The original documents are located in Box 26, folder "Predators (4)" of the James M. Cannon Files at the Gerald R. Ford Presidential Library.

7/18/75 WH Answer Rec 9:45 a.m.

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

Office of the Deputy Administrator

7/17

Jim

Coyotes

Here is a memo on the Toxic substances bill as you requested yesterday. I believe the issue did go to President Ford through an issues memo from Jim Lynn before Russ Train's

testimony in favor of the bill (with qualifications).

John Scarlett

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

SUBJECT: Toxic Substances Control Legislation DATE: JUL 17 1975

FROM: John R. Quarles, Jr.
Deputy Administrator

TO: Mr. James Cannon
Domestic Council

The Administration submitted toxic substances control legislation to the 92nd and 93rd Congresses and the legislation passed both Houses of Congress each time. The Administration's Toxic Substances Control Act was one of the major bills in the Administration's extensive original environmental package submitted to the 92nd Congress in February 1971. In the 92nd Congress there was not sufficient time to convene a conference after it passed; in the 93rd while ample time was available, the conferees were unable to work out an agreed-upon bill.

EPA proposed to submit the previous Administration bill to the 94th Congress; however, before interagency clearance was obtained on the bill, a bill (S. 776) had been introduced in the Senate and hearings held on it. Administration witnesses testified in support of toxic substances legislation and indicated that the Administration would support the Senate bill, S. 776, if it were amended as would be suggested in the report to be submitted on the bill. An interagency group composed of representatives of OMB, EPA, DOC, DOL, and HEW met a number of times and worked out detailed Administration comments and amendments on the Senate bill. These comments and amendments have been sent to the respective Senate and House Committees advising that with the favorable consideration of the proposed amendments we would urge enactment of the toxic substances legislation. A copy of the report and suggested amendments are attached.

In general the toxic substances legislation as supported by the Administration provide the following:

1. The Administrator of EPA would be authorized to issue regulations restricting or prohibiting the use or distribution of hazardous chemical substances.

2. Regulations could be issued prescribing standards for testing chemical substances and the submission of test results.

3. Pre-market notification would be required in advance of the manufacture of any new chemical substance, or of any significant new use of an existing chemical substance.

The legislation did not get enacted in the last two Congresses primarily because of the failure of agreement on the premarket notification and screening provisions and on the requirements as to when existing Federal laws should be used (such as the Clean Air Act, the Federal Water Pollution Control Act) to regulate toxic substances or when the Toxic Substances Control Act should be used. Another controversial provision and highly objectionable to the Administration would require concurrent submission of EPA budget requests, testimony, and legislative proposals to the Congressional Committees at the time of their submission to OMB.

Differing provisions on the above issues are contained in various versions of the several bills before the Congress--S. 776, H.R. 7229, H.R. 7548, and H.R. 7664. How to handle these issues is causing the respective Committees some problems in working out this legislation.

The comments and amendments on S. 776, attached, outline the Administration's position on the legislation. Briefly, with respect to the main issues, the Administration recommends premarket notification on all new chemicals and significant new uses of existing chemicals; that premarket screening be implemented under the imminent hazard provision and limited to substances which may pose an imminent hazard; that other Federal laws such as the Clean Air Act and the Federal Water Pollution Control Act be used to regulate toxic hazards when such are adequate but that the Toxic Substances Control Act be used if more appropriate as determined by the Administrator of EPA.

Finally, the comments on the legislation to the Congressional Committees indicate that EPA remains in accord with the President's stated policy of holding new spending to an absolute minimum and that the legislation could be implemented within the amount ($8 million) already requested in the President's budget, inasmuch as budget requests for toxic substances control the past several years anticipated that the legislation would be enacted by now.

Russ Train at the Senate hearing on March 10, and I at the House hearing last week urged the enactment of the legislation subject to the favorable consideration of the proposed amendments of the Administration. I further indicated, in response to questioning, that if the Congress passed a bill containing objectionable provisions to the Administration, it would certainly invite a veto, and something that we did not wish to see considering the need for the legislation and all the effort which has gone into developing it.

Attachments

TOXIC SUBSTANCES CONTROL ACT BILLS

S. 776 - (Tunney Bill)

H.R. 7229 - (Eckhardt Bill)

H.R. 7548 - (Brodhead Bill)

H.R. 7664 - (McCollister Bill)

All of these toxic substances control bills have the same general thrust and all evolved from the 1971 Administration bill. Many provisions of each are identical or similar.

The Tunney bill, S. 776, most nearly reflects the Administration position and with the amendments suggested to the Committee it would reflect the EPA and the Administration's position.

The Eckhardt bill, H.R. 7229, closely parallels the Tunney bill and practically all the amendments we proposed to the Senate bill apply to H.R. 7229. The list provision limiting the premarket notification provision is the most significant problem with the Eckhardt bill. The list provision is not in the Senate bill and thus not addressed in our comments. Our House testimony does address and oppose it.

The Brodhead bill, H.R. 7548, said to reflect substantial input from some environmental groups, is overly restrictive with respect to its testing and premarket notification and screening requirements to the point that they are almost equivalent to premarket clearance of chemical substances as required for pesticides; and its relationship with other Federal laws is wide open with no guidelines as to which law should be used. The EPA comments on the Senate bill otherwise generally apply to the Brodhead bill.

The McCollister bill, H.R. 7664, generally reflects the House bill as it passed in the last Congress. The list concept for premarket notification and screening and the use of other Federal laws are our greatest problems with it. The EPA comments on the Tunney bill generally apply.

ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

JUN 23 1975

OFFICE OF THE
ADMINISTRATOR

Dear Mr. Chairman:

This is in response to your request of March 6, 1975, for the views of the Environmental Protection Agency on S. 776, the "Toxic Substances Control Act."

We are in accord with the objectives of S. 776 and the general approach taken in the bill to control toxic substances. As we testified before your Subcommittee on the Environment on March 10, 1975, the bill contains the authorities which we believe are essential for effective toxic substances control legislation. We urged the enactment of toxic substances control legislation and indicated that we would have suggestions on some of the specific provisions of S. 776 when we submitted our report.

We note that S. 776 contains significant improvements over some of the toxic substances control bills that have been before the Committee the past four years. Many of these improvements are consistent with past EPA recommendations. It is not our intention in our report by concentrating on suggested revisions to the bill to detract from or fail to recognize the effort and improvements already evident in S. 776.

We have already stated in our testimony our objection to the provision that would preclude the Administrator from forwarding any budget estimates, legislative proposals, comments on legislation, or testimony to the Office of Management and Budget prior to the transmission of these same materials to the Congress. We also stated in our testimony that to designate by statute the specific responsibility of an Assistant Administrator may tend to create a problem of internal management.

We will discuss below a number of additional areas in S. 776 where we have particular problems and where we believe amendments are in order. These proposed amendments are set out in an attachment to this letter along with a number of important additional amendments and brief explanations of each. We urge that all of these amendments be favorably considered by the Committee.

This report on S. 776, including the attached proposed amendments were jointly developed with the other concerned Federal departments and agencies and represents the views of the Administration on S. 776.

Policy of Administration

We are proposing that the 'Declaration of Policy' section of the bill include recognition of the role of this legislation in complementing and supplementing a number of present Federal programs that deal with various aspects of toxic substance control. We are also proposing that the general requirement of the bill for consultation and coordination make specific reference to this policy statement. Such amendments would be of great assistance in the day to day administration of this legislation, both by assuring due regard for the responsibilities of other agencies, and by helping to establish the atmosphere of cooperation and interchange which is vital to the successful operation of comprehensive toxic substances legislation.

In line with this policy, and because of the special role of the Occupational Safety and Health Act of 1970 in providing workers with protection from unsafe or unhealthful working conditions which may be created through the manufacture, distribution or use of toxic substances, we are also proposing some language for the bill and some language for the Committee report to assure that there will be no question about the respective regulatory jurisdictions of EPA and the Department of Labor.

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 bills 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 necessary. 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.

