, if warranted, may order the employer to remedy the effects of any such discriminatory action. Employees and employers may obtain judicial review in the U.S. Courts of Appeals.

EPA will evaluate the potential effects on employment of regulatory actions under TSCA. In response to a petition by an employee, EPA may investigate and hold public hearings concerning job losses or other adverse effects allegedly resulting from a requirement under TSCA. The Agency will make public these findings and recommendations.

Civil and Criminal Penalties

Any person who fails or refuses to comply with any requirement made under TSCA may be subject to a civil penalty of up to \$25,000 for each day of violation. Persons who knowingly or willfully violate the law, in addition to any civil penalties, may be fined up to \$25,000 for each day of violation, imprisoned up to a year, or both.

Enforcement

EPA can inspect any establishment in which chemicals are manufactured, processed, imported to, stored, or held before or after their distribution in com-

merce. No inspection shall include financial, sales, pricing, personnel, or research data, unless specified in an inspection notice.

The Agency can subpoena witnesses, documents, and other information as necessary to carry out TSCA.

Civil actions concerning violations of or lack of compliance with TSCA may be brought to a U.S. district court to restrain or compel the taking of an action. Any chemical substance or mixture that was manufactured, processed, or distributed in commerce in violation of TSCA may be subject to seizure.

Specific enforcement strategies for implementing TSCA regulations have been developed by the Agency. These strategies identify and rank possible violations of a particular regulation, identify the tools available for compliance monitoring and how they will be used, provide a formula for determining application of inspection resources, and establish policy for determining civil penalties under the regulation.

TSCA Assistance Office

As required by TSCA, EPA has established an office to provide technical and other nonfinancial assistance to chemical manufacturers, processors and others who are interested in requirements and activities under this law. To help people understand TSCA's requirements, the TSCA Assistance Office (TAO) provides a toll-free telephone information service, a bi-monthly bulletin, field consultants and other technical assistance upon request.

Further Information

To obtain up-to-date *information* on TSCA requirements, call the TSCA Assistance Office's toll-free line: 800-424-9065 (554-1404 in Washington, D.C.). Outside of the United States call 202-554-1404.

EPA REGIONAL OFFICES

Regional Offices

EPA Region 1
JFK Federal Building
Boston, MA 02203

EPA Region 2
26 Federal Plaza
New York, NY 10278

EPA Region 3
Curtis Building
6th and Walnut Streets
Philadelphia, PA 19106

EPA Region 4
345 Courtland St., NE
Atlanta, GA 30365

EPA Region 5
230 South Dearborn Street
Chicago, IL 60604

EPA Region 6
1201 Elm St
Dallas, TX 75270

EPA Region 7
524 East 11th St
Kansas City, MO 64106

EPA Region 8
1860 Lincoln Street
Denver, CO 80295

EPA Region 9
215 Fremont St
San Francisco, CA 94105

EPA Region 10
1200 Sixth Avenue
Seattle, WA 98101

States Covered

Connecticut, Maine,
Massachusetts, New Hampshire,
Rhode Island, Vermont

New Jersey, New York
Virgin Islands, Puerto Rico

Delaware, Maryland,
Pennsylvania, Virginia,
West Virginia, District of
Columbia

Alabama, Florida, Georgia,
Kentucky, Mississippi,
North Carolina, South
Carolina, Tennessee

Indiana, Illinois,
Michigan, Minnesota,
Ohio, Wisconsin

Arkansas, Louisiana,
New Mexico, Oklahoma,
Texas

Iowa, Kansas, Missouri,
Nebraska

Colorado, Montana, North
Dakota, South Dakota, Utah,
Wyoming

Arizona, California,
Hawaii, Nevada,
American Samoa, Guam,
Trust Territories of
the Pacific, Wake Island

Alaska, Idaho, Oregon,
Washington