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SUMMARY OF THE MAJOR PROVISIONS OF H.R. 10318,

TOXIC SUBSTANCES CONTROL LEGISLATION

The following is a brief summary of the major provisions of the toxic substances control legislation, H.R. 10318, as reported by the Consumer Protection and Finance Subcommittee.

Testing (Section 4)

Section 2(b) sets forth the Congressional policy that hazardous and potentially hazardous chemicals should be adequately tested with respect to their effect on health and the environment and that such testing should be the responsibility of those who manufacture or process such chemicals. Section 4 contains the mechanism for accomplishing this policy objective. Section 4 authorizes the Administrator of the Environmental Protection Agency to issue rules requiring certain manufacturers or processors of potentially harmful chemicals to conduct tests on the chemical. Such rules are to be issued in accordance with the rulemaking procedures prescribed by Section 553 of Title 5 of the U.S. Code, except that manufacturers and processors must be provided an opportunity for an oral hearing on such rules.

Before issuing a rule requiring testing of a chemical, the Administrator must make certain specific findings. They include: (1) that a) the chemical may cause or contribute to an unreasonable risk to health or environment, or b) there may be substantial human or environmental exposure to the chemical; (2) there is insufficient data and experience upon which the health and environmental effects of the chemical can reasonably be determined or predicted; and (3) testing of the chemical is necessary to develop such data.

Section 4 establishes a committee composed of representatives from other Federal agencies with research and regulatory responsibilities over chemicals to make recommendations to the Administrator as to chemicals which should be tested. The committee's recommendations are to be in the form of a list which is to be published in the Federal Register. Within 12 months after the time a chemical appears on the list, the Administrator must either begin a rulemaking proceeding to require testing of the chemical or publish in the Federal Register the reasons why testing is not to be required.

Manufacturing and Processing Notices (Section 5)

Section 5 sets out the notification requirements with which manufacturers of new chemicals and manufacturers and processors of existing chemicals for significant new uses must comply. Section 5 requires the manufacturer of a new chemical substance to give 90 days notice to the Administrator prior to the manufacture of the new chemical. Similar notice must be provided by any person who intends to manufacture or process an existing chemical for a use which the Administrator has determined, by rule, constitutes a significant new use of the chemical. The Administrator may extend the 90-day notification period for an additional 90 days for good cause shown.

The notice to the Administrator is to include the name of the chemical, its chemical identity and molecular structure, proposed categories of use, an estimate of the amount to be manufactured, the byproducts resulting from the manufacture, processing and disposal of the chemical, and any test data related to health and environmental effects which the manufacturer has. In addition, if a rule requiring testing of the chemical has been issued under section 4, the manufacturer must submit the test data developed from the testing along with the other information. If the chemical is on a list of chemicals which the Administrator has found may cause or contribute to an unreasonable risk to health or the environment and if testing of the chemical has not been required under section 4, the manufacturer must submit data which he believes show that the chemical will not cause or contribute to an unreasonable risk to health or environment.

The Administrator is authorized to put into immediate effect a rule prohibiting or limiting the manufacturing of a new chemical or an existing chemical for a significant new use if the Administrator makes the following findings: (1) information available to the Administrator is insufficient to permit a reasoned evaluation of the health or environmental effects of the chemical, and (2) in the absence of such information, the chemical may cause or contribute to an unreasonable risk to health or the environment.

The notification requirement does not apply to chemicals manufactured in small quantities for scientific experimentation or for chemical research or analysis, including research or analysis for product development. Mixtures of inert chemicals are also exempted from the notification requirements.

Regulation of Hazardous Chemical Substances and Mixtures Section 6)

The Administrator may issue rules which prohibit or limit the manufacturing, processing, or distribution of a chemical which causes or contributes to or is likely to cause or contribute to an unreasonable risk. Labeling may also be required for such a chemical. Rulemaking shall be pursuant to Section 553 of Title 5 of the United States Code. However, an opportunity for an oral hearing is required and cross-examination is permitted in certain instances. A proposed rule may be placed into effect upon its publication in the Federal Register if the Administrator determines that (1) a substance or mixture is likely to result in an unreasonable risk prior to the completion of a rulemaking proceeding and (2) such action is necessary to protect the public interest.

The Administrator may order a manufacturer to revise quality control procedures if the manufacturer's present procedures result in unintentionally causing a chemical to cause or contribute to an unreasonable risk. Such an order may not be issued until the manufacturer has been given a full adjudicatory hearing.

Reporting and Retention of Information (Section 8)

The Administrator is authorized to issue rules requiring manufacturers and processors of chemicals to report to EPA the name, chemical identity, proposed uses, estimates of amounts, description of byproducts, adverse health and environmental data, and number of workers exposed to the chemical. Manufacturers of chemical mixtures and research chemicals must submit this data only to the extent the Administrator determines is necessary to efficiently enforce the Act.

Manufacturers, processors, and distributors must retain records of adverse reactions to health or the environment caused by a chemical. The Administrator may require the manufacturer, processor, and distributor of a chemical to provide lists of health and safety studies performed on the chemical. They must tell the Administrator of any information received indicating that a chemical causes or contributes to an unreasonable risk.

Relationship to other Federal Laws (Section 9)

If the Administrator determines that an unreasonable risk presented by a chemical may be prevented or sufficiently reduced by action under a Federal law not administered by EPA, the Administrator shall request the agency administering the law to determine whether a risk exists and if the agency can deal with it under its jurisdiction. If the agency finds no risk or takes action to deal with the risk, EPA may not take any regulatory action against the risk.

The Administrator shall use other laws administered by EPA to protect against unreasonable risks unless the Administrator finds this Act would be more appropriate.

Disclosure of Data (Section 14)

Data provided to the Administrator which falls under the classification of a trade secret cannot be disclosed. Health and safety studies may be disclosed. The person submitting data may designate any part of it as confidential. Data so designated may not be released until the Administrator notifies the person making the designation. Regardless of this section, Congress may obtain any information the Administrator has obtained under this Act.

Citizen's Civil Action (Section 20)

Any person may bring a civil suit to restrain a violation of the Act or to compel the Administrator to perform any non-discretionary duty. The plaintiff may not sue unless EPA and the alleged violator are given 60 days notice or if the EPA is diligently prosecuting the defendant. EPA may intervene in any action against an alleged violator. Costs and attorney's fees may be awarded.

Citizens' Petitions (Section 21)

Any person may petition the Administrator to issue a rule requiring testing or regulating a chemical.
If the Administrator refuses, the petitioner may seek a court order to require the Administrator to begin the rulemaking proceeding. Costs and attorney's fees may be awarded.

SECTION-BY-SECTION ANALYSIS OF H.R. 10318,

TOXIC SUBSTANCES CONTROL ACT, As Reported
By the Consumer Protection and
Finance Subcommittee

SECTION 1 - SHORT TITLE

The Act may be cited as the Toxic Substances Control Act.

SECTION 2 - FINDINGS, POLICY, AND CONGRESSIONAL INTENT

Subsection (a) states findings of Congress that humans and the environment are being exposed to a large number of chemical substances and mixtures each year, some of which may cause or contribute to an unreasonable risk to health or the environment. The effective regulation of such chemical substances and mixtures necessitates intrastate as well as interstate regulation.

Subsection (b) states the policy of the United States that hazardous and potentially hazardous chemical substances and mixtures should be adequately tested, and that such testing should be the responsibility of those who manufacture or process the chemical substances or mixtures. Adequate authority should exist to regulate chemical substances and mixtures which cause or contribute to an unreasonable risk to health or the environment and to take action against such substances and mixtures which are imminent hazards. However, such authority should be

exercised in a manner which does not unduly impede or create unnecessary economic barriers to technological innovation.

Subsection (c) states the Congressional intent that the Act be administered in a reasonable and prudent manner and that environmental, economic, and social impacts of regulatory action be considered.

SECTION 3 - DEFINITIONS

Most of the definitions contained in the bill are self-explanatory. However, a few are particularly singificant to the understanding of the legislation and are discussed below.

The definitions of "chemical substance" and "mixture" are highly important in that they define the regulatory scope of the legislation.

"Chemical substance" is defined to mean (1) any organic or inorganic substance of a particular molecular identity including a combination of such substances occurring either (a) as a result of a chemical reaction of (b) in nature, or (2) any element or uncombined radical. The term is defined to specifically exclude any mixture, pesticides, food, drugs, devices, tobacco or tobacco products, firearms and ammunition, and any source material or special nuclear material defined in the Atomic Energy Act of 1954. In previous House bills, the term "chemical substance" was defined so as to specifically include "mixtures". Since the definition of chemical substance in H.R. 10318 does not include "mixtures", the bill must

explicitly mention "mixtures" anytime the Administrator is to be given regulatory authority over mixtures.

"Mixture" is defined to mean any combination of two or more chemical substances if such substances do not react chemically with each other and if the combination is not the result of a chemical reaction and does not occur in nature.

"Standards for the development of test data" means a prescription of the health and environmental effects and of the characteristics which affect health and the environment for which test data for a chemical substance or mixture ought to be developed and any analysis that is to be performed on such data. Such standards shall, if necessary to assure that the data are reliable and adequate, prescribe the manner in which such data are to be developed and specify the use of a particular test protocol or methodology. Standards for the development of test data for a specific substance or mixture are to be prescribed when the Administrator promulgates a rule requiring testing of the substance or mixture under section 4.

SECTION 4 - TESTING OF CHEMICAL SUBSTANCES AND MIXTURES

(a) Testing Requirements - Section 4(a) authorizes the Administrator of the Environmental Protection Agency to promulgate rules requiring that testing be conducted on a chemical substance or mixture. In order to require testing, the Administrator must first make one of two alternative

findings. The Administrator must either find that (1) the manufacture, distribution in commerce, processing, use, or disposal of a chemical substance or mixture may cause or contribute to an unreasonable risk to health or the environment, or (2) a substance or mixture is or will be produced in substantial quantities and enters or may enter the environment in substantial quantities or there is or may be significant or substantial human exposure to it. The Administrator must then find that there is insufficient data and experience to reasonably determine or predict the effects of the manufacture, distribution in commerce, processing, use, or disposal of the substance or mixture on health or the environment and that testing is necessary to develop such data. The Administrator may require testing of a mixture only if the Administrator makes the additional finding that the risk to health or the environment which the mixture may present may not be reasonably and more efficiently evaluated by testing the chemical substances which comprise the mixture.

(b) Testing Requirement Rule - A rule requiring testing shall identify the chemical substance or mixture which is to be tested, and it shall include the standards for the development of test data (see definition, page 3 above). The rule shall also specify the period within which test data is to be submitted to the Administrator.

Subsection (b)(2) lists certain kinds of testing and

methodology which may be required by the Administrator.

In general the manufacturers and processors of a chemical substance or mixture subject to a section 4 rule are to perform the testing required by the rule. Subsection (b)(3) specifies which manufacturers and processors must do such testing. Under that subsection there must be a relationship between the activity of the manufacturer or processor and the finding made in connection with the issuance of a rule. Thus, for example, if the Administrator made a finding respecting the manufacture of a substance, the persons engaged in that manufacture must do the testing, and, similarly, if the Administrator made a finding respecting the use of a substance, the persons engaged in the manufacture or processing of the substance for that use must do the testing.

Under subsection (b)(4) a section 4 rule requiring testing of a substance or mixture will expire at the end of the period (defined in subsection (c)) during which persons granted an exemption from the testing requirement must reimburse persons who have conducted such testing for their testing costs. The Administrator may repeal such a rule at an earlier date.

Under subsection (b)(5) rules requiring testing are to be promulgated in accordance with section 553 of Title 5 of the United States Code. That section requires public notice and opportunity for written comment prior to finalization of the rule. In addition, the subsection requires the Administrator

to give interested persons an opportunity for an oral hearing regarding the proposed testing rule.

(c) Exemptions - Subsection (c) permits the Administrator to exempt any person from a requirement to conduct tests and submit test data on a chemical substance or mixture if such testing would be duplicative of testing which has been performed or is being performed. Any person receiving an exemption must provide fair and equitable reimbursement to the person who performed the testing on which the exemption is based. In determining what is fair and equitable reimbursement, the Administrator is to consider the competitive positions of the person granted the exemption and the person to be reimbursed and their respective market shares.

(d) Notice - Subsection (d) requires the Administrator to give public notice in the Federal Register of any test data received under section 4. The Federal Register notice is to identify the chemical substance or mixture for which data has been received along with its uses or intended uses and describe the nature of the test data developed. However, the Administrator may not disclose any trade secret data in the public notice.

(e) Priority List - Subsection (e) establishes a committee to make recommendations to the Administrator as to those chemical substances and mixtures which should be given priority consideration for testing. The committee is to be composed of seven members representing the Environmental Protection

Agency, the Occupational Safety and Health Administration, the Council of Environmental Quality, the National Institute for Occupational Safety and Health, the National Institute of Environmental Health Sciences, the National Cancer Institute, and the National Science Foundation.

Within one year after the date of enactment, the committee is to publish a list in the Federal Register designating those chemical substances and mixtures which the committee believes merit priority consideration for testing. The list is to be updated at least every six months. Within twelve months after the inclusion of a chemical substance or mixture on the priority list, the Administrator must either initiate a rulemaking proceeding to require testing of the substance or mixture or publish in the Federal Register the Administrator's reasons for not initiating such a rulemaking proceeding. The Administrator may promulgate a rule to require testing with respect to a chemical substance or mixture which is not contained on the priority list.

SECTION 5 - MANUFACTURING AND PROCESSING NOTICES

Overview of Section 5

Section 5 sets out the notification requirements with which manufacturers of new chemicals and manufacturers and processors of existing chemicals for significant new uses must comply. Section 5 requires the manufacturer of a new chemical substance to give 90 days notice to the Administrator prior to the

manufacture of the new chemical. Similar notice must be provided by any person who intends to manufacture or process an existing chemical for a use which the Administrator has determined, by rule, constitutes a significant new use of the chemical. The Administrator may extend the 90-day notification period for an additional 90 days for good cause shown.

