file toxic chemicals

U.S. toxic-substances-control law: real impact fuzzy until 1980

The U.S. Environmental Protection Agency must first act on several key fronts, such as setting test protocols and defining "significant new uses" of existing chemicals, before the chemical process industries can even begin to grasp the impact of the iust-enacted law.

☐ The Tosic Substances Control Act (TSCA) okayed by President Ford in mid-October rates as one of the most far-reaching pieces of legislation ever to hit the U.S. chemical process industries (CPI). TSCA requires industry to notify the Environmental Protection Agency before marketing new chemicals or commercializing "significant new uses'.' of existing chemicals; under certain conditions, **EP.4** is empowered to require testing, and to delay or ban chemicals manufacture or marketinq (see the bos starting on p. 82 for a synopsis of rhe Act ı.

The President's signature ended six years of fierce battling on Capitol Hill, resulting in a compromise law that most CPI firms have labeled "tough but workable." But the magnitude of the Act's impact is uncertain, and likely will remain so for at least another three years. The key: **EPA's** interpretation of what is meant by Congress's mandate to carry out the Act "in a reasonable and prudent manner."

"In broad terms, things are a lot clearer now than they were, say, when we were dealing with alternatives in the Senate versus the House," notes George S. Dominguez, Ciba-Geigy Corp.'s (Ardsley, N.Y.) director of government relations for safety. health and environment, and director of environmental policy for the Scarsdale, N.Y., based Synthetic Organic Chemical Manufacturers Assn. (SOCMA). "But," he continues, "in order to make a real determination of the Act's impact. any number of EPA regulations have to issue."

GUESSING—Sow, industry can only speculate about how strongly EPA will move on the Act. Points out one industr). executive: "Every action that the Administrator of **EPA** can take within this bill, he can take with respect to categories of chemicals or with individual chemicals. I think common sense dictates that he's going to be discrete in what he classifies as categories, and you're not going to find enormous categories such as alcohols. ethers, esters or aldehydes. But when you start narrowing down the classifications, there's where you can indeed get into problems,. because just as **EPA** generalizes **PCBs,** it could generalize equally well some others. That kind of categorization is probably what you are going to see—limited but still fairly broad."

Worries another: "We don't know yet what tests will be required. how many, what methods, etc. This could have a big impact on costs."

And since the Act exempts research and development chemicals, the definition of commercial quantities rates as a crucial point for industry. Some chemicals makers fear that EPA will be too inflesible on this; they note that for some specialty chemicals production of several hundred pounds a year would be commercial, while for many high-volume substances output of several hundred thousand pounds yearly might still be developmental.

The Act's too new for **EP.4** to have done much to resolve such thorny points. For instance, the agency has "not yet addressed" a number of questions, such as whether it will lean toward chemical categorization, says Glenn Schweitzer, chief of its Office of Tosic Substances.

But EPA maintains it will tread lightly. Indeed, earlier this year the agency's administrator, Russell E. Train, promised a "go slow" enforcement (*Chem. Eng.*, Mar. 15, pp. 53–54). And even if it wanted to move faster and more broadly, the agency couldn't because of lack of money, notes an EPX official—through fiscal 1979, it only has an average of about $13 million/yr to spend on toxics control.

LANDMARKS—These early industry speculations should be resolved over the nest few years as **EPA** and a federal interagency committee* start issuing regulations required by the Act.

One of the first major clarifications will come by November 1977 when EPA must publish an inventor). list of esisting chemical substances. Until that time, manufacturers will not know for certain whether their products will fall into

• Composed of representatives from EPA. the Occupational Safety and Health Adminiriration. the Sational Institute for Occupational Safety and Health, the Council on Environmental Quality. the Dept. of Commerce. the National Science Foundation. the National Cancer Institute and the Sational Institute of Environmental Health Sciences.

002244

A capsule, plain-language guide to the major provisio

Here's a *Chemical Engineering* attempt* to boil down the major sections of the 53-page-long Toxic Substances Control Act (Public Law 94-469):

Section **1—Short** title and table of contents.

Merely cites the Act's name, and labels its **31** sections.

Section 2—Findings, policy and intent.