We anticipate that the Administrator would exercise his discretion to exclude from the definition of chemical substances most substances manufactured in less than commercial quantities for the purpose of testing. Thus, most substances manufactured in less than commercial quantities would be exempt from the testing provisions of the bill. The proposed amendment would however enable EPA to require testing in those cases where the potential threat to health and the environment showed such testing to be necessary.

We are also proposing to add to the Act a definition for a "new chemical substance." This is necessary in order that chemical substances which were used in previous years for some purpose, and such use discontinued, do not become classified as existing chemicals, and thus exempt from certain requirements relating to new substances.

Testing

The testing provisions provide that standards for test protocols would be promulgated, rather than the test protocol itself. Testing would be required only for substances which the Administrator determines may present an unreasonable risk to health or the environment, where there are insufficient data to conclude that such a risk does or does not exist, and where testing would assist in making such a determination.

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.

A further amendment we are proposing with regard to the testing provisions is a specific requirement that the Administrator must consider alternative methods for meeting the standards for test protocols proposed by a manufacturer, such as one that might be less costly or more effective. This would ensure that industry is allowed to use the best test protocols in meeting the testing standards.

Premarket Screening

We are proposing an amendment which will delete the authority in the bill to treat a rule proposed under section 6 during the premarket review period of a product as a final rule. Thus a chemical substance or product may be manufactured and distributed after the premarket review period unless a restriction is obtained under the imminent hazard provision of the Act. The substance or product, however, remains subject to all other provisions of the Act and a rule proposing restrictions on the substance or product may be proposed immediately during the premarket review period under section 6 and the rule making proceedings initiated at that time.

If it appears that the manufacture, processing, or distribution of a chemical substance or product will result in any unreasonable threat to human health or the environment prior to the completion of the rule making proceedings, action may be taken to restrict or ban it under the imminent hazard provisions of the bill, thus preventing it from becoming a threat to health or the environment.

Quotas

Another difficulty we have with S. 776 concerns the requirement that the Administrator provide for the assignment of quotas in any regulation limiting the amount of a substance which may be manufactured, imported, or distributed. The mandatory requirement of a quota system would make the regulatory process vastly more cumbersome and difficult to administer. Thus, we recommend that the quota provision be deleted. The Act already 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. In our view, 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. Nevertheless, we strongly recommend against becoming involved in the establishment of quotas for various manufacturers, even in such limited situations.

Economic Impact

S. 776 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 are already inherent in the requirement that he consider all relevant factors. This amendment is submitted in lieu of other proposals that have already been made for the mandatory preparation of detailed economic impact statements at the time a regulation is promulgated.

Health and Safety Studies

We are proposing a revision of the requirement for the submission of health and safety studies, or lists of such studies, in order to provide some flexibility in this requirement. This should lessen the burden to industry in compiling the lists or submitting the studies, and to EPA in not being overburdened with information it does not need or cannot effectively use. 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.

Confidential Information

We are recommending that the confidentiality provision, section 15 of S. 776, be amended in several respects. First, the substantive criterion for withholding data as confidential should be the test established by the Freedom of Information Act, 5 U.S.C. 552(b)(4). Our proposed amendment would have the effect of requiring nondisclosure of information obtained under the Toxic Substances Control Act which may be withheld under 5 U.S.C. 552(b)(4), i.e., "trade secrets and commercial or financial information obtained from a person and privileged or confidential." This will make the confidentiality standard more definite (because there exists a body of case law interpreting 5 U.S.C. 552(b)(4)), and will promote uniformity.

In addition to the exemption for disclosure to Federal officers and employees, a separate provision should allow disclosure to EPA contractors and their employees, under appropriate safeguards and after appropriate EPA findings that disclosure is necessary. EPA accomplishes a great deal of its investigatory and analytical tasks by contract. If contractors are not allowed access to information under this bill, EPA could not perform its duties satisfactorily without substantial manpower increases. The recently-enacted Privacy Act, 5 U.S.C. 552a, provides that, for purposes of the section of the Privacy Act which imposes penalties on Government employees for wrongful use or disclosure of information entitled to confidentiality, Government contractors and their employees are to be considered Goverment employees (5 U.S.C. 552a(m)). We recommend inclusion of such a provision in the toxic substances bill. Our proposed amendments allow disclosure to contractors, and include a penalty for wrongful disclosure of information by Government employees (including contractors and their employees).

We also believe that the provisions relating to qualified scientists and individual names are not necessary. The term "qualified scientists" would be difficult to interpret, and in any event a scientist would have no greater rights under the subsection than would any person under our (proposed) basic confidentiality criterion. We believe that the Federal Privacy Act and the Freedom of Information Act provide ample protection of the rights of individuals whose names appear in health and safety records.

Finally, with regard to access of information by Congress, we believe that such confidential information should be made available upon written request.

Exemption from Federal Preemption

We do not recommend the provisions of S. 776 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.

Interagency Cooperation and Coordination

Several amendments are being proposed to the Act to provide for the maximum cooperation and coordination among the several agencies of the Federal Goverment which have programs and responsibilities concerned with toxic substances. These amendments also would clarify that the Act is intended to complement and supplement existing laws and regulations such as the occupational health and safety requirements.

A number of Federal agencies, particularly the Department of Health, Education, and Welfare and the Occupational Health and Safety Administration of the Department of Labor have extensive responsibilities relating to toxic substances and human health and would stand to benefit from various provisions of the Act. For example, test results and other data generated in this area would, of course, be valuable to them and should be made available to all agencies concerned.

We are also recommending that the provision contained in previous bills before the Congress directing the Council on Environmental Quality to coordinate a study on the feasibility of establishing a standard classification system for chemical compounds and means of obtaining rapid access to information on such substances be restored to the Act. This section provides CEQ the lead in establishing information systems in a manner currently being initiated. This is being done in conjunction with the agencies that would have been represented on the interagency committee as set out in the provision proposed to be deleted.

Appropriations

We wish to make clear that our budget requests over the past several years have included funds to handle work anticipated to be required under toxic substances legislation, in the expectation that it would by now have been a reality. Consequently, considerable ground work has been laid and we anticipate that activities during fiscal year 1976 can be met within the $8 million requested in the President's budget. Furthermore, we would point out that EPA wishes to remain in accord with the President's stated policy of holding new spending to an absolute minimum. Consequently we would point out that the authorization levels in S. 776 are in excess of amounts required to implement its provisions.

We have outlined above in our letter a number of the proposed amendments to the Act which we consider important; the attachment contains both these and additional amendments which we believe are of equal importance. We strongly believe that the adoption of these amendments would improve and strengthen the legislation and enable EPA to protect the health and the environment to the greatest practical extent while at the same time relieving the industry as well as the Government of some burdensome requirements.

With the favorable consideration of these proposed amendments, we would urge the enactment of S. 776.

My staff and I stand ready to assist your Committee in any way possible.

We are advised by the Office of Management and Budget that there is no objection to the submission of this report from the standpoint of the program of the President.

Sincerely yours,

John Quarles

John R. Quarles, Jr.
Acting Administrator

Honorable Warren G. Magnuson
Chairman, Committee on Commerce
United States Senate
Washington, D.C. 20510

Enclosure

TOXIC SUBSTANCES CONTROL ACT

PROPOSED AMENDMENTS BY EPA AND OTHER FEDERAL AGENCIES TO S. 776

1. DEFINITIONS

a. Page 4, lines 1 and 2, delete the language "or in some other way suitable for formation of a group for the purposes of this Act".

Explanation. This amendment would delete the open-ended authority to designate almost any grouping as a "category of chemical substances".

b. Page 4, line 5, delete paragraph (3) and insert new paragraph (3).

"(3) 'Chemical substance' means any chemical substance which (A) has an organic or inorganic particular molecular identify; (B) is any combined or uncombined radical or element; or (C) is any mixture; 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 such as scientific laboratory reagents and samples, or 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, substances from the requirements of the Act, or a particular provision, where it does not need to be regulated, cannot be effectively regulated, or where meeting the requirements might be an undue burden. Scientific laboratory reagents, samples, and other chemical substances manufactured in less than commercial quantities are examples.