The notice to the Administrator is to include the name of the chemical, its chemical identity and molecular structure, proposed categories of use, an estimate of the amount to be manufactured, the byproducts resulting from the manufacture, processing and disposal of the chemical, and any test data related to health and environmental effects which the manufacturer has. In addition, if a rule requiring testing of the chemical has been issued under section 4, the manufacturer must submit the test data developed from the testing along with the other information. If the chemical is on a list of chemicals which the Administrator has found may cause or contribute to an unreasonable risk to health or the environment and if testing of the chemical has not been required under section 4, the manufacturer must submit data which he believes show that the chemical will not cause or contribute to an unreasonable risk to health or environment.

The Administrator is authorized to put into immediate effect a rule prohibiting or limiting the manufacturing of a new chemical

or an existing chemical for a significant new use if the Administrator makes the following findings: (1) information available to the Administrator is insufficient to permit a reasoned evaluation of the health or environmental effects of the chemical, and (2) in the absence of such information, the chemical may cause or contribute to an unreasonable risk to health or the environment.

The notification requirement does not apply to chemicals manufactured in small quantities for scientific experimentation or for chemical research or analysis, including research or analysis for product development. Mixtures of inert chemicals are also exempted from the notification requirements.

(a) Notification for Manufacture of New Chemical Substances

Subsection (a) requires any person who manufactures a new chemical substance to give the Administrator 90 days notice prior to the manufacture of such substance. The notification is to include the name of the chemical substance, a reasonable estimate of the amount of the substance to be manufactured or processed, any test data in the possession or control of the person giving the notice which relates to the effect of the substance on health or the environment, and insofar as is reasonably ascertainable, the chemical identity and molecular structure of the substance, the proposed categories of uses, and the description of the byproducts resulting from the manufacture, processing, use, or disposal of the substance. (See subsection (h).) If testing of the substance has been required under section 4, the test data must be submitted at the time of notification. (See subsection (e).)

(b) Notification for the Manufacture or Processing of a Chemical Substance for a Significant New Use - Subsection (b) requires any person who intends to manufacture or process a chemical substance for a significant new use to provide 90 days notice to the Administrator prior to the manufacture or processing of the substance for such new use. The notification is to consist of the same information listed in the discussion of subsection (a) above. If testing has been required under section 4, the test data must be submitted at the time of notification. (See subsection (e).) The determination that a use is to constitute a significant new use of a chemical substance is to be made by rule by the Administrator. In issuing such a rule, the Administrator is to consider the projected volume of manufacturing and processing of the substance for such use, the extent to which such use changes the type or form of exposure of humans or the environment to the substance, and the extent to which such use increases the magnitude and duration of exposure of humans or the environment to the substance. (See subsection (g).)

(c) Notification for the Manufacture or Processing of Listed Chemical Substances - Within twelve months after the enactment of the Toxic Substances Control Act, the Administrator shall by rule compile a list of chemical substances which the Administrator finds may cause or contribute to an unreasonable risk to health or the environment. (See subsection (i)). In compiling the list, the Administrator is to identify those uses of any chemical

substance listed which would constitute significant new uses of such substance. No person may manufacture a new chemical substance which is included on the list described above without first giving notification to the Administrator of the intent to manufacture such substance. Such notice must be given 90 days prior to the manufacture of the substance, and it is to consist of the information described in the discussion of subsection (a) above. Also if the Administrator has issued a rule under section 4 requiring the testing of the substance, the test data developed pursuant to the testing requirement must be submitted to the Administrator 90 days in advance of the manufacture of the substance. If the Administrator has not required testing of the substance under section 4, the manufacturer must submit information which the manufacturer believes shows that the substance will not cause or contribute to an unreasonable risk to health or the environment. (See subsection (e).) Similar requirements apply to the manufacture or processing of a listed chemical substance for a significant new use.

(d) Application of a Section 6 Rule - Subsection (d) authorizes the Administrator to propose and make immediately effective a rule limiting or prohibiting the manufacture of a new chemical substance or the manufacture of a substance for a significant new use. In order to place such a rule into effect, the Administrator must determine that information is insufficient to permit a reasoned evaluation of the effects of the substance on health or environment, and in the absence of such information, the

manufacture, processing, distribution in commerce, use, or disposal of such substance may cause or contribute to an unreasonable risk to health or the environment.

(e) Requirement Respecting Submission of Test Data - Subsection (e) describes when test data must be submitted to the Administrator prior to the manufacture or processing of a new chemical substance or a substance for a significant new use. The requirements of subsection (e) have been discussed in the paragraphs relating to subsections (a), (b), and (c).

(f) Extension of Notice Period - The Administrator may extend the 90-day notification period for an additional 90 days for good cause shown.

(g) Determination of a Significant New Use - Subsection (g) describes how the Administrator is to determine if a new use of a chemical substance constitutes a significant new use of such substance. The provisions of subsection (g) have already been described in the discussion relating to subsection (b), above.

(h) Content of Notice; Publication in the Federal Register - Subsection (h) describes the information which is to be included in the notification given to the Administrator prior to the manufacture or processing of a new chemical substance or a chemical substance for a significant new use. The information is listed in the discussion relating to subsection (a) above. Subsection (h) requires the Administrator to provide public notice in the Federal Register of data received under the notification requirements of section 5. Trade secret data is not to be disclosed in such public notice.

(i) Chemical Substances List - Subsection (i) contains the requirement that the Administrator compile a list of chemical substances which the Administrator finds may cause or contribute to an unreasonable risk to health or the environment. Substances on the list are subject to the notice requirements of subsection (c).

The list is to be compiled by rule in accordance with the informal notice and comment rulemaking provisions of section 553 of Title 5 of the United States Code. In addition to the notice and comment requirements, subsection (i) requires that the Administrator give any interested person an opportunity for an oral hearing at which data, views, or arguments may be submitted. A written transcript is to be kept of any oral presentation.

(j) Petition for Standards for the Development of Test Data -

Subsection (j) permits any person intending to manufacture or process a chemical substance for which notice has been required under subsection (a), (b) or (c) and for which testing has not been required under section 4, to petition the Administrator to prescribe standards for the development of test data for such substance.

(k) Exemptions-

Test Marketing

The Administrator may exempt any person from the notification requirements of section 5 to permit test marketing of a chemical substance if the person can show to the satisfaction of the Administrator that the test marketing will not cause or contribute to an unreasonable risk to health or the environment.

Duplicative Test Data

Subsection (k) also permits the Administrator to exempt any person from the requirement to submit test data if such submission would be duplicative of test data already submitted. The person granted the exemption must provide reimbursement to the person who submitted the test data on which the exemption is based.

Research Chemicals

Notification is not required for those chemical substances manufactured or proposed to be manufactured or processed in small quantities (as defined by the Administrator by rule) solely for scientific experimentation or for chemical research or analysis, including chemical research or analysis during product development.

Chemical Substances With Differing Ratios of Inert Ingredients

As the definition of chemical substance indicates, a chemical substance can be a combination of a number of chemical

substances occurring as a result of a chemical reaction. Under the terms of section 5(a), any chemical substances which is a combination of chemical substances and which is not identical to an existing chemical substance would be subject to the notification requirements. However, section 5(k)(4) provides that a chemical substance which is a combination of other chemical substances will not be subject to the notification requirements if the only difference between it and an existing chemical substance is in the proportion of, or presence or absence of, existing inert chemical substances which are part of the combination.

(I) Definition - For the purposes of section 5, the terms "manufacture" and "process" means to manufacture or process for commercial purposes.

SECTION 6 - REGULATION OF HAZARDOUS CHEMICAL SUBSTANCES AND MIXTURES

(a) Scope of Regulation

Section 6(a) authorizes the Administrator to prohibit or limit the manufacturing, processing, or distribution in commerce of a chemical substance or mixture, to regulate the manner or method of the disposal of a substance or mixture, or to require labeling of a chemical substance or mixture. In order to place such a prohibition or limitation or labeling requirement on a chemical substance or mixture, the Administrator must find

that the substance or mixture causes or contributes to or is likely to cause or contribute to an unreasonable risk to health or the environment.

(b) Testing for Adulterated or Contaminated Substances and Mixtures - If the Administrator has good cause to believe that a particular manufacturer or processor is manufacturing or processing a chemical substance or mixture in a manner which unintentionally causes the substance or mixture to cause or contribute to or to be likely to cause or contribute to an unreasonable risk to health or the environment, the Administrator may by order require the manufacturer or processor to submit a description of the relevant quality control procedures used in manufacturing or processing the substance or mixture. If, after opportunity for a full adjudicatory hearing in accordance with section 554 of Title 5 of the United States Code, the Administrator determines that the quality control procedures are inadequate to prevent the chemical substance or mixture from causing or contributing to an unreasonable risk, the Administrator may order the manufacturer or processor to revise the quality control procedures to the extent necessary to remedy such inadequacies.

(c) Promulgation of Subsection (a) Rules - Rules under section 6(a) shall be promulgated in accordance with section 553 of Title 5 of the United States Code. However, in addition to providing the public notice and opportunity for comment required by section 553, subsection (c) requires that the Administrator also provide an opportunity for the oral presentation of data, views, or arguments. A transcript of any oral presentation shall be kept. Further, the Administrator shall include an opportunity for cross-examination to the extent and in such manner as the Administrator considers necessary and appropriate. If only a single interested person seeks the opportunity for cross-examination, or if the Administrator determines that all persons seeking the opportunity for cross-examination are members of a single class with an identity of interests, the Administrator must provide such single interested person or a representative of the class an opportunity for cross-examination to the same extent permitted by the provisions of section 556 of Title 5 of the United States Code.

(d) Effective Date - The Administrator is to specify in any rule under subsection (a) the date on which it is to take effect. The Administrator may put a proposed rule into effect upon the date of its publication in the Federal Register if the Administrator determines that the manufacture, processing, distribution in commerce, use, or disposal of the chemical substance or mixture

is likely to result in an unreasonable risk to health or the environment before final action can be taken on the rule and if making the proposed rule effective immediately is necessary to protect the public interest. If the Administrator makes a proposed rule effective immediately, the Administrator must provide for an expedited hearing regarding the rule.

SECTION 7 - IMMINENT HAZARDS

(a) Actions Authorized - Subsection (a) authorizes the Administrator to file an action in a United States district court against an imminently hazardous chemical substance or mixture or any article containing such substance or mixture or against any person who manufactures such substance, mixture, or article. If the Administrator has not issued a rule under section 6 respecting an item determined to be an imminent hazard, the Administrator is required by subsection (a) to file a district court action against such item.

(b) Jurisdiction of Court - The courts are authorized to provide for the seizure and condemnation of any imminently hazardous chemical substance or mixture, or article containing such substance or mixture, and may require that any person

who manufactures, processes, or distributes such an imminently hazardous substance, mixture, or article provide public notification of the risk, and recall, replace or repurchase the imminently hazardous substance, mixture, or article.

(c) Venue and Consolidation - An action against a person who manufactures, processes or distributes an alleged imminent hazard may be brought in the United States district court for the District of Columbia or any judicial district in which the defendant is found, is an inhabitant, or transacts business. Proceedings involving identical chemical substances, mixtures, or articles may be consolidated.

(d) Action under Section 6 - Where appropriate, at the same time as filing an action under section 7, the Administrator shall initiate a proceeding for the promulgation of a rule under section 6(a).

(e) Representation - In proceedings involving imminently hazardous chemical substances or mixtures, the Administrator may direct attorneys of the Environmental Protection Agency to appear and represent the Administrator.

(f) Definition - The term "imminently hazardous chemical substance or mixture" means a chemical substance or mixture which causes or contributes to an imminent and unreasonable risk to health or the environment. Such a risk to health or the environment shall be considered imminent if it is shown that the manufacture, processing, distribution, use or disposal of the chemical substance or mixture is likely to result in harm to health or the environment before a final rule promulgated under section 6 can protect against such risk.

SECTION 8 - REPORTING AND RETENTION OF INFORMATION

(a) Reports - Subsection (a) requires the Administrator to promulgate rules under which persons who manufacture or process chemical substances are to maintain records and submit reports. The manufacturer or processor of a mixture or a research chemical shall maintain records and submit reports to the Administrator only to the extent the Administrator determines that the maintenance of records or the submission of reports is necessary for the effective enforcement of the Act. Subsection (a) lists some of the information for which the Administrator may require reporting.

(b) Inventory - For purposes of determining when a chemical substance is a new chemical substance, the Administrator is required by subsection (b) to compile, keep current, and publish a listing of

each chemical substance which is reported to be manufactured or processed in the United States.

(c) Records - Subsection (c) requires manufacturers, processors, and distributors of chemical substances and mixtures to maintain records of adverse reactions to health or the environment alleged to be caused by the substance or mixture.

(d) Health and Safety Studies - Subsection (d) authorizes the Administrator to promulgate rules to obtain lists of health and safety studies on chemical substances and mixtures and copies of such studies.

(e) Notice to Administrator of Unreasonable Risk - Subsection (e) requires any person who manufactures, processes, or distributes in commerce a chemical substance or mixture and who obtains information which reasonably supports the conclusion that such substance or mixture causes or contributes to an unreasonable risk to health or the environment to immediately notify the Administrator.

(f) Definitions - For purposes of section 8, the terms "manufacture" and "process" mean manufacture or process for commercial purposes.

SECTION 9 - RELATIONSHIP TO OTHER FEDERAL LAWS

(a) Laws Not Administered by the Administrator - If the Administrator has reason to believe that a chemical substance or mixture causes or contributes to or is likely to cause or contribute to an unreasonable risk to health or the environment

and if the Administrator determines that such risk may be prevented or reduced to a sufficient extent by action taken under a law not administered by the Administrator, the Administrator shall request that agency to issue an order declaring whether or not the substance or mixture causes or contributes to or is likely to cause or contribute to such a risk and to determine if the risk may be prevented or reduced to a sufficient extent by action taken under laws administered by that agency. If the agency's order declares that there is no risk to health or the environment or if the agency initiates action to protect against such risk, the Administrator may not take any action under sections 6 or 7 of the Act with respect to that risk.

(b) Laws Administered by the Administrator - The Administrator shall use the authority contained in other Federal laws administered in whole or in part by the Administrator to protect against any risk to health or the environment associated with a chemical substance or mixture unless the Administrator determines that such risk may be more appropriately protected against under the Toxic Substances Control Act.

(c) Occupational Safety and Health - In exercising any authority under the Toxic Substances Control Act, the Administrator shall not be deemed to be exercising statutory authority to prescribe or enforce standards or regulations affecting occupational safety and health.