In this section, Congress directs that because people and the environment are esposcd to many chemicals, some of which may pose an "unreasonable risk" to health or the environment, manufacturers and processors of these materials must develop data to assess these risks. The Environmental Protection Agency will have authority to regulate these chemicals, but should carry out the Act "in a reasonable and prudent manner. . . [and] not impede unduly or create unnecessary economic barriers to technological innovation."

Section 3—Definitions.

Subsections (1) and (2) define chemical substances to include organic or inorganic compounds and any element or uncombined radical. but esclude mistures, pesticides, tobacco and tobacco products, nuclear materials, foods, food additives. drugs and cosmetics.

The definition of mistures [subsection (8)] rates as one of the more important concessions won by industrv. Congress wanted EPA to have authoritv over a wide range of substances, but industr) didn't want to be overburdened by a definition that would require every minor formulation change to be viewed as a new substance. So, the Act defines chemical substances and mistures separately. It labels a misture as any combination of two or more chemical substances that are not found in nature and do not chemically react with each other. A change in the proportion of inert ingredients forms a new misture, not a new chemical substance. The combination is also defined as a misture even if a chemical reaction takes place. providing that the reactants form "existing" (rather than "new") substanccs. and providing that these "existing" substanccs could have been made without a chemical reaction. Also, if EPA determines that a misture must be esamincd for toxic potential, the agency must decide whether the questions can more readily be resolved by looking at the mixture's ingredicnts—data for which are much more likely to already be available.

Under subsection (9) "new chemical substance" is defined to mean any chemical substance not included in the inventor) list [see section 8(b) for further details].

Section 4—Testing of chemical substances and mistures.

Under subsecrion (a), if EPA finds that a chemical substance or rnisture may pose an "unreasonable risk" to health or the environment, and there are insufiicient data available to assess possible effects. the .Administrator will order testing. Or, if the material is made in --substantial quantities." raising the risk of possible significant human and environmental esposure. and there aren't enough data around to predict its impact, testing will be mandated.

Subsection (b) requires EPA to set standards for the development of test data. Subsection (c) allows the agency to esempt firms making or processing a given substance from providing duplicative data: if necessary, EPA must then determine fair cost allocations among the manufacturers or processors of that material.

Subsection (e) creates a Federal interagency advisory committee that must prepare a list of priority substances and mistures that the Administrator should consider for rule promulgation. The first list, which gives priority to those materials suspected of causing cancer. gene mutations or birth defects. is required by Oct. 1. 1977 [see test].

Effective January 1, 1979, under subsection (f), the Administrator must take action on suspect substances and mistures. Within 180 days of receipt of data that indicate a material may **pose** an unreasonable risk. EPA must either initiate action to

* Adapted in part from "Summarv and Analvsis of rnr Toxic Substances Control Act" by Cleary, Gottlieb, Steen & Hamilton for the Svnthetic Organic Chemical Manufacturers Assn.

the "existing" or "new" categories.. By definition. materials not on the list will be considered "new." Within thirty days of issuance of the list, manufacturers of new chemical sub-: stances must notify EPX before they begin marketing.

Meanwhile, by October 1977, the interagency committee is mandated to publish a list of esisting substances or mistures for testing, designating up to 50 of them as highest-priority test candidates. Twelve months later, EP.4 either must issue a rule requiring testing of the chemicals on this list or esplain why it is esempting any of them. Therefore. it will be nearly two years from now before chemicals makers know for certain whether their esisting products will require testing to stay on the market.

While these gears are in motion. EPA will be defining "significant new uses" of esisting substances—another action of great moment to the CPI. Although the bill doesn't stipulate when EPA must do this, industry officials feel that .the definition will probably come out in about a year or so.

Also. while the Act doesn't require EPA to issue the testing rules until October 1978, they will likely be available within the nest year. This is because much of the legislation hinges on the testing of possibly hazardoussubstances.

All in all, the **CPI** will start to feel the Act's effects during late 1977 and through 1978. with the real clout probably coming by the beginning

of the new Toxic Substances Control Act

prevent or reduce such risk, or esplain why it doesn't consider the risk to be unreasonable.

Section 5—Manufacturing and processing notices.