We urge the following language be included in the committee report with respect to this definition:

> "Chemical substance would be defined to permit the Administrator the flexibility to provide by regulation for exempting chemical substances in certain categories or in less than commercial quantities from certain provisions of the bill. With respect to those chemical substances, it is anticipated that the Administrator will exercise his discretion to exclude, and thereby exempt, most of them from the testing provisions of the bill. The Administrator retains the authority to require testing in those cases where he finds a potential threat to health and the environment which indicates that such testing is necessary."

c. Page 5, line 2, delete the period and insert a semicolon after "studies" and delete remainder of paragraph; and on line 12, delete "study" and insert "study, including health and safety data developed pursuant to such study,".

Explanation. Correspondence relating to alleged adverse effects on health and similar reports are already required to be maintained in the section 8(d) regarding records, and an amendment is proposed to authorize the Administrator to require submission of such records. There is no need to include unconfirmed complaints and notices in the definition of health and safety data and confusion results when this is attempted. It is also proposed to specifically provide that a health and safety "study" includes health and safety data developed pursuant to such a study.

d. Page 6, insert after line 14 the following and renumber other paragraphs accordingly.

"(15) 'new chemical substance' means any chemical substance which has not been manufactured or imported in commercial quantities into the United States during the 18-month period immediately prior to the effective date of this Act, regardless of its commercial production or importation in the United States prior to such time."

Explanation. A definition of "new chemical substance" is necessary in order that chemical substances that were used in prior years and were discontinued do not become classified as existing chemicals for purposes of the Act.

2. TESTING

a. Page 9, after line 8, insert new paragraph (4) as follows:

"(4) The Administrator will consider alternative methods for meeting the standards for test protocols proposed by any person or governmental entity which is a manufacturer, processor, or importer of such chemical substance."

Explanation. This amendment would specifically direct the Administrator to consider alternative methods for meeting the standards for test protocols proposed by a manufacturer, such as less costly or more effective test protocols.

b. Page 9, line 14, delete the last two sentences in paragraph (1) beginning with "If", 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.

c. Page 11, line 15, insert after "arguments," the following:

"and permit cross-examination to such extent and in such manner as in his discretion he determines is necessary and appropriate in view of the nature of the issue involved, the number of the participants and the nature of the interests of such participants,".

Explanation. This amendment would permit limited cross-examination as is provided in the section 6 rule-making procedures to restrict toxic chemicals.

3. PREMARKET SCREENING; IMMINENT HAZARD

a. Page 12, line 3, after "substance" add the following sentence:

"Subsequent submission or request for submission of additional information shall not be regarded as changing the date of such notice."

Page 13, line 4, delete entire subsection (c); on line 25, delete beginning with "Unless" through "90 days" on line 2, page 14, and insert in lieu thereof "Ninety days"; renumber following subsections accordingly.

Page 14, line 10, after "substance" insert "before or"

Page 22, line 13, after "environment," insert "that should be corrected immediately, and".

Explanation. These amendments will delete the authority in the bill to treat a rule proposed under section 6 during the premarket review period of a product as a final rule.

Thus a chemical substance or product may be manufactured and distributed after the premarket review period unless a restriction is obtained under the imminent hazard provision of the Act. The substance or product, however, remains subject to all other provisions of the Act and a rule proposing restrictions on the substance or product may be proposed immediately during the premarket review period under section 6 and the rule-making proceedings initiated at that time.

If it appears that the manufacture, processing, or distribution of a chemical substance or product will result in any unreasonable threat to human health or the environment prior to the completion of the rule-making proceedings, action may be taken to restrict or ban it under the imminent hazard provisions of the bill, thus preventing it from becoming a threat to health or the environment.

The other amendments would clarify the date premarket notice commences, that restrictive rules under section 6 may be promulgated before or after manufacture or distribution of a substance, and that an imminent hazard is a risk that should be corrected immediately.

4. RESTRICTIONS ON HAZARDOUS CHEMICAL SUBSTANCES

a. Page 17, line 23, delete "condition" and insert in lieu thereof "circumstances", and insert the following language in the committee report with respect to section 6 of the bill:

> "The provisions of section 6 of S. 776 provide EPA with regulatory authority which will complement and supplement existing authority to control hazardous substances but not to preempt authority already vested by statute in other Federal departments or agencies. Proposed new section 9(b) would preclude EPA from taking action under sections 6 and 7 which the Secretary of Labor could take under the Occupational Safety and Health Act. Thus, for example, the Administrator of EPA could not, under section 6(a)(3) require that a substance be labeled so as to prescribe requirements for its safe and healthful

use which apply solely to workers in their place of employment. The Department of Labor, pursuant to the Occupational Safety and Health Act of 1970, already has authority to prescribe safe and healthful working conditions. Similarly, section 6(b)(2) shall not be construed to allow the Administrator of EPA to establish occupational safety and health standards."

Explanation. The clarification to paragraph 6(a)(2), together with the addition of legislative history with respect to paragraphs 6(a)(3) and 6(b)(2), will assist in implementation of the bill's policy to "complement and supplement" existing authority. These changes will assist in avoiding overlap between EPA and the Department of Labor's workplace safety and health authority.

b. Page 18, line 17, page 20, line 23, page 21, lines 6 and 12, delete "adulterated" (or "adulteration") and insert in lieu thereof "contaminated" (or "contamination").

Explanation. We believe that the term "contaminated" (or "contamination") would more clearly express the intent of these provisions instead of "adulterated" which is often understood or defined as an intentional act.

c. Page 19, line 11, delete entire paragraph (3).

Explanation. We believe that the Administrator should not become involved in assigning quotas to industry. The mandatory requirement of a quota system would make the regulatory process vastly more cumbersome and difficult to administer. The Act already 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 the health and the environment. It is expected that the establishment of quotas would seldom, if ever, be necessary as such would be a most stringent requirement. Nevertheless, we strongly recommend against becoming involved in the establishment of quotas.

d. Page 20, after line 15, insert the following:

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

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 proposals that have been made for the mandatory preparation of detailed economic impact statements for issuance at the time any regulation is promulgated.

5. SUITS BY U. S. ATTORNEYS INSTEAD OF BY ADMINISTRATOR

Page 22, line 17, delete all after "may" through "so,", line 19 and insert in lieu thereof:

"request a United States Attorney to petition an appropriate district court of the United States"

Page 39, line 3, delete "Administrator or the".

Page 46, line 7, delete "Administrator (or Attorney General on his behalf)" and insert in lieu thereof "Attorney General".

Page 46, line 8, after "commenced" delete "and is diligently prosecuting" on lines 8 and 9.

Explanation. These amendments would carry out the long-time policy of having the Justice Department responsible for litigation instead of each Agency. In the citizen suit provisions, we believe that it is sufficient if the Attorney General has commenced an action and that it is not necessary to impose a further requirement that he be diligently prosecuting it, a concept which is at best difficult to litigate and at worst could lead to counter-productive court action.

6. SUBMISSION OF RECORDS; HEALTH AND SAFETY STUDIES

a. Page 25, line 3, add at end of sentence:

"The Administrator may require copies of such records pursuant to his responsibilities under sections 4, 5, 6, and 7 of this Act."

Explanation. While the bill provides that records of adverse health effects caused by chemical substances are required to be maintained, no provision is made to require submission of such records. This amendment would correct that omission.

b. Page 25, line 4, delete subsection (e) and insert in lieu thereof:

"(e) Health and Safety Studies. The Administrator shall promulgate regulations under which he may require any person who manufactures, processes, or distributes in commerce any chemical substance (or with respect to paragraph (3), any person who has possession of a study) to submit to him--

(1) 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;

(2) 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;

(3) copies of any such studies appearing on a list submitted pursuant to paragraphs (1) or (2), or otherwise known by him."

Explanation. This amendment would revise the provision requiring industry to report on or submit all health and safety studies. It would require submission of lists of on-going and new studies rather than the study, with a right to require submission of studies. It would authorize the

Administrator to provide by regulation for the types of studies to be included on the lists, and the number of years of prior studies for particular types of studies; and would require a person to also list studies which he knows are being made or have been made.