(d) Coordination - Subsection (d) requires the Administrator to consult and coordinate with other Federal agencies in order to maximize the enforcement of this Act and impose the least burdens of duplication on those subject to regulation under this Act.

SECTION 10 - RESEARCH, COLLECTION, DISSEMINATION AND UTILIZATION OF DATA

(a) Authority - Subsection (a) instructs the Administrator, in cooperation with the Secretary of Health, Education and Welfare and with other appropriate agencies, to conduct such research and monitoring as is necessary to carry out the purposes of the Act.

(b) Data Systems - Subsection (b) requires the Administrator to develop an efficient and effective data retrieval system for use by all Federal agencies dealing with the health and environmental effects of chemical substances and mixtures.

SECTION 11 - INSPECTIONS

(a) In General - Subsection (a) authorizes the Administrator to inspect any establishment, facility, or other premise in which chemical substances or mixtures are manufactured, processed, stored or held and any conveyance used in the transport of substances and mixtures in commerce.

(b) Scope - The inspection shall extend to all things within the premises bearing on whether the requirements of the Toxic Substances Control Act have been complied with.

SECTION 12 - EXPORTS

(a) General - Except for the reporting requirements of section 8, the provisions of the Act shall not apply to any chemical substance, mixture, or an article containing a chemical substance or mixture if it is to be exported from the United States. However, the provisions of the Act shall apply to any item intended for export if the Administrator finds that it will directly or indirectly pose an unreasonable risk to health within the United States or to the environment of the United States.

(b) Notice - If any person exports a chemical substance or mixture for which testing has been required under section 4, for which a rule has been put into effect under section 5 or 6, or with respect to which an action has been filed or relief granted under section 7, the Administrator shall notify the government of the country to which the item is to be exported of the testing requirement, the rule, action, or relief.

SECTION 13 - ENTRY INTO CUSTOMS TERRITORY OF THE UNITED STATES

The Secretary of the Treasury shall refuse entry into the customs territory of the United States of any chemical substance, mixture, or article containing a substance or mixture if it fails to conform with any rule in effect under the Act or if it is otherwise prohibited pursuant to the Act from being distributed in commerce.

SECTION 14 - DISCLOSURE OF DATA

(a) In General - Subsection (a) protects from disclosure any information reported to or obtained by the Administrator that is a trade secret and commercial or financial information obtained from a person and privileged or confidential. However, such information may be disclosed to officers and employees of United States in connection with their official duties, to contractors with the United States if necessary for the performance of the contract, and when relevant in any proceeding under the Act.

(b) Data from Health and Safety Studies - Subsection (b) provides that the confidentiality provisions of subsection (a) do not prohibit the disclosure of health and safety studies submitted under the Act with respect to any chemical substance or mixture which on the date the study is to be disclosed has been offered for commercial distribution or any chemical substance or mixture for which testing is required under section 4 or for which notification is required under section 5.

(c) Desgination of Confidential Information; Disputes - Subsection (c) authorizes any person submitting data to designate those portions which that person believes are entitled to confidential treatment under the Act. If the Administrator proposes to release any information which is so designated, the Administrator must first notify the person who submitted such data of the intent to release it. The data may not be released until the expiration of 30 days after the persons submitting the data has received the notification from the Administrator.

(d) Criminal Penalties for Wrongful Disclosure - Subsection (d) provides that any officer or employee of the United States or former officer or employee of the United States, who knowingly and willfully discloses confidential material shall be guilty of a misdemeanor and fined not more than $5,000.

(e) Access by Congress - All information reported to or obtained by the Administrator under this Act shall be made available to a Congressional committee upon its written request.

SECTION 15 - PROHIBITED ACTS

It shall be unlawful for any person to fail or refuse to comply with any rule or order under sections 4, 5, or 6 or any requirement under section 5, to use for commercial purposes a chemical substance or mixture which such person knew or had reason to know was manufactured, processed, or distributed in commerce in violation of section 5 or 6, or fail or refuse to establish or maintain records, submit reports or permit access to or copying of records as required by the Act, or to fail or refuse to permit entry or inspection as required by section 11.

SECTION 16 - PENALTIES

(a) Civil - Subsection (a) provides for civil penalties of up to $25,000 for each violation of the Act. A civil penalty for a violation of the Act shall be assessed by the Administrator by an order made on

the record after an opportunity for a hearing in accordance with section 554 of Title 5 of the United States Code.

(b) Criminal - Any person who knowingly or willfully violates the Act shall in addition to or in lieu of civil penalties be subject upon conviction to a fine of up to $25,000 for each day of violation or to imprisonment for not more than one year, or both.

SECTION 17 - SPECIFIC ENFORCEMENT AND SEIZURE

(a) Specific Enforcement - Subsection (a) grants jurisdiction to the United States District Courts to restrain any violation of the Act, to restrain any person from manufacturing or processing a chemica substance or mixture prior to the expiration of the period before which such manufacturing or processing is prohibited under section 5, to restrain any person from taking any action prohibited under section 5 or 6, or to compel the taking of any action required by this Act.

(b) Seizure - Any chemical substance, mixture, or article containing a substance or mixture which was manufactured, processed, or distributed in commerce in violation of the Act shall be subject to seizure and condemnation.

SECTION 18 - PREEMPTION

(a) Effect on State Law - If the Administrator requires testing of a chemical substance under section 4, no State or political subdivision may require testing of such substance or mixture for

a similar purpose. If the Administrator prohibits or limits the manufacture or a chemical substance or mixture or requires labeling of such substance or mixture under section 5 or 6, no State or political subdivision may establish or continue in effect a requirement different from the Federal requirement. However, a State or political subdivision may ban the use or distribution of such substance or mixture in its jurisdiction.

(b) Exemption - The Administrator may permit a State or political subdivision to put into effect a requirement differing from the Federal rule if the Administrator determines that compliance with the state requirement would not cause the substance, mixture, or article to be in violation of the Federal requirement and if the State political subdivision requirement provides a significantly higher degree of protection from the risk and does not through difficulties in marketing, distribution, or other factors, unduly burden commerce.

SECTION 19 - JUDICIAL REVIEW

(a) General - Section 19(a) provides for judicial review by the United States Court of Appeals of any rule promulgated by the Administrator under sections 4, 5, or 6. For purposes of review, the record shall include the rule, any transcript required at any oral presentation, any written submission of interested parties, and any other information which the Administrator considers to be relevant and with respect to which the Administrator has given public notice prior to the promulgation of such rule.

(b) Additional Data - The person seeking judicial review may be permitted by the Court to submit additional data, views, or arguments if the petitioner can show that there are reasonable grounds why such information was not presented in the proceeding before the Administrator.

(c) Authority and Review Standards - Subsection (c) requires that the findings or determinations required to be made in the promulgation of a rule be supported by substantial evidence on the record.

(d) Other Remedies - The remedies provided in this section shall be in addition to and not in lieu of any other remedies provided by the law.

SECTION 20 - CITIZEN'S CIVIL ACTION

(a) In General - Subsection (a) authorizes any person to commence a civil action to restrain violations of section 4, 5, or 6 or to compel the Administrator to perform a nondiscretionary act or duty.

(b) Limitation - Prior to bringing a civil action to restrain a violation of the Act, the person bringing the suit must give 60 days notice to the Administrator and to the person who is alleged to have committed the violation. If the Administrator has commenced and is prosecuting a civil action against an alleged violator, no citizen suit may be brought against such person. However, if the Administrator's action is not commenced until after the giving of

notice, the person who provided notice may intervene as a matter of right. Any person desiring to bring an action against the Administrator to compel the performance of a nondiscretionary duty must first give the Administrator 60 days notice of the alleged failure to perform an act or duty. In the case of an action involving an imminent hazard, the notification period is 10 days.

(c) General - The Administrator may intervene as a matter of right in any action under this section. The award of attorneys' fees and expert witnesses' fees is authorized.

(d) Consolidation - Subsection (d) provides for the consolidation of two or more civil actions brought under section 20 involving the same defendant and the same issues or violations.

SECTION 21 - CITIZENS' PETITIONS

(a) In General - Subsection (a) authorizes any person to petition the Administrator to issue a rule requiring testing of a chemical substance under section 4, listing a chemical substance under section 5(i), or banning or limiting the manufacture of a chemical substance or requiring labeling of such substance under section 6.

(b) Procedures - The petition must set forth the facts which allegedly establish that a rule is necessary. The Administrator must either grant or deny the petition within 120 days. If the Administrator denies the petition, the petitioner may bring a

civil action in a United States District Court to compel the Administrator to initiate the rulemaking proceeding requested.

SECTION 22 - NATIONAL DEFENSE WAIVER

Section 22 authorizes the Administrator to waive compliance with the Act upon request of the Secretary of Defense and a determination by the President that the waiver is necessary in the interest of national defense.

SECTION 23 - EMPLOYEE PROTECTION

(a) General - Section 23(a) prohibits any employer from discharging or discriminating against any employee because of the employee's cooperation in enforcing the Act.

(b) Remedy - Subsection (b) provides for a complaint, investigation, and hearing procedure in the event an employee believes that the employee has been subject to discrimination or discharge because of the employee's cooperation in enforcing the Act. If the Secretary of Labor determines that the employee has been wrongfully discharged or discriminated against, the Secretary shall order reinstatement of the employee as well as compensation, and where appropriate, exemplary damages.

(c) Review - Any person adversely affected by an order of the Secretary under this provision may seek judicial review of the order in a United States court of appeals.

(d) Enforcement - Subsection (d) provides for enforcement of an order of the Secretary in the United States district courts.

(e) Exclusion - The provisions of this section are not to apply to any employee who, acting without direction from the employer, deliberately causes a violation of any requirement of the Act.

SECTION 24 - STUDY

(a) Indemnification - The General Accounting Office is to conduct a study of all Federal laws administered by the Environmental Protection Agency to determine whether and under what conditions, if any, indemnification should be accorded any person as a result of action taken by the Administrator under such laws.

(b) Classification, Storage, and Retrieval Study - The Council on Environmental Quality is to coordinate a study of the feasibility of establishing a standard classification system for chemical substances and a standard means for storing and obtaining rapid access to information respecting such substances.

SECTION 25 - ADMINISTRATION OF ACT

(a) Cooperation of Federal Agencies - Subsection (a) authorizes each Federal agency to cooperate with the Administrator to assist the Administrator in carrying out the Act.

(b) Fees - Subsection (b) authorizes the Administrator to require payment of a reasonable fee from any person required to submit test data under section 4 or 5 to defray the costs of administering the Act.

(c) Action with Respect to Categories - Subsection (c) provides that any action which may be taken by the Administrator with respect

to a chemical substance or mixture may be taken with respect to a category of chemical substances or mixtures.

SECTION 26 - AUTHORIZATION FOR APPROPRIATIONS

(a) In General - Subsection (a) contains the following authorizations for appropriations for the Administrator to carry out the Act: for the Fiscal Year ending June 30, 1976, $11,100,000; for the transitional quarter ending September 30, 1976, $2,600,000; and for the Fiscal Year ending September 30, 1977, $10,100,000.

(b) Budget Requests - Whenever the Administrator submits any budget requests, estimates, legislative recommendations, prepared testimony for congressional hearings, or comments on legislation to the President or to the Office of Management and Budget, such information shall simultaneously be transmitted to the Congress.

SECTION 27 - ANNUAL REPORT

Section 27 requires the Administrator to report to the President and Congress annually regarding the administration of the Act.

FILE

EXECUTIVE OFFICE OF THE PRESIDENT
OFFICE OF MANAGEMENT AND BUDGET
WASHINGTON, D.C. 20503

March 11, 1976

Honorable James T. Broyhill
House of Representatives
Washington, D. C. 20515

Dear Mr. Broyhill:

Charlie Leppert of the White House Congressional Relations staff has asked me to provide you with the Administration's position on pending legislation to control toxic substances.

I am pleased to enclose a package of material which Director Lynn sent to Mr. Van Deerlin on February 9 in response to the Chairman's inquiry, which sets forth the Administration's views in some detail.

Please do not hesitate to let Charlie or me know if we can be of further assistance to you on this matter or any other matter.

With kind regards.

Sincerely yours,

Alan Kranowitz

Alan M. Kranowitz
Assistant to the Director
for Congressional Relations

Enclosures

cc: Mr. Leppert

GERALD R. FORD

EXECUTIVE OFFICE OF THE PRESIDENT
OFFICE OF MANAGEMENT AND BUDGET
WASHINGTON, D.C. 20503

FEB 9 1976

Honorable Lionel Van Deerlin
Chairman
Subcommittee on Consumer Protection
and Finance
Committee on Interstate and
Foreign Commerce
House of Representatives
Washington, D.C. 20515

Dear Mr. Chairman:

I am writing in response to your letter in which you, Mr. Eckhardt and Mr. Brodhead identified several potential issues related to the enactment of the Administration's proposals on toxic substances control legislation.

As you are aware, I informed Mr. McCollister on November 13 that the Administration would support the enactment of H.R. 7664 with some modifications. Since that time the Administration has developed amendments to H.R. 7664 which Administrator Train has forwarded to Chairman Staggers. A copy of Administrator Train's letter and our proposed amendments is enclosed. These amendments, which represent a coordinated Administration position, were developed with the participation of many concerned Federal departments and agencies.

Hopefully, after giving full consideration to our proposal, your concerns in respect to the administrative and reporting requirements of H.R. 7664 as amended will be alleviated. In our view, the workload brought about by our amendments will be considerably more manageable than that generated by other proposals.

The Administration urges the enactment of H.R. 7664 as amended since we believe it will provide all the necessary regulatory authority but will not unnecessarily burden either the regulating agency or the regulated industry. If I can provide any further assistance please let me know.

Sincerely yours,

James T. Lynn
Director

Attachments

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

FEB 5 1976

OFFICE OF THE
ADMINISTRATOR

Dear Mr. Chairman:

On November 13, 1975, Mr. James T. Lynn, Director, Office of Management of Budget advised Congressman McCollister of your Subcommittee on Consumer Protection and Finance that the Administration had reassessed its previous position with regard to the toxic substances control legislation and would support H.R. 7664 with some modification.

Enclosed are the Administration's proposed amendments for modifying H.R. 7664. The enclosure summarizes several of the more significant proposals to amend H.R. 7664 and contains all of the proposed amendments and a brief explanation of each.

