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THE WHITE HOUSE

WASHINGTON

ACTION

Last Day: October 11

810111

MEMORANDUM FOR

THE PRESIDENT JIM CANNON AND Quern

S. 3149 - Toxic Substances Control Act

Prateo 10/2/116 .

To Attached for your consideration is S. 3149, sponsored by Senators Tunney and Hartke.

> In general, the enrolled bill provides authority to the Administrator of the Environmental Protection Agency to:

- -- require private industry to provide test data and supply detailed information on specified substances;
- -- prevent, or place limitations on, the marketing of new substances which the Administrator believes harmful; and
- -- ban or limit continued marketing of existing substances.

A detailed explanation of the provisions of the enrolled bill is provided in OMB's enrolled bill report at Tab Α.

OMB, Max Friedersdorf, Counsel's Office (Kilberg) and I recommend approval of the enrolled bill and the attached signing statement which has been cleared by the White House Editorial Office (Smith).

RECOMMENDATION

That you sign S. 3149 at Tab B.

That you approve, the signing statement at Tab C.

Approve /

Disapprove

10/11/76 Mr. friales, her Trudy -An Gananaugh has asked that annunement on this one .

EXECUTIVE OFFICE OF THE PRESIDENT



OFFICE OF MANAGEMENT AND BUDGET

WASHINGTON, D.C. 20503

- OCT 7 1976

MEMORANDUM FOR THE PRESIDENT

Subject: Enrolled Bill S. 3149 - Toxic Substances Control Act Sponsors - Sen. Tunney (D) California and

Sen. Hartke (D) Indiana

Last Day for Action

October 11, 1976 - Monday

Purpose

Provides authority (1) to require testing, including premarket clearance, of certain chemical substances and (2) to restrict the use of certain chemical substances.

Agency Recommendations

Office of Management and Budget	Approval
Environmental Protection Agency	Approval (Signing Statement attached)
Department of Commerce	Approval
Department of Labor	Approval
Department of Health, Education,	
and Welfare	Approval
Department of the Interior	Approval
Council on Environmental Quality	Approval
National Science Foundation	Approval
Office of Science and Technology	
Policy	Approval
Department of Agriculture	Approval
Small Business Administration	No objection(Informally)
Department of Justice	Cites concerns

Background

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

- o Federal Food, Drug, and Cosmetic Act which regulates substances which are used as foods, drugs, or cosmetics;
- o Occupational Safety and Health Act which regulates contact with substances in the work place;
- o Consumer Product Safety Act regulates dangers from consumer products;
- o Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) which regulates substances used as pesticides;
- o Safe Drinking Water Act which regulates the level of toxic substances that can be present in drinking water supplies;
- o The Federal Water Pollution Control Act provides for State and Federal regulation over industrial discharges of toxic pollutants into the Nation's waters; and,
- o The recently enrolled Solid Waste Act would regulate the disposal of all toxic substances.

When the Executive Branch first proposed regulation of toxic substances in 1971, much of this regulatory framework --FIFRA, Consumer Product Safety Act, Safe Drinking Water Act, Federal Water Pollution Control Act, Solid Waste Act -- did not exist. Accordingly, the absence of effective control for many toxic substances -- the original reason for proposing toxic substances legislation -- no longer exists.

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

Differences in legislative approaches in regulation of toxic substances have generally revolved around different treatment for:

- o substances which are already used in the market (existing substances), and
- o newly invented substances, or new uses of existing substances (new substances).

The first attempt at regulation recommended by the Executive Branch in 1971 would have covered only existing substances. This year the Administration agreed to support Congressman McCollister's approach which would have covered only existing substances and those new substances which EPA described in a list as having particular potential for toxic effects on health or the environment.

Opponents of this approach agree that existing substances must be covered but go further and argue that no new substance should be available in the marketplace until EPA is satisfied that it will not be harmful.

The issue this year, therefore, has revolved around the extent to which the Congress was willing to permit new substances to come on the market through various degrees of pre-market clearance from a Federal regulatory agency. Industry argues, of course, that the more difficult it is to bring new products to the market, the less innovation would occur in the private sector. This would adversely affect U.S. consumers through higher prices and a lessened variety of products. It would also put U.S. exporters of substances at a disadvantage vis-a-vis their foreign counterparts.

Summary of the Enrolled Bill

The enrolled bill contains some 53 pages of intricate regulatory material. The Tabs A(1) and A(2) summarize important features (and point out certain differences) in the key provisions of the bill.