7. ADDITIONAL EXEMPTIONS; ADDITIONAL LIMITATION ON AUTHORITY

a. Page 26, line 8, delete "or"; line 10, after "Act)" insert a comma and add "cosmetics (as such term is defined in section 201(i) of the Federal Food, Drug, and Cosmetic Act),"; line 18, replace the period with a semicolon, and add the following:

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

"(4) tobacco and tobacco products."

Explanation. We believe that cosmetics should also be exempted and materials regulated under the AEC Act, and do not believe that tobacco and tobacco products should be regulated under the Toxic Substances Control Act.

b. Page 26, after line 18, add new subsection (b) as follows, and renumber other subsections accordingly:

"(b) Notwithstanding any provision of this Act, the Administrator shall have no authority under sections 6 and 7 of this Act to take any action which the Secretary of Labor is authorized to take pursuant to the Occupational Safety and Health Act. In exercising authority pursuant to this Act, the Administrator shall not, for the purposes of applying section 4(b)(1) of the Occupational Safety and Health Act, be deemed to be exercising statutory authority to prescribe or enforce standards or regulations affecting occupational safety and health."

Explanation. The purpose of these changes is to eliminate the possibility of jurisdictional conflicts between EPA and the Department of Labor where actions taken by one authority might otherwise preclude or duplicate action of the other.

8. INTERAGENCY COOPERATION AND COORDINATION

Page 3, after line 17, add the following new paragraph:

"(5) such authority over chemicals be exercised in such a manner as to complement and supplement existing Federal policies, regulations, and public laws regarding the protection of health and the environment, including occupational health, consumer safety, food, drug, and cosmetic authorities."

Page 28, line 3, delete the sentence after "coordination.--" and insert in lieu thereof

"In administering the provisions of this Act, the Administrator shall consult and coordinate with the relevant agencies and instrumentalities of the Federal Government in accordance with the policies set forth in section 2(b) of this Act."

Page 30, line 2, delete the last sentence of subsection (a) and insert in lieu thereof:

"The Administrator is authorized to make contracts and grants for research and monitoring as necessary to carry out the purposes of this Act in consultation with the Secretary of Health, Education, and Welfare on such contract and grant programs."

Page 30, line 7, delete entire subsection (b) and insert new subsection (b) as follows:

"(b) The Council on Environmental Quality in consultation with the Administrator, the Secretary of Health, Education, and Welfare, the Secretary of Commerce, and the heads of other appropriate departments or agencies, shall coordinate a study of the feasibility of establishing (1) a standard classification system for chemical compounds and related substances, and (2) a standard means for storing and for obtaining rapid access to information respecting such materials. A report on such study shall be published within 18 months after enactment of this Act."

Explanation. These proposed amendments are intended to clearly set forth that it is the policy of the Act that there be the maximum cooperation and coordination among the several agencies of the Federal Government which have programs and responsibilities concerned with toxic substances; that the Act is intended to complement and supplement existing laws and regulations such as the Federal occupational health and safety requirements; and that appropriate provisions are made to establish and to have access to information relating to chemical compounds.

A number of Federal agencies, particularly the Occupational Health and Safety Administration of the Department of Labor have extensive responsibilities relating to toxic substances and human health and would stand to benefit from various provisions of the Act. The testing of chemicals as they relate to the programs of these agencies and the test results and other information and data generated by the legislation would, of course, be valuable to them and must be made available.

One of these amendments specifically provides that the EPA Administrator will consult with the Secretary of Health, Education, and Welfare on any contract and grant programs for carrying out the research and monitoring activities under the Act, but not necessarily on each individual contract or grant.

We are also recommending that the provision contained in the previous bills before the Congress directing the Council on Environmental Quality to coordinate a study on the feasibility of establishing a standard classification system for chemical compounds and means of obtaining rapid access to the information on such substances be restored to

the Act. This section provides CEQ to have the lead in establishing information systems in a manner currently being initiated. This is being done in conjunction with the agencies that would have been represented on the interagency committee as set out in the provision proposed to be deleted.

9. ADDITIONAL ASSISTANT ADMINISTRATOR

Page 28, line 15, delete subsection (a), renumber subsections (b) and (c) accordingly.

Explanation. This amendment would delete the provision for a special category Assistant Administrator for Toxic Substances.

10. ADMINISTRATIVE INSPECTIONS

Page 31, line 6, insert "(a)" after "Sec. 12", and after line 21 insert new subsection (b):

"(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 sections 4(c) and 5(f)."

Explanation. Sections 4(c) and 5(f) authorize 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.

11. DISCLOSURE OF CONFIDENTIAL INFORMATION

Page 34, line 18, delete entire section 15 and insert in lieu thereof the following revised section:

"CONFIDENTIALITY

"Sec. 15. (a) GENERAL.--Any information reported to, or otherwise obtained by, the Administrator or his representative under this Act, which is exempt from mandatory disclosure by reason of section 552(b)(4) of title 5, United States Code, shall be entitled to confidential treatment and shall not be disclosed by the Administrator or by any officer or employee of the United States, except that such information may be disclosed--

(1) to officers and employees of the United States in connection with their official duties;

(2) 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;

(3) when relevant in any proceeding under this Act, except that disclosure in such a proceeding shall be made in such manner as to preserve confidentiality to the extent practicable without impairing the proceeding; or

(4) to the extent that the Administrator determines it is necessary to protect health or the environment.

(b) ACCESS BY CONGRESS.--Notwithstanding any limitation contained in subsection (a) or any other provision of law, all information reported to or otherwise obtained by the Administrator or his representative under this Act shall be made available upon written request of any duly authorized committee of the Congress.

(c) 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 virtue of his employment or official position has obtained possession of, or has access to, material which is entitled to confidential treatment 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 purposes of this subsection (c), any contractor with the United States who is furnished information pursuant to subsection (a)(2), and any employee of any such contractor, shall be considered to be an employee of the United States."

Explanation. This section should be amended in several respects. First, the substantive criterion for withholding data as confidential shaould be the test established by the Freedom of Information Act, 5 U.S.C. 552(b)(4). Our proposed amendment would have the effect of requiring nondisclosure of information obtained under the Toxic Substances Control Act which may be withheld under 5 U.S.C. 552(b)(4), i.e., "trade secrets and commercial or financial information obtained from a person and privileged or confidential." This will make the confidentiality standard more definite (because there exists a body of case law interpreting 5 U.S.C. 552(b)(4)), and will promote uniformity.

In addition to the exemption for disclosure to Federal officers and employees, a separate provision should allow disclosure to EPA contractors and their employees, under appropriate safeguards and after appropriate EPA findings that disclosure is necessary. EPA accomplishes a great deal of its investigatory and analytical tasks by contract. If contractors are not allowed access to information under this bill, EPA could not perform its duties satisfactorily without substantial manpower increases. The recently-enacted Privacy Act, 5 U.S.C. 552a, provides that, for purposes of the section of the Privacy Act which imposes penalties on Government employees for wrongful use or disclosure of

information entitled to confidentiality, Government contractors and their employees are to be considered Government employees (5 U.S.C. 552a(m). We recommend inclusion of such a provision in the toxic substances proposed bill. Our amendments allow disclosure to contractors, and include a penalty for wrongful disclosure of information by Government employees (including contractors and their employees).

We also believe that the provisions relating to qualified scientists and individual names are not necessary. The term "qualified scientists" would be difficult to interpret, and in any event a scientist would have no greater rights under the subsection than would any person under our (proposed) basic confidentiality criterion. We believe that the Federal Privacy Act and the Freedom of Information Act provide ample protection of the rights of individuals whose names appear in health and safety records.

Finally, with regard to access of information by Congress, we believe that release of such confidential information should be upon written request.

12. STATE EXEMPTION FROM FEDERAL PREEMPTION

Page 42, 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.

13. CITIZEN SUITS FOR DISCRETIONARY ACTION

Page 45, line 13, delete language after "Act" through line 16, and insert in lieu thereof:

"which is not discretionary with the Administrator.".

Explanation. This amendment would make the provision conform with the usual citizen suit provision and not authorize suits against the Administrator for discretionary acts. It would thus prevent the possibility of every decision of the Administrator from being re-decided in the district courts.