These proposed amendments to H.R. 7664 were jointly developed with the other concerned Federal departments and agencies and represent the views of the Administration on the toxic substances control legislation.

With the favorable consideration of these proposed amendments we would urge the enactment of H.R. 7664.

Sincerely yours,

Russell E. Train

Russell E. Train
Administrator

Honorable Harley O. Staggers
Chairman, Committee on
Interstate and Foreign Commerce
House of Representatives
Washington, D.C. 20515

Enclosure

January 29, 1976

PROPOSED AMENDMENTS TO H.R. 7664, THE "TOXIC SUBSTANCES CONTROL ACT OF 1975" BY MR. MCCOLLISTER

Summarized below are several of the significant proposals to amend H.R. 7664. A number of other amendments have also been developed which would improve the effectiveness of the bill. All of the proposed amendments are set out and explained in the pages following this summary.

Definitions

We are proposing that the definition of "chemical substance" be amended to provide the Administrator with some flexibility to exclude, in appropriate situations, certain substances from the definitions and thus from the requirements of the Act or from particular provisions of the Act. It would be almost impossible to draft the bill to exempt certain substances from the Act or, as more likely the case, from certain provisions of the Act in each situation where such is appropriate. Scientific laboratory reagents are an example. Here it may very well be appropriate to exclude such products from the testing and regulatory provisions, but not necessarily the reporting and adverse effects provisions when they are used by certain research or scientific laboratories; on the other hand, we would not likely wish to exclude high school laboratories from any labeling requirements. An exclusion may also be in order for a substance not manufactured in commercial quantities. An excessive burden and inconvenience to the industry or the user would be averted with this flexibility in the Act.

Testing

There is a provision in the testing requirement of the bill that we foresee as an undue burden upon the Administrator. While we agree that provision should be made for the sharing of testing costs in the event that there is more than one manufacturer of a substance for which testing is required, we are very reluctant to become involved in designating which manufacturer (or possibly a third party) should conduct the tests if the parties cannot reach an agreement. We are therefore recommending deletion of the provisions authorizing the Administrator to designate which party should do the testing.

We are also proposing that the criterion by which the Administrator would require testing be revised so as to authorize the requirement when a chemical may pose an unreasonable risk to health or the environment, rather than when "necessary to protect

against unreasonable risk to health or the environment". When the latter positive situation occurs, presumably the Administrator would take action under section 6.

Premarket Notification

Section 5 of H.R. 7664 provides that within eighteen months after enactment of the Act the Administrator shall by rule compile a list of chemical substances (or chemical substances with respect to a particular use or uses) which the Administrator finds are likely to pose substantial danger to health or environment. Substantial danger to health or the environment is defined to mean an unreasonable risk of death, or widespread or severe personal injury or illness, or of widespread or severe harm to the environment. If a new chemical substance or a significant new use of a chemical substance is on the list, the Administrator would receive 90 days premarket notification from the manufacturer or processor. The substantial danger test above is so strict that it would place an impossible burden on the Administrator to know or predict in advance when such a new chemical or new use will come about, and any substance placed on the list would almost certainly be subject to the imminent hazard provisions of section 7 upon manufacture. We are proposing instead an "unreasonable risk" standard for promulgating the list. This would not have the defects outlined above and would focus premarket notification on harmful chemicals and not require notification on all new substances.

Quotas

An amendment is being proposed to the quota provisions of H.R. 7664 to provide cooperative action with the Secretary of Commerce where quotas have to be established. The Act provides that when it is necessary to adopt a rule with respect to a chemical substance to protect against an unreasonable risk, the Administrator shall select the least stringent requirement practicable consistent with protection of health and the environment. Restrictions limiting the amount of a substance that may be manufactured would be the most stringent requirement, other than a total ban, and the establishment of quotas would seldom be necessary. However, in the event quotas have to be established we recommend that the Secretary of Commerce be involved in setting them.

Economic Impact

H.R. 7664 would require that the Administrator consider a number of relevant factors in promulgating rules with respect to a chemical substance. We are proposing that a specific provision be added that he also must consider the economic

impact of such action, including, but not limited to, consideration of the effects on business, employment, and the national economy. Consideration of these factors is already inherent in the requirement that he consider all relevant factors. We suggest this amendment in lieu of the mandatory preparation of detailed economic impact statements at the time a regulation is promulgated and suggest the economic impact statement provision be deleted.

Reporting Initial Manufacture

We propose to amend the provisions requiring manufacturers, importers, and processors to make reports to the Administrator so as to give the Administrator the authority to require when appropriate that the manufacturer of a new chemical substance submit a report on that substance on the day its manufacture for commercial purposes begins. Only by this means will the Administrator be able to maintain a complete inventory of chemical substances. An inventory is necessary if the Administrator is to have any idea what chemicals are being marketed and which may need to be regulated.

Health and Safety Studies; Adverse Reactions

We are proposing that a provision be added to the reporting section requiring the submission of lists of health and safety studies. The amendment would require submission of lists of on-going and new studies, rather than the study, with a right to require the submission of a given study. It would authorize the Administrator to provide by regulation the types of studies to be included on the lists and the number of years for which prior studies must be listed. The amendment would also provide that a person would list studies which he knows are being made or have been made. We are also suggesting a provision be added to the reporting section requiring records of adverse reactions to human health or the environment be available for submission to the Administrator at his request.

Small Business Exemption

We recognize that there may be a need due to a financial burden for exempting some small businesses from some of the reporting requirements of the Act. At the same time, some businesses manufacture such toxic substances that they need to be regulated no matter how small they are. Therefore, we propose an amendment which provides the Administrator with authority to exempt a small business concern from the reporting provisions for reasons of undue financial burden but requires the report of initial manufacture and prohibits exemption where

a chemical substance may present an unreasonable risk to health or the environment, making it subject to sections 4(a) (testing), 5(a) (list of "risk" chemicals), or 6(a) (regulation of "risk" chemicals). The Administrator is required to consult with the Administrator of the Small Business Administration in defining "small business concern".

Relationship of Other Laws

The bill would in some instances provide authority to regulate toxic chemical substances which it may be possible to regulate under a law administered by another agency. When this occurs, there is the question of which authority should govern. We propose that authority not be exercised under section 6 (regulation of chemicals) and section 7 (imminent hazards) where action is more appropriate under the law of some other agency. Other agencies would be requested by the Administrator to determine if a risk is presented or is likely to be presented by a chemical substance or mixture, and if such risk can be prevented or reduced to a sufficient extent by actions under their law. The agencies would then either determine that the substance or mixture does not pose or is not likely to pose an unreasonable risk to health or the environment or initiate action to protect against such a risk.

Questions which could occur over the validity of actions taken under the Toxic Substances Control Act where other authorities exist would be avoided under this amendment.

Exemption from Federal Preemption

We do not recommend the provisions of H.R. 7664 which would allow State and local agencies to petition the Administrator for exemption from the Federal preemption requirements. State and local agencies would be allowed to regulate any toxic substance until such time as the Administrator puts into effect regulations for testing or restricting a substance. Thereafter, they could impose only a total ban on a substance. In view of the fact that the bill authorizes the Administrator to regulate with respect to geographic areas there would appear to be no need for a State or local agency to duplicate any regulations with respect to a substance after Federal regulations are in effect.

PROPOSED AMENDMENTS TO H.R. 7664, THE TOXIC SUBSTANCES CONTROL ACT

AUTHORITY TO EXEMPT IN DEFINITION

Page 4, line 2, delete the period after "mixture" and insert a semicolon and the following:

"Provided, however, the Administrator may by regulation exclude from this definition as it applies to this Act, or to any provision of this Act, certain categories of chemical substances, including laboratory reagents, catalysts, selected mixtures, and chemical substances not manufactured in commercial quantities."

Explanation. This amended definition of a "chemical substance" would provide the Administrator with flexibility to exclude, in appropriate cases, a substance from the requirements of the Act, or from a particular provision (not already excluded) where such substance does not need to be regulated, cannot be effectively regulated, or where meeting the requirements might be an undue burden.

NEW CHEMICAL SUBSTANCES

Page 4, after line 19, insert the following as paragraph (8) and renumber paragraph (8) as paragraph (9).

"(8) The term "new chemical substance" means any chemical substance not included in the inventory of chemical substances compiled and published under section 8(b)."

Explanation. H.R. 7664 needs to be modified to ensure that the Administrator may issue a requirement for reporting of "new chemical substances" at the time of manufacture. A "new chemical substance" can be defined by reference to the inventory of all existing chemical substances to be published by EPA according to section 8(b) as amended.

TESTING - SECTION 4

1. Standards for Test Protocols

a. Page 6, line 17, change title of section 4 to "STANDARDS FOR TEST PROTOCOLS"

Explanation. Conforming amendment (see Explanation in b. below).

b. Page 6, lines 18-25, delete all of subsection (a) and insert in lieu thereof the following:

"Section 4. (a). If the Administrator determines that-

(1) the manufacture, distribution in commerce, processing, use or disposal of a chemical substance may pose an unreasonable risk to health or the environment; and

(2) that testing such chemical substance is necessary to determine whether an unreasonable risk to human health and the environment does or does not exist; then he may, by rule, prescribe standards for a test protocol for such substance, and require, in accordance with subsection (d), that one or more persons formulate a test protocol for such substance in accordance with such standards, and perform the tests required by such protocol."

Explanation. If the Administrator could demonstrate that testing is "necessary to protect against unreasonable risk to health or the environment" (H.R. 7664), presumably he could take restrictive action under section 6. The revised section 4(a) is a far more appropriate determination for issuing a testing requirement in that it reflects the uncertainty of the risk that would prompt the Administrator to require testing.

The revised language permits the Administrator to prescribe the standards for a test protocol rather than the protocol itself, which would be developed by the affected manufacturer in accordance with the standards. The advantage is flexibility, in that the protocol can be more closely tailored to the chemical substance and the questions it poses; and through standards the Agency can require results of testing rather than specific testing methods.

In addition, instead of being required in each instance to follow narrowly defined procedures for testing, the industry should have the flexibility when appropriate to develop efficient test protocols in accordance with the Administrator's standards.

c. Page 7, line 9 to 14. Delete lines 9 to 14 and insert in lieu thereof the following:

"(3) the extent to which testing of such substance may result in the development of data upon which the effects of such substance or mixture on health or the environment can reasonably be determined or predicted;

(4) the existence of data concerning the effects of the chemical substance or mixture on health or the environment; and"

Explanation. These two amendments do not alter the intent of the original provisons but conform the language to the use of "standards for test protocols" instead of "test protocols."

d. Page 7, line 21. Delete line 21 through "tests" and substitute the following:

"(c) Standards for a test protocol may require that such protocol may include, but is not limited to, tests"

Explanation. It is necessary to make clear that standards for test protocols do not necessarily entail development of specific test protocols but rather methodologies or guidelines for development of test protocols. It is also necessary to make clear that the test protocol is not limited to those tests specifically named.

e. Additional conforming amendments to sections 5 and 8.

Page 11, line 14: delete "in accordance with a test protocol" and insert in lieu thereof "under a test protocol, in accordance with standards".

Page 11, line 15: insert a comma after "4".

Page 12, line 1: delete "in accordance with a test protocol" and insert in lieu thereof "under a test protocol, in accordance with standards".

Page 12, line 2: insert a comma after "4".

Page 12, line 11: insert "standards for a" after "applicable".

Page 12, line 12: delete "has" and insert in lieu thereof "have".

Page 12, lines 13 and 17-18: insert "standards for" before "a test protocol".

f. Additional conforming amendments to section 3, DEFINITIONS:

Page 5, lines 3-16, definition of "test protocol": delete the dash on line 3 and subparagraph heading "(A)" on line 4; delete the comma at the end of line 9 and insert in lieu thereof a period; and delete lines 10-16.

Page 4, line 23: insert a new paragraph after new paragraph (9) as follows and renumber subsequent paragraphs accordingly:

"(10) the term "standards for a test protocol" means standards prescribing the nature and quality of a test protocol, including:

(A) the manner in which test protocols are to be developed to determine the human health and environmental effects of a chemical substance,

(B) any analysis that is to be performed on test data developed, and

(C) any requirements to be met in the design of any test protocol necessary to insure the reliability and adequacy of test data developed."

2. Designating who should perform testing

Page 8, line 11, delete the last sentence in paragraph (d) beginning with "If" through line 21, and insert in lieu thereof:

"If such an arrangement is made the Administrator shall be notified and the remaining such persons shall be exempted from requirements to perform tests."

Explanation. We do not believe that the Administrator should become involved in designating which party (or a third party) should perform tests if the parties cannot agree among themselves. If a cost-sharing arrangement is made for one of the parties to do the testing, however, provision should be made to exempt the other parties from the testing requirements.

3. Timely submission of test data:

Page 8, line 22: delete section (e) and insert in lieu thereof:

"(e) Any manufacturer, processor, or importer who is required to perform the tests called for in a test protocol under this section shall promptly transmit to the Administrator the test data developed pursuant to such test protocol."

Explanation. This amendment will ensure that the test data shall be promptly transmitted to the Administrator after completion.

PREMARKET NOTIFICATION LIST

a. Page 10, line 1, Section title, after "SCREENING", delete remainder of section title.

b. Page 10, line 8, after "finds", delete remainder of paragraph through line 13, and add in lieu thereof the following:

"may pose an unreasonable risk to health or the environment."

c. Page 15, line 13, after "substances", delete "as likely to pose substantial danger" and add in lieu thereof "which may pose an unreasonable risk".

Explanation. The substantial danger test in the current provision is so strict that no substance would be placed on the list unless at the same time it was subject to regulations applicable to a Hazardous Chemical Substance under section 6 and an Imminent Hazard under section 7. The proposed "unreasonable risk" standard for the list would focus premarket notification on harmful chemicals and not require notification on all new substances.

AMENDMENTS TO SECTION 6--REGULATIONS

1. Assigning Quotas

Page 18, line 13, delete "uses, shall include provision for" and insert in lieu thereof "uses shall be prescribed by the Administrator in consultation with the Secretary of Commerce. The Secretary of Commerce in consultation with the Administrator shall by rule provide for".

Page 18, line 14, after "quotas" add "to the extent necessary".

Page 18, line 19 and 20, delete "The Administrator shall by rule prescribe criteria which" and insert "Such criteria".