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

- o require private industry to provide test data and supply detailed information on specified substances;
- o prevent, or place limitations on, the marketing of new substances which the Administrator believes harmful; and,
- o ban or limit continued marketing of existing substances.

On the crucial issue of regulating substances before entering the market (new substances) the Congress:

- o rejected the McCollister approach of a list and required notification of EPA as to all new substances (See (a) on Tab A(1)); $\frac{1}{2}$ /
- o exempted certain broad categories of substances such as mixtures (as distinguished from compounds), substances used in experimental work, substances which only react during the manufacturing process, or -upon application -- any other substance which does not present an unreasonable risk (See (b) and (c) on Tab A(1)); and,
- o provided EPA with the authority to ban or limit substances pending formal rulemaking in two situations;
 - -- where the information is insufficient to assess risk and the substances would be produced in large quantities (d) on Tab A(l)); and,
 - -- where the substance presents an unreasonable risk
 (e) on Tab A(1));

However, in the first instance, if a company objects to the action, EPA would have to obtain a court order; in the second instance, while a rule to limit could be made administratively, a rule to ban would require a court order.

With respect to existing substances, the Congress:

- o required formal rulemaking procedures -- an adversary
 process recommended by the Administration (a) on Tab
 A(2)); but
- o provided EPA with the authority to ban or limit substances pending formal rulemaking; for a ban EPA must obtain a court order; any other limitation can be made effective administratively (b or c on Tab A(2)); and,
- o at any time, the EPA Administrator can commence civil action in Federal court against any imminently.hazardous material (d on Tab A(2)).

1/ The references to Tab A(1) and A(2) relate to the bill's regulatory mechanism as marked on Tabs A(1) and A(2).

Other provisions require:

- o EPA Administrator to take into consideration other laws when applying this one (a somewhat less automatic provision than the Administration recommended) 2/
- o Non-disclosure of company data except in certain instances generally in a form recommended by the Administration; and provided for citizen petitions -a provision strongly opposed by the Administration.<u>3</u>/

In late March 1976, the Senate, by vote of 60-13 passed S.3149. The bill was essentially the one sponsored by Senator Tunney early in 1975. The bill was substantially different from the Administration's approach. In August, the House, by a vote of 319-45 passed its version of the toxic substances legislation (H.R. 14032) which was a compromise position worked out among Congressmen Eckhardt, Broyhill, McCollister and the Manufacturing Chemists Association. Its provisions, although calling for premarket notification on all new chemical substances, was not as distant from the Administration's approach of using an advance list as was the Senate bill.

The conference version of S. 3149 then passed the Senate and House by votes of 73-6 and 360-36, respectively. The bill reflects the House provisions to a greater extent than the Senate provisions. The majority and minority members of the House and Senate committees support the legislation as does the Manufacturing Chemists Association.

- 2/ The toxic substances bill also exempts from coverage, pesticides, cigarettes, tobacco products, firearms, and ammunition, food, food additives, drugs, cosmetics, medical devices, and nuclear materials which are all regulated under other statutes.
- 3/ Other significant provisions would (1) require EPA to ban or restrict the use of any chemical substance presenting a serious or widespread risk of cancer, gene mutations or birth defects; (2) prohibit the manufacture, sale or distribution of polychlorinated biphenyls (PCBs) within two and one-half years, unless exempted; (3) require the Administrator, upon request of the President, to waive compliance with any provision on the basis of National defense; and, (4) direct EPA to study the need for indemnification of companies subject to regulation under any law administered by EPA.

Agency Views

Nearly all of the agencies express strong support for S. 3149 and recommend its approval. In its attached enrolled bill letter, EPA notes that the bill is substantially in line with the Administration's approach in every important respect.

Although generally in favor of the bill, Justice opposes the authority that EPA would have to litigate, on its own behalf, civil suits under the Act. Justice suggests that you indicate your concern about this feature of the bill in a signing statement.

Arguments for Approval

- S. 3149 would:
 - -- limit the potential coverage of its pre-market notification provisions by a series of exemptions either discretionary or explicit:
 - the Administrator could exempt any substance if the manufacturer shows that it does not present an unreasonable risk;
 - (2) the Administrator could exempt substances for test marketing purposes; and,
 - (3) research and development chemicals would be exempted.
 - -- limit the coverage of the reporting section by exempting small businesses unless they are the subject of a testing or specific regulatory rule;
 - -- reduce its potential coverage significantly by exempting a broad range of chemical substances;
 - -- provide information we do not currently have about toxic substances entering the environment; and,
 - -- unlike some other current environment statutes, require an assessment of both the costs associated with the regulation and the risks to health and the environment from the substance.