14. INDEMNIFICATION STUDY

Page 52, line 17, delete all of section 25 and renumber section 26 accordingly.

Explanation. This amendment would delete the requirement for a study on Federal indemnification under laws administered by EPA. We believe sufficient information already exists to recommend against indemnification under programs administered by EPA.

15. SUBMISSIONS OF BUDGETS AND TESTIMONY TO CONGRESS

Page 54, line 15, delete all of subsection (c).

Explanation. This amendment would delete the requirement that Agency budget requests, testimony and comments on legislation must not be submitted to OMB prior to submission to Congress. We continue to object to this provision.

16. ADDITIONAL MISCELLANEOUS AMENDMENTS

Page 2, line 16, add after "substances":

"which may present an unreasonable risk to health or the environment".

Page 3, line 8, insert after "to" the following:

"ensure that adequate testing is conducted by those persons who manufacture, import or process, to".

Page 5, line 17, after "ecological studies" insert "monitoring studies,".

Page 8, line 4, delete "proscribed" and insert "prescribed".

Page 8, line 20, insert after "that" "one or more of the following".

Page 8, line 24, insert after "synergistic properties," "persistence,".

Page 10, line 6, delete "section 5(g)" and insert "section 5(f)".

Page 22, line 12, delete "any".

Page 22, line 13, delete "threat" and insert in lieu thereof "risk".

Page 29, line 15, delete the period and add "if appropriate.".

Page 33, line 20, delete "delivery" and insert in lieu thereof "release"; line 22, delete "three months" and insert in lieu thereof "90 days"; and on line 25, delete "deliver" and insert in lieu thereof "release".

Page 34, line 1, after "decision" insert "by the Administrator"; line 4, delete "article, together with the" and insert in lieu thereof "article as set forth in the Customs entry plus the estimated"; line 5, delete "forfeiture of" and insert in lieu thereof "liability for assessment of liquidated damages equal to"; line 6, delete "refusal" and insert in lieu thereof "failure"; line 10, delete "delivery" and insert in lieu thereof "release"; line 11, insert a comma after "payment" and delete "of" and the comma after "charges"; and on line 16, delete "of subsection (a)".

Page 39, line 5, "section 17," should read "section 16,".

Explanation. These amendments are technical corrections or are otherwise self-explanatory.

ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

JUN 27 1975

OFFICE OF THE
ADMINISTRATOR

Dear Mr. Chairman:

This is in response to your requests of June 3, 1975 and June 17, 1975, for the views of the Environmental Protection Agency on H.R. 7229 and H.R. 7664, similar versions of the "Toxic Substances Control Act", pending before your Committee.

This Agency and other concerned Federal departments and agencies have just recently completed the development of the Administration's position on S. 776, a similar version of the Toxic Substances Control Act that is pending before the Senate Commerce Committee. Because many of the provisions in the House bills are identical or similar to provisions in the Senate bill, and in order to expedite our comments to you with regard to this legislation, we are submitting our detailed comments on the Senate bill to you. These comments on the similar Senate legislation and our testimony now scheduled to be presented before your Subcommittee on Consumer Protection and Finance on July 10, 1975, will constitute our report to you on the toxic substances control legislation.

Subject to adoption of the Administration's recommendations on this legislation as set out in our attached report on S. 776, and as will be included in our testimony before the Subcommittee, we would urge enactment of the Toxic Substances Control Act.

My staff and I stand ready to assist your Committee in any way possible toward the enactment of satisfactory legislation to control hazardous substances.

We are advised by the Office of Management and Budget that there is no objection to the submission of this report from the standpoint of the program of the President.

Sincerely yours,

John Quarles

John R. Quarles, Jr.
Acting Administrator

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

Enclosure

STATEMENT OF
HONORABLE JOHN R. QUARLES, JR.
DEPUTY ADMINISTRATOR
ENVIRONMENTAL PROTECTION AGENCY
BEFORE THE
SUBCOMMITTEE ON CONSUMER PROTECTION AND FINANCE
COMMITTEE ON INTERSTATE AND FOREIGN COMMERCE
HOUSE OF REPRESENTATIVES
JULY 10, 1975

Good morning, Mr. Chairman and members of the Subcommittee. I welcome the opportunity to join you today to discuss one of our most urgently needed environmental laws -- the Toxic Substances Control Act.

Since Darwin man has recognized the ability of living things to adapt to their environments. The great diversity of life in our biosphere reflects the successful resistance of man and other species to the myriad of chemicals found in nature. However, the advent of chemical technology in the past decades has introduced billions of pounds of new chemicals that are often alien to the environment, persistent, and unknown in their interactions with living things.

This development of synthetic chemicals has resulted in over 25,000 different chemicals in industrial use, with some 600 new chemical compounds being introduced annually into commercial use. As the number and variety of chemicals continues to increase so does the contamination of our

ecosystem, a fact we are just beginning to appreciate fully. The discovery of these substances in dangerous concentrations has all too frequently been made only after a substance has been widely dispersed throughout the environment and a strange outbreak of illness or death alerts scientists to its unanticipated effects.

Presently, the Nation's population and environment provide testing grounds for determining the effects a toxic substance has on human or environmental health. The authority contemplated by the Toxic Substances Control Act would establish requirements for testing substances believed to pose an unreasonable risk before they are dispersed by various means throughout the environment and are difficult, if not impossible, to control.

The history of the problem of polychlorinated biphenyls (PCB's) clearly illustrates the need for such an approach to controlling toxic substances. While PCB's were first produced in 1929, it was in 1966 that Swedish scientists discovered PCB's in fish and wildlife and first suspected their persistence and presence throughout the environment. Subsequently, PCB's were identified as the cause of many bizarre and frightening incidents, by now well catalogued in scientific literature, affecting both humans and wildlife. Fortunately the chemical was produced in the U.S. by only

one manufacturer and in the face of this disturbing evidence the manufacturer voluntarily limited distribution and use to only those situations in which environmental release is least likely. Nevertheless, due to their unique chemical properties -- particularly stability and persistence -- PCB's remain a serious environmental problem. Even today -- two years after initiation of the new distribution pattern -- PCB's continue to be found in fish of the Great Lakes at concentrations in excess of 5 ppm, the limit established by the Food and Drug Administration as safe for human consumption. Had there been in 1929 a law like the one before you today this problem could have been considerably reduced or even prevented. Had there been adequate testing for environmental fate and persistence the use and distribution patterns are likely to have been far different than they were in fact. Had there been more producers or less cooperative producers this law would have been essential for the mitigation of the PCB's problem.

Last year's experience with vinyl chloride further underscores the need for authority to require testing and access to testing results. The discovery that long-term occupational exposure to vinyl chloride can cause a rare liver cancer illustrates the need for more adequate testing and for better information about new chemicals before facilities and workers are committed to their production. While the discovery that

vinyl chloride -- the twenty-second most produced chemical -- presents a serious hazard to workers is very alarming, frankly under current law there could well be other similar chemicals to which workers are now exposed about which we have inadequate test data. I am confident that the vast majority of the chemicals will pose no problems. However, it is imperative that we have the legislative basis to uncover and control these uses that are dangerous to many or the environment.

Other examples of chemicals once considered safe for widespread use which have migrated through the environment to pose unknown but potentially serious threats to our well being and to the environment include the fluorocarbons (Freons) which are used extensively in aerosol spray cans, and in refrigeration and air conditioning systems. The scientific community has become increasingly concerned about fluorocarbons in the stratosphere where their photo-disintegration, releasing chlorine, has been alleged to result in a depletion of the ozone layer which protects the earth from excessive amounts of ultra-violet radiation. Many investigators believe that increased ultraviolet radiation could result in an increase in skin cancer rates and in adverse effects upon vegetation and climate. While it is highly speculative that scientists could have predicted the problem of fluorocarbons in the stratosphere when they were first marketed for refrigerants or aerosols,

the magnitude of their potential harm may warrant regulatory control.

This problem was addressed in the recent report released by an interagency task force on the Inadvertent Modification of the Stratosphere (IMOS). Russell Peterson, Chairman of the Council on Environmental Quality which has been involved in coordinating the task force, discussed the fluorocarbon problem and IMOS' findings in more detail when he appeared before the Committee.