Page 18, line 22, after "the" delete "market shares, productive capacity," and insert "current and past market shares, productive capacity, captive consumption,".

Explanation. This amendment is being proposed to the quotas provisions of H.R. 7664 to provide cooperative action with the Secretary of Commerce where quotas have to be established. The Act provides that when it is necessary to adopt a rule with respect to a chemical substance to protect against an unreasonable risk, the Administrator shall select the least stringent requirement practicable consistent with protection of health

and the environment. Restrictions limiting the amount of a substance that may be manufactured would be the most stringent requirement, other than a total ban, and the establishment of quotas would seldom be necessary. However, in the event quotas have to be established we recommend that the Secretary of Commerce be involved in setting them.

2. Economic Impact Analysis

Page 19, line 11: delete "and"; Page 19, line 13: delete the period and insert in lieu thereof: "; and"; Page 19, after line 13: add a new subparagraph 4 as follows:

"(4) the economic impact of such action, including but not limited to, consideration of effects on business, employment, and the national economy."

Page 21, line 21: delete all of subsection (g).

Explanation. This amendment would specifically require the Administrator to consider economic impact in promulgating regulations, already inherent in the requirement that he consider all relevant factors. This would be in lieu of the mandatory preparation of detailed economic impact statements for issuance at the time any regulation is required, which provision is deleted by the amendment.

AMENDMENTS TO SECTION 8, REPORTS

1. Reporting Initial Manufacture

a. Page 24, line 23, after "any" insert "person who is a".

b. Page 24, line 25 - page 25, line 1: delete "and at such more frequent time" and insert in lieu thereof "or such times".

Explanation. Authority should be provided in the legislation enabling the Administrator to learn of the existence of a new chemical substance as soon as manufacture begins. This is minimal authority, intended to inform him of the initiation of the manufacture of a new chemical substance. Therefore, the amendment authorizes the Administrator to require of a chemical manufacturer that he initially reports on the day on which manufacture of a new chemical begins and provides the other specified information. This amendment would also permit the reporting time in periods useful to the Administrator and geared to the different types of reports which he has authority to request. Such periods may be more or less frequent than one year.

2. Reporting Adulteration

Page 25, line 16: Between lines 16 and 17 insert a new subparagraph (E) as follows, and renumber subsequent subparagraphs accordingly:

"(E) Records pertaining to quality control procedures and adulteration as defined in subsection 6(e)."

Explanation. While subsection 6(e) authorizes the Administrator to require a manufacturer or processor to submit a description of quality control procedures, there should be additional authority to obtain records pertinent to such procedures, such as those demonstrating the procedures are being followed, and to incidents of adulteration.

3. Reporting Health and Safety Studies: Adverse Reactions

Page 25, line 1, after "require," insert "on any chemical substance manufactured, imported, or processed,".

Page 25, after line 21, insert the following:

"(G) Health and safety information, including:

(i) lists of health and safety studies in progress on or initiated after the date of enactment of this Act, conducted by or for such person, or known to such person;

(ii) lists of health and safety studies conducted by or for such person, or known to have been made by any person, prior to the date of enactment of this Act;

(iii) at the request of the Administrator, copies of any such studies appearing on a list submitted pursuant to paragraphs (i) or (ii), in the possession or control of such person.

(H) Records of adverse reactions to human health or the environment or adverse results in health and safety studies known or alleged to have been caused by the chemical substance. Such records may consist of, but not be limited to, consumer allegations of personal injury or harm to health, reports of occupational disease or injury, and reports of complaints of injury to the environment submitted to the person by individuals or governmental agencies. The Administrator may require copies of such records pursuant to his responsibilities under sections 4, 5, 6, and 7 of this Act."

Explanation. The proposed amendment would require the submission of lists of health and safety studies and would require

submission of lists of on-going and new studies rather than the study itself with a right to require the submission of a given study. It would authorize the Administrator to provide by regulation the types of studies to be included on the lists and the number of years for which prior studies must be listed. The amendment would provide that a person would list studies which he knows are being made or have been made. The amendment also provides that records of adverse reactions to human health or the environment be available for submission to the Administrator at his request.

4. Exemptions from Reporting Requirements

a. Page 24, lines 22 and 23: delete "Except as provided in subsections (b) and (c), the" and insert in lieu thereof "The".

b. Page 26, line 6: after line 6, insert a new paragraph (4) as follows:

"(4)(A) The Administrator may, by rule, exempt from or modify for any manufacturer, importer, or processor who is a small business concern all or part of the reporting requirements of this section where such requirements would cause an undue financial burden on such small business; provided, however, no exemption or modification shall be authorized until after the initial reporting is made under this section and such exemption or modification shall discontinue when there is a significant change in the amount of the substance manufactured, imported or processed from the amount last reported.

(B) No exemption or modification of reporting requirements shall be authorized under paragraph (4)(A) with respect to a chemical substance or an article containing such substance--

(i) for which a testing requirement has been prescribed under section 4(a) of this Act;

(ii) which is contained in the list of chemical substances which the Administrator has by rule identified and published in the Federal Register under section 5(a) of this Act; or

(iii) which is covered by a rule under section 6 of this Act.

(C) For purposes of this subsection the Administrator shall define a small business concern, in consultation with the Administrator of the Small Business Administration."

c. Page 27: Delete all of subsection (c) and renumber subsection (d) as (c).

Explanation. Subsection (b) of the existing H.R. 7664 is a small business reporting exemption provision. The amendment would eliminate that blanket exemption and provide that there is authority to exempt for reasons of undue financial burden. Subsection (c) of the existing H.R. 7664 requires the Administrator to make specified exemptions, an authority which is provided for in the amendment to the definition of "chemical substances" at page 4, line 2.

5. Inventory

a. Page 26, line 7, delete entire section (b) and insert in lieu thereof:

"(b) The Administrator shall compile, keep current, and publish an inventory of each chemical substance which any person reports under subsection (a) which is manufactured or processed in the United States. A chemical substance shall be included in such an inventory as of the earliest date (as determined by the Administrator) on which such substance was manufactured or processed in the United States."

Explanation. Such an inventory would be useful to the Administrator in conducting his responsibilities under the Act.

RELATIONSHIP TO OTHER LAWS

1. Page 28, after line 8: insert a new paragraph (2) as follows, and renumber subsequent paragraphs accordingly:

"(2) any source material, special nuclear material, or byproduct material as defined in the Atomic Energy Act of 1954 (42 USC 2011), as amended, and regulations issued pursuant thereto;"

Explanation. The amendment adds a class of materials to the exemption provision, as those materials are already adequately regulated under existing law.

2. Page 28, line 24: delete all of subsections (b), (c), and (d) and insert the following subsections in lieu thereof.

"(b) Laws Not Administered by the Administrator:

(1) If the Administrator has reason to believe that the manufacture, processing, distribution in commerce, use, or disposal of a chemical substance or mixture poses or may pose an unreasonable risk to health or the environment, and if such risk may be prevented or reduced by action taken under a law not administered by the Administrator, the Administrator shall request the agency which administers such law (A) to determine if there is such a risk and (B) if the agency determines that there is such risk to determine if such risk may be prevented or reduced to a sufficient extent by action taken under such law. Any such request shall be accompanied by a detailed statement of the information on which it is based. The agency receiving the request shall make the requested determination within such time as the Administrator specifies in the request, but such time specified may not be less than ninety days from the date the request was made. The report of an agency in response to a request made under this paragraph shall be accompanied by a detailed statement of the findings and conclusions of the agency respecting the determinations requested to be made.

(2) If the Administrator makes a request under paragraph (1) with respect to a chemical substance or mixture and the agency to which such request was made either--

(A) determines that such substance or mixture does not pose or is not likely to pose an unreasonable risk to health or the environment, or

(B) initiates, within the time specified in the request under paragraph (1) in response to such request, action under the law (or laws) administered by such agency to protect against such a risk,

the Administrator may not take any action under section 6 or 7 of this Act with respect to such substance or mixture.

(3) If the Administrator has initiated action under section 6 or 7 with respect to a chemical substance or mixture which was the subject of a request made to an agency under paragraph (1), such agency shall before taking action under the law (or laws) administered by it to protect against such risk to health or the environment associated with such substance or mixture consult with the Administrator for the purpose of avoiding duplication of Federal action against the risk.

(c) Laws Administered by the Administrator.--The Administrator shall coordinate actions taken under this Act with actions taken under other Federal laws administered in whole or in part by the Administrator. The Administrator shall use the authorities contained in such other Federal laws to protect against any risk to health or the environment associated with a chemical substance or mixture unless the Administrator determines that such risk may be more appropriately protected against under this Act. This subsection shall not be construed to relieve the Administrator of any requirement imposed on the Administrator by such other Federal laws.

(d) Occupational Safety and Health.--In exercising any authority under this Act, the Administrator shall not, for purposes of section 4(b)(1) of the Occupational Safety and Health Act of 1970, be deemed to be exercising statutory authority to prescribe or enforce standards or regulations affecting occupational safety and health.

(e) Coordination.--In administering this Act, the Administrator shall consult and coordinate with the Secretary of Health, Education, and Welfare and heads of any other appropriate Federal executive department or agency, any relevant independent

regulatory agency, and any other appropriate instrumentality of the Federal Government for the purpose of achieving the maximum enforcement of this Act while imposing the least burdens of duplication on those subject to the Act and for other purposes.

Explanation. The proposed amendment provides that the Administrator has no authority under section 6 (regulation of chemicals) and section 7 (imminent hazards) if the following occurs. Other agencies would be requested by the Administrator to determine if a risk is presented or is likely to be presented by a chemical substance or mixture, and if such risk can be prevented or reduced to a sufficient extent by actions under another law. The agencies would then either determine that the substance or mixture does not pose or is not likely to pose an unreasonable risk to health or the environment or initiate action within 90 days to protect against such a risk. H.R. 7664 could presently be interpreted so as to draw into question many regulatory actions that would be taken under the Toxic Substances Control Act. The commitment of resources and protracted delays which could result from litigation could undermine the implementation of this legislation and seriously detract from effective use of this authority to protect health and the environment.

ADVISORY PANELS

Page 30, line 9: delete all of section 10, Chemical Substances Board, and renumber subsequent sections accordingly.

Explanation: The section would add a substantial administrative step to a complicated regulatory procedure, in that all rules to be proposed under sections 4, 5, and 6 (except in two specified instances) would have to be presented to the Board for a scientific report.

There is, of course, a need for scientific advice. However EPA already has a Hazardous Materials Advisory Committee fully qualified and able to advise on matters pertaining to toxic substances. The Agency program office would be staffed with a substantial number of qualified scientists. As with the Agency's Pesticide Program, the Administrator would draw on the many outside sources of advice in order to assure his decisions were soundly based in scientific knowledge, but as a matter of course in the normal rule-making process. The academic community and such national groups as NAS, NSF, and NIH are sources presently relied upon. In addition, EPA will submit its draft regulations to other concerned agencies as a standard executive branch procedure to ensure adequate input both of a scientific and substantive nature.

INSPECTION OF RECORDS FOR REIMBURSEMENT FOR TESTING

Page 35 after line 2 insert new subsection (b) as follows and renumber existing subsections (b) and (c) accordingly:

"(b) Notwithstanding the provisions of subsection (a), the Administrator shall have authority to inspect financial data records pertaining to testing costs when he orders contribution or reimbursement for the costs of performing tests in connection with the provisions of section 5(f)."

Explanation. Section 5(f) authorizes the Administrator to determine the equitable contribution or reimbursement of testing costs where more than one person benefits from the testing. This amendment would authorize access to financial data on testing costs in order for the Administrator to carry out the requirement to apportion the costs among those benefiting from the testing.

DISCLOSURE OF CONFIDENTIAL INFORMATION

Page 40, line 14, delete entire section 15 and insert in lieu thereof the following revised section:

"CONFIDENTIALITY

Sec. 15. (a) GENERAL.--The use by any person to his own advantage, or revealing, other than to the Administrator or officers or employees of the Environmental Protection Agency who have a need to know for the performance of their official duties, or to officers or employees of another Federal agency who have a need to know for the performance of their official duties, or to the courts when relevant in any judicial proceeding under this Act any information acquired pursuant to this Act concerning trade secrets, information which is likely to cause substantial harm to the competitive position of the person submitting the information, or which would likely impair the Government's ability to obtain necessary information in the future is prohibited.

(b) DATA FROM HEALTH AND SAFETY STUDIES.--Subsection (a) does not prohibit the disclosure of--

(1) any health and safety study submitted under this Act with respect to--

(A) any chemical substance or mixture which on the date the study is to be disclosed has been offered for commercial distribution, or

(B) any chemical substance or mixture for which testing is required under section 4 or for which notification is required under section 5, and

(2) any data reported to, or otherwise obtained by the Administrator from such a study.

This subsection does not authorize the release of data which discloses processes used in the manufacturing or processing of a chemical substance or mixture, or proprietary formulations.

(c) RELEASE OF INFORMATION TO CONTRACTORS.--(1) Notwithstanding any limitation in subsection (a) such information may be disclosed to contractors with the United States and employees of such contractors if in the opinion of the Administrator such disclosure is necessary for the satisfactory performance by the contractor of a contract with the United States entered into on or after the effective date of this Act for the performance of work in connection with this Act.

(d) CRIMINAL PENALTY FOR WRONGFUL DISCLOSURE.--(1) Any officer or employee of the United States, or former officer or employee of the United States, who by possession of, or who has access to, material which is prohibited from release under subsection (a), and who knowing that disclosure of the specific material is prohibited by this section, willfully discloses the material in any manner to any person not entitled to receive it, shall be guilty of a misdemeanor and fined not more than $5,000.

(2) For the purpose of this subsection, any contractor with the United States and any employee of any such contractor who is furnished information pursuant to subsection (c)(1) shall be considered to be an employee of the United States.

Explanation. This section should be amended in several respects. This legislation requires substantial information to be submitted to the Government upon specific request of the Administrator. In addition, the legislation does not preclude voluntary submission of information prior to or after manufacture. If individuals are not assured that trade secret and confidential information as outlined in this section will not be released except to authorized individuals it is highly likely that information which the Agency could utilize would either be

difficult to obtain in a timely fashion and/or simply not available. It is important, however, that all information obtained pursuant to the Act be made available to contractors of the United States if such disclosure is necessary for the satisfactory performance of the contract. Since much of the Agency's workload undoubtedly will be contractual this provision is vital to the legislation's successful implementation.