Finally, the enrolled bill has the near unanimous support of the concerned agencies. The legislation passed by wide margins and with bi-partisan support in all the committees.

Arguments Against Approval

- -- the legislation provides extensive discretionary authority for the Administrator and could result in overregulation;
- -- at least one major chemical producer Dow has voiced strong and continued objections to the legislation;
- -- the legislation will undoubtedly create a huge paperwork burden;
- -- the legislation impacts most heavily on small businesses since their ability to respond administratively, legally, or in the formal rulemaking procedures is relatively more expensive than for larger companies; and,
- -- in light of the general policy of minimizing regulation, this legislation is unquestionably a major new regulatory authority, extremely complex and potentially very expansive.

Conclusion

On balance, we believe the arguments for approval are the stronger, and accordingly, we join the agencies in recommending approval. EPA has prepared a signing statement which we have edited and recommend for your consideration. We do not share Justice's view that the provision giving EPA separate civil litigating authority is so objectionable as to be cited in a signing statement. We do, however, feel that the signing statement should clearly state that the Government pledges to minimize the potential for overburdensome regulation while still protecting health and the environment.

INC

Paul H. O'Neill Acting Director

Enclosures



FOOTNOTES:

(1) Exempts mixtures; exempts substances used for scientific experimentation.

(2) Requires that at least 90 days prior to manufacturing, processing, or distributing any new chemical substance, or any new use, EPA must be notified.

(3) Administrator, upon application, may exempt (a) any substance if it does not present a risk, (b) substances reactive only during manufacture (c) substances for test marketing purposes.

(4) EPA can require testing on substances -- that may present an unreasonable risk of injury to health or the environment, but only if there is insufficient information and testing is necessary to develop the information or,

> --if the substance will be produced substantial quantities, infor-mation is lacking and if the substance would enter the environment in substantial quantities with significant human exposure.

mation as necessary to carry out the the subject of a specific regulatory rule.

(5) If there is insufficient information (7) If the Administrator had on the substances effects and it could present an unreasonable risk and would enter the environment in substantial quan-he may make an action to ban tities, a proposed rule to limit or ban pending completion of formal rulemaking would go into effect at the end of the 90 day pre-market notification period if (1) there were no objection by the manufacturer, or (2) if the manufacturer did so object, EPA was able to obtain a court (a)(b)(c)(d)(e) refer to injunction.

EPA is authorized to require any infor- (6) If the Administrator had reason to believe a substance presents an unreason-Act. Small businesses are exempt from able risk, he may limit a substance by the reporting sections unless they are Administrative action pending completion of formal rulemaking.

reason to believe a substance presents an unreasonable risk a substance immediately effective, pending completion of formal rulemaking, if he is able to obtain a court injunction.

discussion in enrolled bill memorandum text.

refer to EPA actions in effect that prevent marketing of a substance pending completion of formal rulemaking.

MARKET-----EPA ASKS FOR TESTS (1)

EPA ASKS FOR INFORMATION (2) -

ONJE	<u>-</u>		
	EPA ACTION		
	EPA DOES NOTHING	*******	CONTINUE MARKETING
(4)	EPA ACTS TO LIMIT OR BAN AS INMINENT HAZARD (3) ACTION REQUIRED TO UPHOLD EPA FINDING ACTION FINAL		
	LIMIT OR BAN WHILE PRODUCT <u>REMAINS</u> ON THE MARKET PENDING COMPLETION OF FORMAL RULEMAKING	(6) Formal Rulemaking Procedures	
	REMOVED FROM MARKET PENDING COMPLETION OF FORMAL RULEMAKING	(a)	DO NOTHINGCONTINUE MARKETING
(c)	(4) TO LINITEPA CAN ACT ADMINISTRATIVELY	(ADVERSARY	ACTION FINAL
(Ъ)	TO BAN ⁽⁵⁾ COURT ACTION REQUIRED TO UPHOLD EPA FINDINGACTION FINAL REJECT EPA FINDINGACTION MARKETING	PROCESS)	

FOOTNOTES:

- (1) SPA can require testing on substances ---that may present an unreasonable risk of injury to health or the environment, but only if there is insufficient information and testing is necessary to develop the information or, ---if the substance will be produced
 - in substantial quantities, information is lacking and if the substance would enter the environment in substantial quantities with significant human exposure.