The recent attention that has been focused on organic contaminants in drinking water brings the immediacy of the problem of toxic substances control into every home. EPA's National Organics Reconnaissance Survey of the drinking water supplies of 80 cities found chloroform, a suspected carcinogen, in the finished waters of all of them. Analyses of the drinking water of 5 cities found over 180 organics, many of which probably come from industrial sources or agricultural run-off. Some of the organics detected are suspected to be naturally occurring and others the possible result of the very treatment processes necessary to control disease-causing organisms in drinking water.

While the presence of these contaminants in drinking water is certainly cause for concern, our knowledge of the health effects of these pollutants in the minute quantities

to which we are exposed in drinking water is extremely tenuous. As you are probably aware, EPA is currently conducting an extensive program directed to the drinking water problem to establish the degree of hazard, if any, and prescribe appropriate controls.

Nonetheless, the discovery of these contaminants clearly indicates that the past policy of permitting uncontrolled proliferation of chemicals in the environment can no longer be tolerated. In some cases it might be more effective to determine the risks involved with these chemicals before their production in significant commercial quantities rather than to try to control the dispersal of the chemicals after the fact. While the health implications posed by these low level chemicals will be extremely difficlt to determine, we cannot afford to wait twenty or thirty years until the insidious effects of these and other substances are painfully clear.

The recent evidence implicating bischloromethylether (BCME), a strong carcinogen, as the cause of several workers' deaths from lung cancer in one Philadelphia factory, illustrates our tragic ignorance of chemicals which may be undermining our health and welfare. BCME is formed when formaldehyde reacts with hydrochloric acid. While BCME

is a recognized occupational problem, there may be other situations that bring formaldehyde into close proximity to hydrochloric acid resulting in the release of BCME. Under the pending legislation we could identify such situations, require testing for chemical reactions and environmental fate to clarify the problem, and if necessary, take appropriate regulatory action.

All these examples underline the inadequacy of our present approach to controlling toxic substances. Existing Federal laws fail to deal evenly and comprehensively with toxic substances problems. While some authority exists to control the production of certain categories of toxic substances, such as pesticides, drugs, and food additives, most existing Federal authorities are designed to prevent harmful exposure only after the substances have been introduced into production. The Clean Air Act and the Federal Water Pollution Control Act deal with toxic substances at the point at which they become emissions or effluents. Even the recently enacted Safe Drinking Water Act, while providing long-needed protection against contaminants in drinking water, deals with the problem at a point where the contaminants are very difficult to control.

Other authorities are limited in scope or are directed to protecting specific segments of the population such as the Consumer Product Safety Act and the Occupational Safety and Health Act. In reality, however, many chemical problems affect more than one segment of the population; the cases of fluorocarbons in the stratosphere and organics in drinking water illustrate situations where a chemical hazard may be of concern to the entire population. Yet, in these cases as in others, our patchwork defense is woefully inefficient and ineffective.

Another major shortcoming of existing legislation is the general lack of authority to require test data and other information about the properties and effects of a chemical -- data that are essential for regulatory decision making. With the exception of certain premarket requirements for pesticides, drugs and food additives, no testing is required for the vast majority of existing chemicals and of new chemicals prior to their introduction into commerce. The results of acute toxicity tests performed to ascertain the safety of a chemical during handling in manufacturing might be all that is known about the toxicity of a chemical before it is produced in significant quantities and becomes dispersed throughout the ecosystem. Review of new chemicals to assess their toxicological and ecological effects and to require further testing if necessary is an essential aspect of toxic substances control

legislation. Likewise, authority to require testing of selected chemicals already in use is very important. This authority would enhance the effectiveness of other health and environmental legislation by providing information essential to regulatory action. For example, testing could be required of a chemical believed to be an occupational hazard and these data could contribute to improving standards under the Occupational Safety and Health Act.

The toxic substances control bills pending before the Committee, H.R. 7229, H.R. 7548, and H.R. 7664, generally contain the elements necessary for an effective approach towards toxic substances regulation. While we are in accord with many of the provisions of these bills we have also made a number of recommendations with regard to similar toxic substances control legislation pending in the Senate and have submitted these recommendations on the Senate bill to the House Committee. However, I would like to take this opportunity to comment briefly at this time on several provisions that appear in H.R. 7229, and in some cases the other two bills.

On several prior occasions we have stated our objection to the provision that would preclude the Administrator from forwarding any budget estimates, legislative proposals, comments on legislation, or testimony to the Office of

Management and Budget prior to the transmission of these same materials to the Congress. We do not believe that it is a desirable requirement and urge that it be deleted altogether.

In regard to section 4, Criteria for Data Development, we anticipate some problems in regard to obtaining the required information to accompany the list of chemicals. Among other things, this information includes the volume of production, and use of a chemical and its "magnitude, means, and duration of exposure to human beings and the environment". A major problem in meeting the requirements of the section is the task of estimating the magnitude and duration of human and environmental exposure of these substances. To provide reasonable estimates of exposure will require at least environmental fate testing and/or monitoring beforehand. In view of these factors, we believe that the supportive data that can be "reasonably ascertained" for the 300 chemicals during the first year may well be very limited.

The provision that causes us most concern is section 5, Notification and Premarket Screening of New Chemicals. This provision which directs the Administrator to list the new chemicals or significant new uses of existing chemicals for which premarket notification is required seems to fall far short of the stated objective of the Act: to provide "adequate authority . . . to regulate the distribution and use

of chemical substances found to pose unreasonable risks to health and the environment". Unless the Administrator has authority to require notification for every new chemical, chances are great that the proliferation of chemicals with otherwise unforeseen health consequences will continue. 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.

We believe that the Agency should receive premarket notification on every new chemical substance and significant new use of an existing substance along with certain information that is generally readily obtainable, and including test data if such is required or is available. This approach would provide the Agency with the necessary information to make a preliminary assessment of any hazard involved. This authority would fulfill the objectives of the legislation to provide "adequate authority" to deal with the problem of toxic substances threatening health and environment.

Under H.R. 7229, premarket screening is provided by authorizing the EPA Administrator to propose a rule during the premarket review period to restrict or otherwise control a chemical substance or product and to make it immediately effective, or by instituting proceedings under the imminent hazard provision of the bill.

We suggest deleting the authority in the bill which allows a rule proposed during the premarket review period to become immediately effective and treated as a final rule. Thus under our suggestion, a chemical substance or product may be manufactured and distributed after the premarket review period unless a restriction is obtained under the imminent hazard provision. The substance or product, however, remains subject to all other provisions of the Act and a rule providing restrictions on the substance or product may be proposed immediately during the premarket review period under section 6 of the Act and the rule making proceedings initiated at that time.

The provision allowing a proposed rule to ban or restrict a product to become immediately effective as a final rule appears to be an unnecessary abridgement of the normal rule making process, considering the other safeguards in the bill. If it appears that the manufacture, processing, or distribution of a chemical substance or product will result in any unreasonable threat to human health or the environment prior to the

completion of the rule making proceedings, immediate action may be taken to restrict or ban it under the imminent hazard provision of the bill.

In the past the issue of premarket notification has frequently been related to the issue of the costs of the legislation to industry. Some have argued that the premarket notification delay and possible testing requirements would impose undue costs to industry. Contrary to these predictions, I believe a comprehensive premarket notification approach should be economically preferable to industry. By examining the potential dangers associated with the production and use of a product before investing considerable capital, the chemical industry can avoid the serious disruption and losses attendant to remedial action after the fact.

With regard to the direct costs of the legislation that are likely to affect the chemical industry, I would like to emphasize that we are vitally concerned that such costs not be excessive and that the health and environmental benefits resulting from the legislation be commensurate with the costs. In a preliminary cost analysis based on the provisions of S. 776, the similar toxic substances control bill in the Senate, we estimate that the costs to industry associated with implementation of the legislation should be on the order of $80 to $140 million annually. We are currently refining the details

of these estimates but we anticipate that the general range will be about the same. There will of course be some variation depending on the final version of the legislation that is adopted. On the order of two-thirds of these costs would likely be attributable to the highly speculative areas of premarket screening and regulatory actions, with almost all of the remainder associated with the somewhat more predictable, but still very uncertain, requirements concerning industrial testing and reporting.