ENVIRONMENTAL PREDICTION AND ASSESSMENT

Page 43, line 17 insert after "resources to" "predict and".

Explanation. The content of section 19 should reflect the intention of the title which is to permit EPA in association with other agencies to become involved in predicting and assessing the environmental consequences of the introduction of new chemical substances into the environment.

STATE EXEMPTION FROM FEDERAL PREEMPTION

Page 45, line 14, delete subsection (b).

Explanation. This amendment would delete the provision that would allow State and local governments to petition to be exempted from Federal preemption requirements.

JUDICIAL REVIEW

Page 47, line 10: delete "not"; line 11: insert "not" after "are".

Explanation: The amendment would provide that the Administrator's findings shall be affirmed unless not supported by the record. Thus, the person contesting the rules must show that the record does not support them, rather than this burden being on the Administrator.

NINETY-FOURTH CONGRESS
LIONEL VAN DEERLIN, CALIF., CHAIRMAN
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PHONE (202) 225-7190

Congress of the United States
House of Representatives
COMMITTEE ON INTERSTATE AND FOREIGN COMMERCE

SUBCOMMITTEE ON CONSUMER PROTECTION AND FINANCE
WASHINGTON, D.C. 20515

November 19, 1975

Mr. James T. Lynn
Director
Executive Office of the President
Office of Management and Budget
Washington, D. C. 20503

Dear Mr. Lynn:

Thank you for the copy of your November 13 letter to Representative John Y. McCollister regarding toxic substances control legislation. As the authors of H.R. 10318, we were surprised and concerned to learn that the Administration has changed its position regarding pre-market notification. This is especially true in light of the strong statements made by Administration witnesses during our hearings in which they recommended a notification provision similar to that included in our bill. The reversal of the Administration's position is of particular concern because of the absence of any new factual developments which would justify such a reversal.

We share your concern that the legislation, particularly the pre-market notification provision, not be overly burdensome either to the regulating agency or to the regulated industry. However, H.R. 7664 will not achieve your stated goal of reducing the regulatory workload of Government and the burden on manufacturers. Quite the contrary, as we illustrate below, section 5 of H.R. 7664 will place administrative and reporting burdens on both industry and the Environmental Protection Agency far in excess of the notification provision in H.R. 10318.

As you recognize in your letter, the success of the pre-market notification provision in H.R. 7664 is dependent upon the Administrator having adequate access to information under the reporting provisions of the bill. Realistically, information regarding every potential new chemical will have to be reported to the Administrator sufficiently far in advance

of commercial production so that the Administrator may determine whether the substance should be included on the pre-market notification list. In light of industry figures indicating that less than 15% of all chemicals produced on an experimental level are ever produced commercially, it is likely that manufacturers will be forced to submit, and the agency will be faced with the task of reviewing, reports on innumerable substances which will never be produced commercially.

The agency's difficult review job will be further compounded by the fact that much of the marketing and production information which could bear significantly on whether or not the substance could pose an unreasonable risk may not be available at the time of reporting. After reviewing the reports, the agency will then have to conduct a rulemaking proceeding to list those substances for which pre-market notification is to be required.

In review, the pre-market notification provisions of H.R. 7664 will involve the following steps: (1) issuance of rules under section 8 requiring reporting on all potential new chemical substances; (2) submission of reports by manufacturers regarding all potential new substances; (3) review of the reports by the Administrator; (4) issuance of rules under section 5 listing those substances for which pre-market notification will be required; and (6) pre-market notification of the listed chemicals ninety days prior to manufacture.

In contrast, H.R. 10318 merely requires notification of all new chemical substances ninety days in advance of commercial production. Since the Administrator will receive notification regarding only those substances which will be produced commercially, this could reduce by several the number of substances on which manufacturers will be required to report and which the Administrator will be required to review.

The notification provision of H.R. 10318 has the further advantage of insuring that the Administrator will receive information on all new chemical substances prior to their being manufactured commercially. Under the reporting and list concept of H.R. 7664, it is possible that a report regarding a substance could be submitted too late for the Administrator to take any action. Deputy Administrator John Quarles, in testifying before our subcommittee regarding the list concept, stated that it would be "highly unlikely that the Administrator would fortuitously

include all potentially hazardous new chemicals that are being contemplated by industry on the list. The possibility that there will be significant numbers of unidentified substances which are health and/or environmental threats seem to be compelling reasons for a comprehensive requirement for notification, as the Agency has recommended in the past." The statement is no less true now than when made by Mr. Quarles--whether or not it still represents Administration policy.

In light of the fact that the notification provisions of H.R. 7664 will result in imposing greater burdens on both industry and the Government while providing less effective protection for health and the environment, we recommend that the Administration again reassess its position regarding the legislation.

Sincerely,

Lionel Van Deerlin
Chairman

Bob Eckhardt

William M. Brodhead

THE WHITE HOUSE
WASHINGTON

5/12 --

in response to request by Jack Marsh, called Subctee. on Consumer Protection to find status of toxic substances bill.

Hearings held in Nov., and on 12/3/75 Subctee. marked up HR 10318, which includes provisions of 3 bills, including Mr. McCollister's (HR 7664).

Full ctee. will consider in May.

Janet

File

EXECUTIVE OFFICE OF THE PRESIDENT
OFFICE OF MANAGEMENT AND BUDGET
WASHINGTON, D.C. 20503

February 11, 1976

MEMORANDUM TO: VERN LOEN
CHARLIE LEPPERT
TOM LEOFFLER

FROM: ALAN M. KRANOWITZ AMK

RE: Toxic Substances

Attached is a memo which I sent to Max on toxic substances. The attachment I sent to Max was Senate-oriented; the attachment to this note relates to the House legislation.

Attachments

EXECUTIVE OFFICE OF THE PRESIDENT
OFFICE OF MANAGEMENT AND BUDGET
WASHINGTON, D.C. 20503

February 11, 1976

MEMORANDUM TO: MAX FRIEDERSDORF

FROM: ALAN M. KRANOWITZ AMK

RE: Toxic Substances

To date:

-- On the House side, all interested parties have been informed that the Administration supports the McCollister version of the bill, with some amendments. The amendments have been sent to all interested parties and the matter -- for the moment -- is on track.

-- On the Senate side, almost nothing has been done on the new Administration approach. EPA has gone only to Ted Stevens with the Administration package (the McCollister bill plus amendments) and Stevens has not yet made up his mind on whether or not he will introduce the Administration bill. EPA has talked to no one else. They feel that the Senate has come a long way from where they were two years ago on the subject and that there is no hope in trying to accomplish anything else on the Senate side, especially since mark-up in the full Commerce Committee will take place on Tuesday, February 17. They appear to feel that all of the eggs should be placed in the House basket.

OMB strongly disagrees with EPA:

-- While EPA is right about the House being the key player in this matter, it seems to me that we ought to make an effort on the Senate side. If we can clean up only one item in the Senate bill, that will make the job in Conference just a little bit easier.

Things to be done:

-- The Administration bill needs to be introduced Monday, preferably by a member of the Commerce Committee

(Pearson, Griffin, Buckley -- or Ted Stevens if he can be pushed into it). (Copies of the complete Administration bill are attached).

-- If there is an easy way to do it, it would be helpful to get the Commerce Committee mark-up put off for a couple of days. Given the current recess, a mark-up next Tuesday doesn't leave us too much time to work the bill.

-- Individual members of the Commerce Committee ought to be knowledgeable about the individual problems we have with the Senate version, because one member or another might well be willing to handle at least one issue in the mark-up session. Perhaps meetings could be scheduled for Thursday, Friday, or Monday with appropriate minority members or staff of the Commerce Committee. We could produce an OMB briefing team very quickly, perhaps with EPA participation.

After you kick this around with Bill and Joe, we stand ready to provide whatever assistance you desire.

Attachment

cc:
Bill Kendall
Joe Jenckes

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

FEB 5 1976

OFFICE OF THE
ADMINISTRATOR

Dear Mr. Chairman:

On November 13, 1975, Mr. James T. Lynn, Director, Office of Management of Budget advised Congressman McCollister of your Subcommittee on Consumer Protection and Finance that the Administration had reassessed its previous position with regard to the toxic substances control legislation and would support H.R. 7664 with some modification.

Enclosed are the Administration's proposed amendments for modifying H.R. 7664. The enclosure summarizes several of the more significant proposals to amend H.R. 7664 and contains all of the proposed amendments and a brief explanation of each.

These proposed amendments to H.R. 7664 were jointly developed with the other concerned Federal departments and agencies and represent the views of the Administration on the toxic substances control legislation.

With the favorable consideration of these proposed amendments we would urge the enactment of H.R. 7664.

Sincerely yours,

Russell E. Train

Russell E. Train
Administrator

Honorable Harley O. Staggers
Chairman, Committee on
Interstate and Foreign Commerce
House of Representatives
Washington, D.C. 20515

Enclosure

January 29, 1976

PROPOSED AMENDMENTS TO H.R. 7664, THE "TOXIC SUBSTANCES CONTROL ACT OF 1975" BY MR. MCCOLLISTER

Summarized below are several of the significant proposals to amend H.R. 7664. A number of other amendments have also been developed which would improve the effectiveness of the bill. All of the proposed amendments are set out and explained in the pages following this summary.

Definitions

We are proposing that the definition of "chemical substance" be amended to provide the Administrator with some flexibility to exclude, in appropriate situations, certain substances from the definitions and thus from the requirements of the Act or from particular provisions of the Act. It would be almost impossible to draft the bill to exempt certain substances from the Act or, as more likely the case, from certain provisions of the Act in each situation where such is appropriate. Scientific laboratory reagents are an example. Here it may very well be appropriate to exclude such products from the testing and regulatory provisions, but not necessarily the reporting and adverse effects provisions when they are used by certain research or scientific laboratories; on the other hand, we would not likely wish to exclude high school laboratories from any labeling requirements. An exclusion may also be in order for a substance not manufactured in commercial quantities. An excessive burden and inconvenience to the industry or the user would be averted with this flexibility in the Act.

Testing

There is a provision in the testing requirement of the bill that we foresee as an undue burden upon the Administrator. While we agree that provision should be made for the sharing of testing costs in the event that there is more than one manufacturer of a substance for which testing is required, we are very reluctant to become involved in designating which manufacturer (or possibly a third party) should conduct the tests if the parties cannot reach an agreement. We are therefore recommending deletion of the provisions authorizing the Administrator to designate which party should do the testing.

We are also proposing that the criterion by which the Administrator would require testing be revised so as to authorize the requirement when a chemical may pose an unreasonable risk to health or the environment, rather than when "necessary to protect

against unreasonable risk to health or the environment". When the latter positive situation occurs, presumably the Administrator would take action under section 6.

Premarket Notification

Section 5 of H.R. 7664 provides that within eighteen months after enactment of the Act the Administrator shall by rule compile a list of chemical substances (or chemical substances with respect to a particular use or uses) which the Administrator finds are likely to pose substantial danger to health or environment. Substantial danger to health or the environment is defined to mean an unreasonable risk of death, or widespread or severe personal injury or illness, or of widespread or severe harm to the environment. If a new chemical substance or a significant new use of a chemical substance is on the list, the Administrator would receive 90 days premarket notification from the manufacturer or processor. The substantial danger test above is so strict that it would place an impossible burden on the Administrator to know or predict in advance when such a new chemical or new use will come about, and any substance placed on the list would almost certainly be subject to the imminent hazard provisions of section 7 upon manufacture. We are proposing instead an "unreasonable risk" standard for promulgating the list. This would not have the defects outlined above and would focus premarket notification on harmful chemicals and not require notification on all new substances.

Quotas

An amendment is being proposed to the quota provisions of H.R. 7664 to provide cooperative action with the Secretary of Commerce where quotas have to be established. The Act provides that when it is necessary to adopt a rule with respect to a chemical substance to protect against an unreasonable risk, the Administrator shall select the least stringent requirement practicable consistent with protection of health and the environment. Restrictions limiting the amount of a substance that may be manufactured would be the most stringent requirement, other than a total ban, and the establishment of quotas would seldom be necessary. However, in the event quotas have to be established we recommend that the Secretary of Commerce be involved in setting them.

Economic Impact

H.R. 7664 would require that the Administrator consider a number of relevant factors in promulgating rules with respect to a chemical substance. We are proposing that a specific provision be added that he also must consider the economic

impact of such action, including, but not limited to, consideration of the effects on business, employment, and the national economy. Consideration of these factors is already inherent in the requirement that he consider all relevant factors. We suggest this amendment in lieu of the mandatory preparation of detailed economic impact statements at the time a regulation is promulgated and suggest the economic impact statement provision be deleted.

Reporting Initial Manufacture

We propose to amend the provisions requiring manufacturers, importers, and processors to make reports to the Administrator so as to give the Administrator the authority to require when appropriate that the manufacturer of a new chemical substance submit a report on that substance on the day its manufacture for commercial purposes begins. Only by this means will the Administrator be able to maintain a complete inventory of chemical substances. An inventory is necessary if the Administrator is to have any idea what chemicals are being marketed and which may need to be regulated.

Health and Safety Studies; Adverse Reactions

We are proposing that a provision be added to the reporting section requiring the submission of lists of health and safety studies. The amendment would require submission of lists of on-going and new studies, rather than the study, with a right to require the submission of a given study. It would authorize the Administrator to provide by regulation the types of studies to be included on the lists and the number of years for which prior studies must be listed. The amendment would also provide that a person would list studies which he knows are being made or have been made. We are also suggesting a provision be added to the reporting section requiring records of adverse reactions to human health or the environment be available for submission to the Administrator at his request.

Small Business Exemption

We recognize that there may be a need due to a financial burden for exempting some small businesses from some of the reporting requirements of the Act. At the same time, some businesses manufacture such toxic substances that they need to be regulated no matter how small they are. Therefore, we propose an amendment which provides the Administrator with authority to exempt a small business concern from the reporting provisions for reasons of undue financial burden but requires the report of initial manufacture and prohibits exemption where

a chemical substance may present an unreasonable risk to health or the environment, making it subject to sections 4(a) (testing), 5(a) (list of "risk" chemicals), or 6(a) (regulation of "risk" chemicals). The Administrator is required to consult with the Administrator of the Small Business Administration in defining "small business concern".