The major thrust of this section—the premarket-notification provisions of the Act—requires that industry give **EP.4** 90-day advance notice of intention to manufacture all new products and, all esisting products that are to be put to "significant new use." By giving EPA notice before commercial production begins. the agency can take action against dangerous chemicals without significantly undermining jobs and capital investments. Congress reasons. EPA can estend the premarket notification period by 90 days if it shows "good cause" [subsection (c)].

As the premarket notification period comes to an end. the .Administrator is authorized under subsection (e) to issue an order restricting or prohibiting the manufacture. marketing or use of a new chemical substance. or the proposed significant new use of an existing chemical, if enough information is not available to evaluate the health and environmental effects. If the manufacturer objects, the Administrator must seek an injunction. The injunction would be dissolved after the manufacturer had submitted adequate test data.

Subsection (f) requires EPA to take various actions, such as limiting or banning a new chemical substance or a proposed significant new use of an existing substance that may present an imminent, unreasonable risk.

Cnder subsection (g), the Administrator must explain at the end of the notification period his reason for not prohibiting or limiting the manufacture. processing. distribution, use or disposal of the chemical substance.

Subsection (h) provides various exemptions, including: the submission of duplicative data; chemicals produced in small quantities and used solely for research and development; chemicals not deemed to pose an unreasonable risk; and short-lived intermediates.

Section 6—Regulation of hazardous chemical substances and mixtures.

Unlike section 5, which applies only to new chemicals and significant new uses of existing chemicals, section 6 provides EPA with a wide array of weapons to prohibit, limit or otherwise regulate a gamut of substances—esisting and new chemicals and mistures, alike.

Subsection (a) dictates that the Administrator use the "least burdensome" method to protect against risk. while subsection (c) requires EPA to consider the regulation's effect on the national economy. small business, technological innovation. the environment and public health.

In subsection (e). the Act calls for the eventual phaseout of polychlorinated biphenyls. with manufacture to cease by Jan. 1, 1979. and processing and distribution prohibited by July 1 of that year. (However, the sole U.S. producer of PCBs. Monsanto Chemical Co., already has pledged to be out of the business by the end of 1977—see *Chem. Eng.*, Aug. 30. pp. 66.68).

Section 7—Imminent hazards.

This section gives the .Administrator further authority to quickly regulate against chemical substances or mistures that *'presentan imminent and unreasonable risk of serious or widespread injury." Even before rule-making is initiated under section 6, EPA can file suit for corrective remedies, such as seizure or recall of chemicals.

Section 8—Reporting and retention of information.

This section gives the .Administrator the power to get the information he needs to accomplish the goals of the Act. For esample. subsections (a). (c) and (d) require manufacturers and processors to submit reports and health studies to EPA, and keep a wide range of records for periods of up to 30 years. It minimizes these burdens for small businesses. Under subsection **(b),** the Administrator is mandated to compile, keep up to date, and publish a list of every chemical substance made in the U.S.

Sections **9-31—Administrative** provisions of the Act. The rest of the Act deals with TSCA's administrative aspects. including coordination with other federal agencies, penalties, judicial review, citizens' civil actions, and the like.

of the nest decade. At that time. industry should be able to put some firm figures on TSCA's actual costs—in terms of money, manpower, staffing changes, lost innovation, and similar aspects.

INITIAL EFFORTS—As best they can, industry trade organizations already are tning to get an early reading for their members of what the Act will mean. For esample, within weeks of TSCA's passage SOCMA's legal counsel, Cleary, Gottlieb. Steen & Hamilton (Washington, D.C.), issued an 80-page report analyzing and summarizing the Act, while spelling out the new law's possible impact on chemicals makers.

In addition, the Manufacturing Chemists Assn. (Washington, D.C.) now is planning to present three meetings titled "The .Approaching Toxics Era," the first of which at presstime was slated to be held on Nov. 11 in Houston. Tes., with the others to follow on Dec. 7 in \Vash-ington, D.C., and Jan. **13** in Los .+-geles. Also, MCA has formed a Chemical Regulations Advisory Committee that had its first meeting about TSCA on October 20, to start work on a study of how the legislation might affect company staffing. record keeping, reporting, data gathering and various other functions. At presstime, a task force within this advisory committee was firming up plans for a series of meetings to be held across the countn beginning in February. The topic: 'Corporate readiness for TSCA."

Larry J. **Ricci**