When placed in perspective of the sales and profits of the chemical industry these costs are relatively modest. In 1974, the sector of industry most directly affected by the legislation (i.e. chemical and allied products less food additives, cosmetics, drugs, and pesticides) had sales of about $72 billion, profits after taxes exceeding $5.5 billion, and research and development expenditures of about $2 billion. If all industrial sectors which could be affected by the legislation are considered, the sales volume in 1974 was probably double this level, and profits and research and development expenditures were also much higher.

I appreciate the contribution that members of this Committee have made in the past four years in the development of this legislation. My staff and I stand ready to work with you to accomplish its enactment. I am ready to respond to any questions that you may have.

STATEMENT OF
HONORABLE RUSSELL E. TRAIN
ADMINISTRATOR
ENVIRONMENTAL PROTECTION AGENCY
BEFORE THE
SUBCOMMITTEE ON ENVIRONMENT
COMMITTEE ON COMMERCE
UNITED STATES SENATE
MARCH 10, 1975

Good morning, Mr. Chairman and members of the Subcommittee. I welcome the opportunity to discuss with you the need for legislation to provide urgently needed information concerning the proliferation of toxic substances throughout our environment, and to provide a means for controlling toxic substances problems that cannot be effectively addressed under existing authorities.

My message is not new to you. This is now the third Congress in which we have discussed toxic substances control legislation. The new and ominous aspect we must consider, however, is that with each passing year the need to control the mounting and increasingly complex quantity of toxic substances intensifies.

In April 1971 the Council on Environmental Quality, when I was Chairman, published a report stating a high priority need for a program to test and control hazardous chemical substances. Since that time, the potential threat posed to the environment by chemicals has increased dramatically and the manifestations

of previously latent problems have been far too frequent. However, our knowledge of the character and extent of the array of chemical problems that surround us has not increased correspondingly.

A main thrust of the pending legislation is to improve our understanding of the chemicals which in so many respects we enjoy and depend upon. Basic to the philosophy of toxic substances control is the recent recognition of the need to identify the potential hazards of a chemical before it has caused any delayed and possible irreversible damage. With an estimated 500 to 700 new chemicals entering commerce in significant quantities each year, probably over 2,000 new chemicals have entered the marketplace since the C.E.Q. Report. Had a toxic substances control law been in place, it is likely that some of these chemicals would have been discovered to have toxic effects in certain circumstances. Appropriate prescriptions for their production and use could have been determined and potential adverse consequences minimized.

Substances once considered safe for widespread use are now suspect and undergoing intensive re-examination. Often these substances have been used over long time periods with great regularity.

As a result the Nation's people and environment continue to serve as the testing grounds for health and environmental

hazards. The dangers associated with the widespread and incompletely regulated use of PCB's and mercury are well documented and well known.

Last year's experience with vinyl chloride underscores the need to insure that such high volume chemicals are carefully evaluated early in their life cycles.

While the discovery that vinyl chloride -- the twenty-second leading chemical -- presents a serious hazard to human health has been very alarming, it is even more disturbing to consider the yet unknown, undiscovered effects of the other billions of pounds of chemicals produced each year. I am confident that the vast majority of the chemicals will pose no problems. However, it is imperative that we have the legislative basis to uncover those uses that are dangerous to man or the environment.

We recognize that in the past both government and industry have been somewhat complacent with regard to the potential environmental threat from the evermore abundant number of chemicals in production. This complacency can be attributed in part to the relative absence of visible and uncontrolled dangers from exposures to these chemicals during their long histories. In addition, since most chemicals are manufactured by a number of companies, there is often a lack of incentive for an individual company to invest its resources to clarify the safety aspects of a chemical's usage.

However, we are now beginning to realize that many chemical substances unless properly controlled may pose a serious threat to our well being and to the environment.

Recently, the scientific community has become concerned about the potential problems of ozone depletion caused by the photo-disintegration of fluorocarbons (Freons) in the stratosphere. Freon, itself harmless, is used extensively in aerosol spray cans and refrigeration systems.

It is generally believed that decreases in stratospheric ozone result in increased levels of ultraviolet radiation at the surface of the earth. Many investigators believe that increased ultraviolet radiation could result in an increase in skin cancer rates and in adverse effects upon vegetation and climate. Several theoretical models, unverified experimentally, predict up to 18 percent depletion of stratospheric ozone by the year 2000 if current production and release rates of fluorocarbons continue through 1990. It is believed that ozone depletion is a long-term phenomenon and that only partial recovery is predicted by the year 2050 if fluorocarbon production and release to the atmosphere were to cease by 1990. Even if fluorocarbon release stops now, or in a few years, a 5 to 8 percent depletion of ozone is predicted.

There is concern that these changes might be significant enough to cause agricultural, biological, climatic and human

health effects. The extent of changes such as decreased crop yields and increased skin cancer are unknown.

While it is unclear that production of fluorocarbon compounds would have been identified as a threat to the stratosphere under requirements of toxic substances control legislation, the existance of this legislation today would significantly improve the Federal government's effectiveness in dealing with this problem, should it be necessary.

The Reserve Mining case brought to the Nation's attention the lack of sufficient data on the health effects of asbestos. Also, at present the nature and extent of exposure of the general public to asbestos products are unknown. Animal studies might be required to help determine the health effects of ingestion of asbestos. Further, under the reporting requirement, we could acquire information on the various uses of asbestos as a basis for better estimating the degree of exposure of the public to asbestos in its various forms.

Another example is polybrominated biphenyls, PBB's which are in some respects similar to polychlorinated biphenyls, PCB's. As the result of mistaking PBB's for an animal feed supplement, thousands of cattle and chickens in Michigan were contamined by PBB's and had to be destroyed. In light of the known toxic properties of PBB's labeling or other steps under this legislation might be appropriate.

The problem of bischloromethylether (BCME), a strong carcinogen, has been of interest to this Committee. BCME is formed when formaldehyde reacts with hydrochloric acid. BCME is a recognized occupational problem, and there may be other situations that bring formaldehyde into close proximity to hyrdochloric acid resulting in the release of BCME. Under this legislation we could identify situations of possible concern, require testing for chemical reactions and environmental fate to clarify the problem, and if necessary, take appropriate regulatory action.

Today our society makes great use of many such substances. The questions we are asking about them, and many others should have been asked and answered before these chemicals became so widely used.

These several problems I have just outlined are examples of the failure of present authorities to provide adequate controls. We need authority that would enable the Federal government to deal evenly and comprehensively with toxic substances problems at the earliest point where they could best be tested and controlled. There is no justification whatever for waiting to see the effects of toxic chemicals upon the Nation's population or environment before deciding whether or not to control them or for attempting to control them only after they have been widely dispersed into the environment.

Current authorities such as the Clean Air Act and the Federal Water Pollution Control Act deal with toxic substances at the point at which they become effluents or emissions. The Federal Food, Drug and Cosmetic Act, the Consumer Product Safety Act, and other consumer protection authority do not address the problems of environmental protection nor the question of human exposure to toxic substances through environmental routes. The Occupational Safety and Health Act deals only with certain phases of exposure to a substance--the worker in his work-place. The Federal Insecticide, Fungicide, and Rodenticide Act, while dealing with a very significant group of toxic chemicals, is quite limited within the vast arena of chemicals produced and used in this country. Even the recently enacted Safe Drinking Water Act, while providing long-needed protection against contaminants in drinking water, deals with the problem at a point where the contaminants are far more difficult to control than where they could be under comprehensive toxic substances authority.

Certainly it is time that a systematic and comprehensive approach to the control of toxic substances be provided; it is clear that such an approach is not available under existing Federal authorities. I would like to see toxic substances legislation designed to help identify these hazards and to provide the basis for corrective action. It would do this in several ways.

First, the legislation would provide authority to collect necessary information about the chemicals which are now in production: what quantities are being produced, what are the various uses, what by-products are being generated, and in certain cases, what testing has shown about the chemical.