Relationship of Other Laws

The bill would in some instances provide authority to regulate toxic chemical substances which it may be possible to regulate under a law administered by another agency. When this occurs, there is the question of which authority should govern. We propose that authority not be exercised under section 6 (regulation of chemicals) and section 7 (imminent hazards) where action is more appropriate under the law of some other agency. Other agencies would be requested by the Administrator to determine if a risk is presented or is likely to be presented by a chemical substance or mixture, and if such risk can be prevented or reduced to a sufficient extent by actions under their law. The agencies would then either determine that the substance or mixture does not pose or is not likely to pose an unreasonable risk to health or the environment or initiate action to protect against such a risk.

Questions which could occur over the validity of actions taken under the Toxic Substances Control Act where other authorities exist would be avoided under this amendment.

Exemption from Federal Preemption

We do not recommend the provisions of H.R. 7664 which would allow State and local agencies to petition the Administrator for exemption from the Federal preemption requirements. State and local agencies would be allowed to regulate any toxic substance until such time as the Administrator puts into effect regulations for testing or restricting a substance. Thereafter, they could impose only a total ban on a substance. In view of the fact that the bill authorizes the Administrator to regulate with respect to geographic areas there would appear to be no need for a State or local agency to duplicate any regulations with respect to a substance after Federal regulations are in effect.

PROPOSED AMENDMENTS TO H.R. 7664, THE TOXIC SUBSTANCES CONTROL ACT

AUTHORITY TO EXEMPT IN DEFINITION

Page 4, line 2, delete the period after "mixture" and insert a semicolon and the following:

"Provided, however, the Administrator may by regulation exclude from this definition as it applies to this Act, or to any provision of this Act, certain categories of chemical substances, including laboratory reagents, catalysts, selected mixtures, and chemical substances not manufactured in commercial quantities."

Explanation. This amended definition of a "chemical substance" would provide the Administrator with flexibility to exclude, in appropriate cases, a substance from the requirements of the Act, or from a particular provision (not already excluded) where such substance does not need to be regulated, cannot be effectively regulated, or where meeting the requirements might be an undue burden.

NEW CHEMICAL SUBSTANCES

Page 4, after line 19, insert the following as paragraph (8) and renumber paragraph (8) as paragraph (9).

"(8) The term "new chemical substance" means any chemical substance not included in the inventory of chemical substances compiled and published under section 8(b)."

Explanation. H.R. 7664 needs to be modified to ensure that the Administrator may issue a requirement for reporting of "new chemical substances" at the time of manufacture. A "new chemical substance" can be defined by reference to the inventory of all existing chemical substances to be published by EPA according to section 8(b) as amended.

TESTING - SECTION 4

1. Standards for Test Protocols

a. Page 6, line 17, change title of section 4 to "STANDARDS FOR TEST PROTOCOLS"

Explanation. Conforming amendment (see Explanation in b. below).

b. Page 6, lines 18-25, delete all of subsection (a) and insert in lieu thereof the following:

"Section 4. (a). If the Administrator determines that-

(1) the manufacture, distribution in commerce, processing, use or disposal of a chemical substance may pose an unreasonable risk to health or the environment; and

(2) that testing such chemical substance is necessary to determine whether an unreasonable risk to human health and the environment does or does not exist; then he may, by rule, prescribe standards for a test protocol for such substance, and require, in accordance with subsection (d), that one or more persons formulate a test protocol for such substance in accordance with such standards, and perform the tests required by such protocol."

Explanation. If the Administrator could demonstrate that testing is "necessary to protect against unreasonable risk to health or the environment" (H.R. 7664), presumably he could take restrictive action under section 6. The revised section 4(a) is a far more appropriate determination for issuing a testing requirement in that it reflects the uncertainty of the risk that would prompt the Administrator to require testing.

The revised language permits the Administrator to prescribe the standards for a test protocol rather than the protocol itself, which would be developed by the affected manufacturer in accordance with the standards. The advantage is flexibility, in that the protocol can be more closely tailored to the chemical substance and the questions it poses; and through standards the Agency can require results of testing rather than specific testing methods.

In addition, instead of being required in each instance to follow narrowly defined procedures for testing, the industry should have the flexibility when appropriate to develop efficient test protocols in accordance with the Administrator's standards.

c. Page 7, line 9 to 14. Delete lines 9 to 14 and insert in lieu thereof the following:

"(3) the extent to which testing of such substance may result in the development of data upon which the effects of such substance or mixture on health or the environment can reasonably be determined or predicted;

(4) the existence of data concerning the effects of the chemical substance or mixture on health or the environment; and"

Explanation. These two amendments do not alter the intent of the original provisons but conform the language to the use of "standards for test protocols" instead of "test protocols."

d. Page 7, line 21. Delete line 21 through "tests" and substitute the following:

"(c) Standards for a test protocol may require that such protocol may include, but is not limited to, tests"

Explanation. It is necessary to make clear that standards for test protocols do not necessarily entail development of specific test protocols but rather methodologies or guidelines for development of test protocols. It is also necessary to make clear that the test protocol is not limited to those tests specifically named.

e. Additional conforming amendments to sections 5 and 8.

Page 11, line 14: delete "in accordance with a test protocol" and insert in lieu thereof "under a test protocol, in accordance with standards".

Page 11, line 15: insert a comma after "4".

Page 12, line 1: delete "in accordance with a test protocol" and insert in lieu thereof "under a test protocol, in accordance with standards".

Page 12, line 2: insert a comma after "4".

Page 12, line 11: insert "standards for a" after "applicable".

Page 12, line 12: delete "has" and insert in lieu thereof "have".

Page 12, lines 13 and 17-18: insert "standards for" before "a test protocol".

f. Additional conforming amendments to section 3, DEFINITIONS:

Page 5, lines 3-16, definition of "test protocol": delete the dash on line 3 and subparagraph heading "(A)" on line 4; delete the comma at the end of line 9 and insert in lieu thereof a period; and delete lines 10-16.

Page 4, line 23: insert a new paragraph after new paragraph (9) as follows and renumber subsequent paragraphs accordingly:

"(10) the term "standards for a test protocol" means standards prescribing the nature and quality of a test protocol, including:

(A) the manner in which test protocols are to be developed to determine the human health and environmental effects of a chemical substance,

(B) any analysis that is to be performed on test data developed, and

(C) any requirements to be met in the design of any test protocol necessary to insure the reliability and adequacy of test data developed."

2. Designating who should perform testing

Page 8, line 11, delete the last sentence in paragraph (d) beginning with "If" through line 21, and insert in lieu thereof:

"If such an arrangement is made the Administrator shall be notified and the remaining such persons shall be exempted from requirements to perform tests."

Explanation. We do not believe that the Administrator should become involved in designating which party (or a third party) should perform tests if the parties cannot agree among themselves. If a cost-sharing arrangement is made for one of the parties to do the testing, however, provision should be made to exempt the other parties from the testing requirements.

3. Timely submission of test data:

Page 8, line 22: delete section (e) and insert in lieu thereof:

"(e) Any manufacturer, processor, or importer who is required to perform the tests called for in a test protocol under this section shall promptly transmit to the Administrator the test data developed pursuant to such test protocol."

Explanation. This amendment will ensure that the test data shall be promptly transmitted to the Administrator after completion.

PREMARKET NOTIFICATION LIST

a. Page 10, line 1, Section title, after "SCREENING", delete remainder of section title.

b. Page 10, line 8, after "finds", delete remainder of paragraph through line 13, and add in lieu thereof the following:

"may pose an unreasonable risk to health or the environment."

c. Page 15, line 13, after "substances", delete "as likely to pose substantial danger" and add in lieu thereof "which may pose an unreasonable risk".

Explanation. The substantial danger test in the current provision is so strict that no substance would be placed on the list unless at the same time it was subject to regulations applicable to a Hazardous Chemical Substance under section 6 and an Imminent Hazard under section 7. The proposed "unreasonable risk" standard for the list would focus premarket notification on harmful chemicals and not require notification on all new substances.

AMENDMENTS TO SECTION 6--REGULATIONS

1. Assigning Quotas

Page 18, line 13, delete "uses, shall include provision for" and insert in lieu thereof "uses shall be prescribed by the Administrator in consultation with the Secretary of Commerce. The Secretary of Commerce in consultation with the Administrator shall by rule provide for".

Page 18, line 14, after "quotas" add "to the extent necessary".

Page 18, line 19 and 20, delete "The Administrator shall by rule prescribe criteria which" and insert "Such criteria".

Page 18, line 22, after "the" delete "market shares, productive capacity," and insert "current and past market shares, productive capacity, captive consumption,".

Explanation. This amendment is being proposed to the quotas provisions of H.R. 7664 to provide cooperative action with the Secretary of Commerce where quotas have to be established. The Act provides that when it is necessary to adopt a rule with respect to a chemical substance to protect against an unreasonable risk, the Administrator shall select the least stringent requirement practicable consistent with protection of health

and the environment. Restrictions limiting the amount of a substance that may be manufactured would be the most stringent requirement, other than a total ban, and the establishment of quotas would seldom be necessary. However, in the event quotas have to be established we recommend that the Secretary of Commerce be involved in setting them.

2. Economic Impact Analysis

Page 19, line 11: delete "and"; Page 19, line 13: delete the period and insert in lieu thereof: "; and"; Page 19, after line 13: add a new subparagraph 4 as follows:

"(4) the economic impact of such action, including but not limited to, consideration of effects on business, employment, and the national economy."

Page 21, line 21: delete all of subsection (g).

Explanation. This amendment would specifically require the Administrator to consider economic impact in promulgating regulations, already inherent in the requirement that he consider all relevant factors. This would be in lieu of the mandatory preparation of detailed economic impact statements for issuance at the time any regulation is required, which provision is deleted by the amendment.

AMENDMENTS TO SECTION 8, REPORTS

1. Reporting Initial Manufacture

a. Page 24, line 23, after "any" insert "person who is a".

b. Page 24, line 25 - page 25, line 1: delete "and at such more frequent time" and insert in lieu thereof "or such times".

Explanation. Authority should be provided in the legislation enabling the Administrator to learn of the existence of a new chemical substance as soon as manufacture begins. This is minimal authority, intended to inform him of the initiation of the manufacture of a new chemical substance. Therefore, the amendment authorizes the Administrator to require of a chemical manufacturer that he initially reports on the day on which manufacture of a new chemical begins and provides the other specified information. This amendment would also permit the reporting time in periods useful to the Administrator and geared to the different types of reports which he has authority to request. Such periods may be more or less frequent than one year.

2. Reporting Adulteration

Page 25, line 16: Between lines 16 and 17 insert a new subparagraph (E) as follows, and renumber subsequent subparagraphs accordingly:

"(E) Records pertaining to quality control procedures and adulteration as defined in subsection 6(e)."

Explanation. While subsection 6(e) authorizes the Administrator to require a manufacturer or processor to submit a description of quality control procedures, there should be additional authority to obtain records pertinent to such procedures, such as those demonstrating the procedures are being followed, and to incidents of adulteration.

3. Reporting Health and Safety Studies: Adverse Reactions

Page 25, line 1, after "require," insert "on any chemical substance manufactured, imported, or processed,".

Page 25, after line 21, insert the following:

"(G) Health and safety information, including:

(i) lists of health and safety studies in progress on or initiated after the date of enactment of this Act, conducted by or for such person, or known to such person;

(ii) lists of health and safety studies conducted by or for such person, or known to have been made by any person, prior to the date of enactment of this Act;

(iii) at the request of the Administrator, copies of any such studies appearing on a list submitted pursuant to paragraphs (i) or (ii), in the possession or control of such person.

(H) Records of adverse reactions to human health or the environment or adverse results in health and safety studies known or alleged to have been caused by the chemical substance. Such records may consist of, but not be limited to, consumer allegations of personal injury or harm to health, reports of occupational disease or injury, and reports of complaints of injury to the environment submitted to the person by individuals or governmental agencies. The Administrator may require copies of such records pursuant to his responsibilities under sections 4, 5, 6, and 7 of this Act."

Explanation. The proposed amendment would require the submission of lists of health and safety studies and would require

submission of lists of on-going and new studies rather than the study itself with a right to require the submission of a given study. It would authorize the Administrator to provide by regulation the types of studies to be included on the lists and the number of years for which prior studies must be listed. The amendment would provide that a person would list studies which he knows are being made or have been made. The amendment also provides that records of adverse reactions to human health or the environment be available for submission to the Administrator at his request.

4. Exemptions from Reporting Requirements

a. Page 24, lines 22 and 23: delete "Except as provided in subsections (b) and (c), the" and insert in lieu thereof "The".

b. Page 26, line 6: after line 6, insert a new paragraph (4) as follows:

"(4)(A) The Administrator may, by rule, exempt from or modify for any manufacturer, importer, or processor who is a small business concern all or part of the reporting requirements of this section where such requirements would cause an undue financial burden on such small business; provided, however, no exemption or modification shall be authorized until after the initial reporting is made under this section and such exemption or modification shall discontinue when there is a significant change in the amount of the substance manufactured, imported or processed from the amount last reported.

(B) No exemption or modification of reporting requirements shall be authorized under paragraph (4)(A) with respect to a chemical substance or an article containing such substance--

(i) for which a testing requirement has been prescribed under section 4(a) of this Act;

(ii) which is contained in the list of chemical substances which the Administrator has by rule identified and published in the Federal Register under section 5(a) of this Act; or

(iii) which is covered by a rule under section 6 of this Act.

(C) For purposes of this subsection the Administrator shall define a small business concern, in consultation with the Administrator of the Small Business Administration."

c. Page 27: Delete all of subsection (c) and renumber subsection (d) as (c).

Explanation. Subsection (b) of the existing H.R. 7664 is a small business reporting exemption provision. The amendment would eliminate that blanket exemption and provide that there is authority to exempt for reasons of undue financial burden. Subsection (c) of the existing H.R. 7664 requires the Administrator to make specified exemptions, an authority which is provided for in the amendment to the definition of "chemical substances" at page 4, line 2.

5. Inventory

a. Page 26, line 7, delete entire section (b) and insert in lieu thereof:

"(b) The Administrator shall compile, keep current, and publish an inventory of each chemical substance which any person reports under subsection (a) which is manufactured or processed in the United States. A chemical substance shall be included in such an inventory as of the earliest date (as determined by the Administrator) on which such substance was manufactured or processed in the United States."

Explanation. Such an inventory would be useful to the Administrator in conducting his responsibilities under the Act.

RELATIONSHIP TO OTHER LAWS

1. Page 28, after line 8: insert a new paragraph (2) as follows, and renumber subsequent paragraphs accordingly:

"(2) any source material, special nuclear material, or byproduct material as defined in the Atomic Energy Act of 1954 (42 USC 2011), as amended, and regulations issued pursuant thereto;"

Explanation. The amendment adds a class of materials to the exemption provision, as those materials are already adequately regulated under existing law.

2. Page 28, line 24: delete all of subsections (b), (c), and (d) and insert the following subsections in lieu thereof.

"(b) Laws Not Administered by the Administrator:

(1) If the Administrator has reason to believe that the manufacture, processing, distribution in commerce, use, or disposal of a chemical substance or mixture poses or may pose an unreasonable risk to health or the environment, and if such risk may be prevented or reduced by action taken under a law not administered by the Administrator, the Administrator shall request the agency which administers such law (A) to determine if there is such a risk and (B) if the agency determines that there is such risk to determine if such risk may be prevented or reduced to a sufficient extent by action taken under such law. Any such request shall be accompanied by a detailed statement of the information on which it is based. The agency receiving the request shall make the requested determination within such time as the Administrator specifies in the request, but such time specified may not be less than ninety days from the date the request was made. The report of an agency in response to a request made under this paragraph shall be accompanied by a detailed statement of the findings and conclusions of the agency respecting the determinations requested to be made.

(2) If the Administrator makes a request under paragraph (1) with respect to a chemical substance or mixture and the agency to which such request was made either--

(A) determines that such substance or mixture does not pose or is not likely to pose an unreasonable risk to health or the environment, or

(B) initiates, within the time specified in the request under paragraph (1) in response to such request, action under the law (or laws) administered by such agency to protect against such a risk,

the Administrator may not take any action under section 6 or 7 of this Act with respect to such substance or mixture.

(3) If the Administrator has initiated action under section 6 or 7 with respect to a chemical substance or mixture which was the subject of a request made to an agency under paragraph (1), such agency shall before taking action under the law (or laws) administered by it to protect against such risk to health or the environment associated with such substance or mixture consult with the Administrator for the purpose of avoiding duplication of Federal action against the risk.

(c) Laws Administered by the Administrator.--The Administrator shall coordinate actions taken under this Act with actions taken under other Federal laws administered in whole or in part by the Administrator. The Administrator shall use the authorities contained in such other Federal laws to protect against any risk to health or the environment associated with a chemical substance or mixture unless the Administrator determines that such risk may be more appropriately protected against under this Act. This subsection shall not be construed to relieve the Administrator of any requirement imposed on the Administrator by such other Federal laws.

(d) Occupational Safety and Health.--In exercising any authority under this Act, the Administrator shall not, for purposes of section 4(b)(1) of the Occupational Safety and Health Act of 1970, be deemed to be exercising statutory authority to prescribe or enforce standards or regulations affecting occupational safety and health.

(e) Coordination.--In administering this Act, the Administrator shall consult and coordinate with the Secretary of Health, Education, and Welfare and heads of any other appropriate Federal executive department or agency, any relevant independent

regulatory agency, and any other appropriate instrumentality of the Federal Government for the purpose of achieving the maximum enforcement of this Act while imposing the least burdens of duplication on those subject to the Act and for other purposes.

Explanation. The proposed amendment provides that the Administrator has no authority under section 6 (regulation of chemicals) and section 7 (imminent hazards) if the following occurs. Other agencies would be requested by the Administrator to determine if a risk is presented or is likely to be presented by a chemical substance or mixture, and if such risk can be prevented or reduced to a sufficient extent by actions under another law. The agencies would then either determine that the substance or mixture does not pose or is not likely to pose an unreasonable risk to health or the environment or initiate action within 90 days to protect against such a risk. H.R. 7664 could presently be interpreted so as to draw into question many regulatory actions that would be taken under the Toxic Substances Control Act. The commitment of resources and protracted delays which could result from litigation could undermine the implementation of this legislation and seriously detract from effective use of this authority to protect health and the environment.

ADVISORY PANELS

Page 30, line 9: delete all of section 10, Chemical Substances Board, and renumber subsequent sections accordingly.

Explanation: The section would add a substantial administrative step to a complicated regulatory procedure, in that all rules to be proposed under sections 4, 5, and 6 (except in two specified instances) would have to be presented to the Board for a scientific report.

There is, of course, a need for scientific advice. However EPA already has a Hazardous Materials Advisory Committee fully qualified and able to advise on matters pertaining to toxic substances. The Agency program office would be staffed with a substantial number of qualified scientists. As with the Agency's Pesticide Program, the Administrator would draw on the many outside sources of advice in order to assure his decisions were soundly based in scientific knowledge, but as a matter of course in the normal rule-making process. The academic community and such national groups as NAS, NSF, and NIH are sources presently relied upon. In addition, EPA will submit its draft regulations to other concerned agencies as a standard executive branch procedure to ensure adequate input both of a scientific and substantive nature.

INSPECTION OF RECORDS FOR REIMBURSEMENT FOR TESTING

Page 35 after line 2 insert new subsection (b) as follows and renumber existing subsections (b) and (c) accordingly:

"(b) Notwithstanding the provisions of subsection (a), the Administrator shall have authority to inspect financial data records pertaining to testing costs when he orders contribution or reimbursement for the costs of performing tests in connection with the provisions of section 5(f)."

Explanation. Section 5(f) authorizes the Administrator to determine the equitable contribution or reimbursement of testing costs where more than one person benefits from the testing. This amendment would authorize access to financial data on testing costs in order for the Administrator to carry out the requirement to apportion the costs among those benefiting from the testing.

DISCLOSURE OF CONFIDENTIAL INFORMATION

Page 40, line 14, delete entire section 15 and insert in lieu thereof the following revised section:

"CONFIDENTIALITY

Sec. 15. (a) GENERAL.--The use by any person to his own advantage, or revealing, other than to the Administrator or officers or employees of the Environmental Protection Agency who have a need to know for the performance of their official duties, or to officers or employees of another Federal agency who have a need to know for the performance of their official duties, or to the courts when relevant in any judicial proceeding under this Act any information acquired pursuant to this Act concerning trade secrets, information which is likely to cause substantial harm to the competitive position of the person submitting the information, or which would likely impair the Government's ability to obtain necessary information in the future is prohibited.

(b) DATA FROM HEALTH AND SAFETY STUDIES.--Subsection (a) does not prohibit the disclosure of--

(1) any health and safety study submitted under this Act with respect to--

(A) any chemical substance or mixture which on the date the study is to be disclosed has been offered for commercial distribution, or

(B) any chemical substance or mixture for which testing is required under section 4 or for which notification is required under section 5, and

(2) any data reported to, or otherwise obtained by the Administrator from such a study.

This subsection does not authorize the release of data which discloses processes used in the manufacturing or processing of a chemical substance or mixture, or proprietary formulations.

(c) RELEASE OF INFORMATION TO CONTRACTORS.--(1) Notwithstanding any limitation in subsection (a) such information may be disclosed to contractors with the United States and employees of such contractors if in the opinion of the Administrator such disclosure is necessary for the satisfactory performance by the contractor of a contract with the United States entered into on or after the effective date of this Act for the performance of work in connection with this Act.

(d) CRIMINAL PENALTY FOR WRONGFUL DISCLOSURE.--(1) Any officer or employee of the United States, or former officer or employee of the United States, who by possession of, or who has access to, material which is prohibited from release under subsection (a), and who knowing that disclosure of the specific material is prohibited by this section, willfully discloses the material in any manner to any person not entitled to receive it, shall be guilty of a misdemeanor and fined not more than $5,000.

(2) For the purpose of this subsection, any contractor with the United States and any employee of any such contractor who is furnished information pursuant to subsection (c)(1) shall be considered to be an employee of the United States.

Explanation. This section should be amended in several respects. This legislation requires substantial information to be submitted to the Government upon specific request of the Administrator. In addition, the legislation does not preclude voluntary submission of information prior to or after manufacture. If individuals are not assured that trade secret and confidential information as outlined in this section will not be released except to authorized individuals it is highly likely that information which the Agency could utilize would either be

difficult to obtain in a timely fashion and/or simply not available. It is important, however, that all information obtained pursuant to the Act be made available to contractors of the United States if such disclosure is necessary for the satisfactory performance of the contract. Since much of the Agency's workload undoubtedly will be contractual this provision is vital to the legislation's successful implementation.

ENVIRONMENTAL PREDICTION AND ASSESSMENT

Page 43, line 17 insert after "resources to" "predict and".

Explanation. The content of section 19 should reflect the intention of the title which is to permit EPA in association with other agencies to become involved in predicting and assessing the environmental consequences of the introduction of new chemical substances into the environment.

STATE EXEMPTION FROM FEDERAL PREEMPTION

Page 45, line 14, delete subsection (b).

Explanation. This amendment would delete the provision that would allow State and local governments to petition to be exempted from Federal preemption requirements.

JUDICIAL REVIEW

Page 47, line 10: delete "not"; line 11: insert "not" after "are".

Explanation: The amendment would provide that the Administrator's findings shall be affirmed unless not supported by the record. Thus, the person contesting the rules must show that the record does not support them, rather than this burden being on the Administrator.

FOR IMMEDIATE RELEASE October 12, 1976

Office of the White House Press Secretary

THE WHITE HOUSE

STATEMENT BY THE PRESIDENT

I have signed S. 3149, the "Toxic Substances Control Act." I believe this legislation may be one of the most important pieces of environmental legislation that has been enacted by the Congress.

This toxic substances control legislation provides broad authority to regulate any of the tens of thousands of chemicals in commerce. Only a few of these chemicals have been tested for their long-term effects on human health or the environment. Through the testing and reporting requirements of the law, our understanding of these chemicals should be greatly enhanced. If a chemical is found to present a danger to health or the environment, appropriate regulatory action can be taken before it is too late to undo the damage.

The legislation provides that the Federal Government through the Environmental Protection Agency may require the testing of selected new chemicals prior to their production to determine if they will pose a risk to health or the environment. Manufacturers of all selected new chemicals will be required to notify the Agency at least 90 days before commencing commercial production. The Agency may promulgate regulations or go into court to restrict the production or use of a chemical or to even ban it if such drastic action is necessary.

The bill closes a gap in our current array of laws to protect the health of our people and the environment. The Clean Air Act and the Water Pollution Control Act protect the air and water from toxic contaminants. The Food and Drug Act and the Safe Drinking Water Act are used to protect the food we eat and the water we drink against hazardous contaminants. Other provisions of existing laws protect the health and the environment against other polluting contaminants such as pesticides and radiation. However, none of the existing statutes provide comprehensive protection.

This bill provides broad discretionary authority to protect the health and environment. It is critical, however, that the legislation be administered in a manner so as not to duplicate existing regulatory and enforcement authorities.

In addition, I am certain that the Environmental Protection Agency realizes that it must carefully exercise its discretionary authority so as to minimize the regulatory burden consistent with the effective protection of the health and environment.

The Administration, the majority and minority members of the Congress, the chemical industry, labor, consumer, environmental and other groups all have contributed to the bill as it has finally been enacted. It is a strong bill and will be administered in a way which focuses on the most critical environmental problems not covered by existing legislation while not overburdening either the regulatory agency, the regulated industry, or the American people.

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FOR IMMEDIATE RELEASE OCTOBER 12, 1976

Office of the White House Press Secretary

THE WHITE HOUSE

FACT SHEET

S. 3149 - THE TOXIC SUBSTANCES CONTROL ACT

The President today signed S. 3149 - The Toxic Substances Control Act. This Act provides, for the first time, comprehensive authority for the Federal Government to regulate all substances or the use of all substances that may produce toxic effects.

HIGHLIGHTS

This new law will better enable us to minimize the risk of unknown hazards to health of the environment from toxic substances while permitting us to continue to reap the benefits which these substances can contribute.

The bill contains some 53 pages of intricate regulatory material.

Generally speaking, the bill gives authority to the EPA Administrator to:

-- require private industry to provide test data and supply detailed information on specified substances;

-- prevent, or place limitations on, the marketing of new substances which the Administrator believes harmful; and,

-- ban or limit continued marketing of existing substances.

The Toxic Substances Control Act is designed to prevent problems. By allowing early and selective regulation of only those uses that are likely to be hazardous, the Act minimized adverse regulatory impacts on the chemical industry. In addition, this preventative approach should help reduce the need for regulations under other laws which hurt important industries such as fishing, food processing, and the many other manufacturers who rely on chemical products.

BACKGROUND

New chemical substances are being formulated rapidly and new commercial applications are being found almost daily. The production of metals, metal compounds and synthetic organics, which has been growing at a rate of 10 to 15% over the past 20 years, will continue to provide many new benefits to our society. For example, organic chemicals, which can be tailored in structure and properties to fit almost any imaginable need, are being used in ever-increasing quantities to produce dyes, pigments, flavors, perfumes, plastics, rubber products, detergents, pharmaceuticals, and so on. Yet, substances which in some applications have been extremely useful have been found in other applications to cause unanticipated and undesirable side effects on the environment and human health. Examples are vinyl chloride, polychlorinated and polybrominated biphenyls, kepone, fluorocarbons, and lead.

more

There presently exists a number of statutory authorities to regulate toxic substances. Among these are the:

-- Federal Food, Drug, and Cosmetic Act which regulates substances which are used as foods, drugs, or cosmetics;

-- Occupational Safety and Health Act which regulates contact with substances in the work place;

-- Consumer Product Safety Act regulates dangers from consumer products;

-- Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) which regulates substances used as pesticides;

-- Safe Drinking Water Act which regulates the level of toxic substances that can be present in drinking water supplies;

-- The Federal Water Pollution Control Act provides for State and Federal regulation over industrial discharges of toxic pollutants into the Nation's waters.

However, there are certain important gaps in the regulatory framework. For example, there is presently no effective way to regulate PCB's until and unless their dispersion into the environment affects water supply. This type of situation would be subject to control under various provisions of the bill.

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