Second, premarket notification would be required for new chemicals and significant new uses of existing chemicals. This premarket notification provision would require reports to the Administrator prior to commercial production. It should not delay commercial production, but would provide critical information well in advance of large scale exposure to man or the environment.

This approach to the control of toxic substances has often been labeled a "front end" approach. I think it makes a lot of sense, not only from the perspective of a consumer or an environmentalist, but also from the point of view of the chemical industry. By examining the potential dangers associated with the production and use of a product before investing considerable capital, the chemical industry can later avoid the serious disruption and losses attendant to remedial action after the fact. Thus, this approach should be far more attractive than the present unpredictable and sometimes costly system of ad hoc controls.

Third, one of the key provisions of the legislation is the development of the standards for test protocols. This

provision is designed to insure that the environment does not become the testing laboratory and the general public the test species for chemicals with uncertain effects.

The areas of testing for chronic health effects and for environmental effects are central to this legislation and should be most carefully considered. To ensure that such tests are adequate, reliable, and have a degree of consistency, standards for test protocols should be developed and promulgated. At the same time, we must be particularly sensitive to the problems of overstandardization which could stifle industrial innovation in advancing the state of the art.

Recent extensive review of approaches to testing by the National Academy of Sciences and others provides a good starting point for development of standards for testing. Such testing must be designed to improve our ability to determine the intended and unintended effects of chemicals and to make better regulatory decisions that maximize benefits and minimize risks.

Fourth, any toxic substances control legislation should enable EPA to deal with toxic substance problems which cannot be effectively addressed within the existing regulatory framework. As you know, a variety of authorities now exist to control pieces of the toxic substances problem. This additional authority would only be invoked when other authorities are considered inadequate.

Finally, the proposed legislation would provide for appropriate legal, administrative, and enforcement tools such as civil, criminal, and injunctive relief provisions; citizen suit provisions; and appropriate inspection authority.

I might add at this point, Mr. Chairman, that should this legislation be enacted, a number of other Federal agencies which have responsibilities in this area would stand to benefit from provisions of the Act. For example, test results and other information and data generated by the legislation would be valuable to these agencies.

With regard to S. 776, the Committee bill, I am pleased to note that it contains the authorities I believe are essential for effective toxic substances legislation and we are in accord with many of its provisions. We will have suggestions on some of its specific provisions when we submit our report on the bill.

I would, however, like to comment briefly on the Committee bill at this time.

As you know, Mr. Chairman, we have already on several occasions stated our objection to the provision that would preclude the Administrator from forwarding any budget estimates, legislative proposals, comments on legislation, or testimony to the Office of Management and Budget prior to the transmission of these same materials to the Congress. We do not

believe that it is a desirable requirement and urge that it be deleted altogether.

I note also Mr. Chairman that provision is made in S. 776 for the President to appoint with the advice and consent of the Senate an Assistant Administrator for Toxic Substances who is specially qualified in that area. I presume this would be an Assistant Administrator in addition to those authorized under Reorganization Plan No. 3 of 1970. Of course, I can hardly say that the services of another Assistant Administrator would not be welcome, but to designate by statute the specific responsibility of an Assistant Administrator may tend to create a problem of internal management.

I know that this Committee does not need to be convinced of the necessity for toxic substances legislation. I appreciate the contribution the Committee has made in the development of such legislation and my staff and I stand ready to work with you to accomplish its enactment. I am ready to answer any questions that you might have.

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

July 21, 1975

DEPUTY ADMINISTRATOR

Dear Jim:

I just want to say that I am appreciative of the way you and your staff handled the predator control issue. I feel we had a full fair opportunity to make our input on the issue, and although our first choice might have been to make no modification at all I believe that the result we reached is certainly sound from an environmental point of view. In particular Todd Hullin seems to have done an extremely fair and thorough job in pulling all of the facts together.

I want to assure you that I personally will follow up on our review of the M-44 to make sure that we complete our work so that we can make a decision within the time frame which we previously indicated to you and which the President set forth in his statement.

With best regards.

Sincerely yours,

John

John R. Quarles, Jr.

Honorable James M. Cannon
Office of the Domestic Council
Office of the President
Washington, D. C. 20500

P-109 for September

THE WHITE HOUSE
WASHINGTON

DATE: July 23

TO: Tod Hullin

FROM: JIM CAVANAUGH

SUBJ:

FYI ✓

Action ____

File
Coyotes

July 21, 1975

Dear Senator:

Thank you for your July 17 letter to the President urging that he take no action with respect to Executive Order 11643 until reports of the Economic Research Service of the Department of Agriculture relating to the predator problem are released.

As you may have noted, the President did issue an Executive Order on July 18 amending E. O. 11643. I am enclosing a copy for your consideration. If you wish to discuss the provisions of the amended Order, I will be pleased to arrange for a discussion with the appropriate members of the staff.

With kindest regards,

Sincerely,

William T. Kendall
Deputy Assistant
to the President

Urging President not to abolish or weaken E.O. 11643 which advocates reasonable positions on Fed. lands and in Federal programs.

The Honorable James L. Buckley
United States Senate
Washington, D.C. 20510

Enclosure

bcc: w/incoming to James Cannon - for your information

WTK:EF:VO:vo

JAMES L. BUCKLEY
NEW YORK

7-21

United States Senate

WASHINGTON, D.C. 20510

July 17, 1975

The Honorable Gerald R. Ford
The White House
Washington, D.C. 20500

Dear Mr. President:

It has come to my attention that once more efforts are underway to substantially weaken or abolish President Nixon's 1972 Executive Order halting the use of predator poisons on Federal lands and in Federal programs. Executive Order #11643 is an important step toward the development of intelligent Federal policy which strikes a balance between economic and environmental interests. Abolishing the Order will simply increase the difficulties facing those who support sensible environmental policies within the Congress, without conferring any corresponding social benefit upon the Nation.

As I wrote to Secretary Morton in February, 1974, I believe the emotional nature of the debate over predator control has tended to obscure the important facts of the case.

1) Mechanical techniques of predator control are available and have proven equal and superior to predator poisons. The rate of kill for coyotes in F.Y. '72, '73, and '74 was respectively 71,091; 76,490; and 71,750.

2) Data on sheep losses is highly suspect because the data collection techniques are dominated by extrapolation, estimation, and surmise with an inadequate fraction of observed losses. Even taking the data at face value, the perturbation in the reported loss rate between F.Y. '72 and F.Y. '73 is not substantially different from reported loss rates when field poisons were used. Indeed, using the more accurate Department of Agriculture figures, (sheep inventories at the beginning of the year, plus the number of lambs born, minus the number of sheep at the end of the year), sheep losses to all causes has risen less than 1% from 1970 to 1974.

3) Both EPA and the Department of the Interior have been using a coyote-specific predator control agent (M-44) on a selective use, experimental permit basis. This

program, combined with already available mechanical techniques should be tried before any consideration is given to more Draconian measures.

4) The use of general field poisons has potentially devastating effects on local wildlife -- effects which may have a substantial impact on the balance of nature in the area. Upsetting the balance of nature may have more serious consequences for wool growers than the predation problem they now face.

These points are especially valid when one considers that the Congress appropriated over one million dollars for the Economic Research Service of the Department of Agriculture to study all facets of the decline of the wool industry and the extent to which predator losses play a part. Draft versions of these reports are due to be completed within the next three months, with the final version due for publication in November.

I strongly urge you to resist efforts to weaken the ban on the use of general field agents, supporting instead limited and predator-specific control programs where there is a demonstrated need to do so.

The reports ordered by Congress will clarify where, and even if, a demonstrated need to utilize any form of predator poisons exists. May I further urge that you take no action to weaken or abolish Executive Order #11643 until you have an opportunity to carefully examine and weigh the information contained in the reports.

Respectfully,

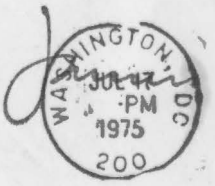
Jim

James L. Buckley

United States Senate

WASHINGTON, D.C. 20510

OFFICIAL BUSINESS



L. Budget

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The Honorable Gerald R. Ford
The White House
Washington, D.C. 20500