(2) EPA is authorized to require any information, as necessary to carry out the Act. Small businesses are exempt from the reporting sertions unless they are the subject of a specific resultory rule. (3) Complete ban of a substance, pending completion of formal rulemaking, can be accomplished only by obtaining a court injunction but only if the court determines the substance is an imminent hazard.

(4) EPA may, by administrative action limit the use of a substance pending completion of the formal rulemaking procedures.

(5) In order to han a substance pending completion of formal rulemaking, EPA must obtain a court order.

 (a) (b) (c) (d) refer to discussion in the enrolled bill memorandum text. (6) Regulation of hazardous substances under Section 6 of the Act follow formal rulemaking procedures. The Administrator is authorized to limit in a variety of ways, or ban the manufacture, distribution, or processing of a chemical substance. The standard is if the substance presents or would present an unreasonable risk of injury to health or the environment. The Administrator is also required to consider and publish a statement regarding effects of the substance, and the environment, the benefits of the use of the substance, and the economic consequences of the regulation.

* Refer to EPA actions in effect that would withdraw the substance from the market pending completion of formal rulemaking procedures.

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TAB A(2) <u>EXISTING CHEMICALS</u> REGULATORY MECHANISM 1

STATEMENT BY THE PRESIDENT

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

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

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

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

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

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

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

2



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2

THE WHIT		5 (10/8/76 NO.: 9
Date: October 8	Time: 1030am	mit
FOR ACTION: George Humphreys Max Friedersdorf Bobbie Kilberg Glenn Schleede Robert Hantmann FROM THE STAFF SECRETARY	cc (for information):	Steve McConahey Ed Schmults Jack Marsh
DUE: Date: October 9	Time: noon	

SUBJECT:

S.3149-Toxic Substances Control Act

ACTION REQUESTED:

For Necessary Action

- For Your Recommendations

Prepare Agenda and Brief

X For Your Comments

Draft Remarks

_ Draft Reply

REMARKS:

please return to judy johnston, ground floor west wing

NWB need Saturday burne hast day is Mon.

1018 3:15 p.m. Copy sent to research of

PLEASE ATTACH THIS COPY TO MATERIAL SUBMITTED.

If you have any questions or if you anticipate a delay in submitting the required material, please telephone the Staff Secretary immediately.

James M. Cannol For the Presse

D

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

OCT 7 1976

MEMORANDUM FOR THE PRESIDENT

Subject: Enrolled Bill S. 3149 - Toxic Substances Control Act

Sponsors - Sen. Tunney (D) California and Sen. Hartke (D) Indiana

Last Day for Action

October 11, 1976 - Monday

Purpose

Provides authority (1) to require testing, including premarket clearance, of certain chemical substances and (2) to restrict the use of certain chemical substances.

Agency Recommendations

Office of Management and Budget

Environmental Protection Agency

Department of Commerce Department of Labor Department of Health, Education, and Welfare Department of the Interior Council on Environmental Quality National Science Foundation Office of Science and Technology Policy Department of Agriculture Small Business Administration Department of Justice

Approval

Approval (Signing Statement attached) Approval Approval

Approval Approval Approval Approval

Approval Approval No objection(Informally) Cites concerns

THE WHITE HOUSE

WASHINGTON

October 11, 1976

CANNON JIM CAVANAUGH

MEMORANDUM FOR:

MAX L. FRIEDERSDORF $/// (\gamma)$

FROM: SUBJECT:

S.3149-Toxic Substances Control Act

The Office of Legislative Affairs concurs with the agencies that the Toxic Substances Control Act should be signed.

> Passed Senate 3/26/76 60-13 Conf. Report passed Senate 9/28/76 73-6

Passed House 8/23/76 319-45 Conf passed 9/28

Attachments

٣

THE WHITE HOUSE

ACTION MEMORANDUM

DUE: Date: October 9

WASHINGTON

Date: October 8 FOR ACTION: Storge Humphreyst cc (for information): Steve McConahey Friedersdorft Ed Schmults Bobbie Kilberg Glenn Schleede Bobet Halfmen FROM THE STAFF SECRETARY

SUBJECT:

S.3149-Toxic Substances Control Act

ACTION REQUESTED:

____ For Necessary Action

For Your Comments

____ For Your Recommendations

Time: noon

_____ Prepare Agenda and Brief

-___ Draft Remarks

_ Draft Reply

REMARKS:

please return to judy johnson, ground floor west wing

PLEASE ATTACH THIS COPY TO MATERIAL SUBMITTED.

If you have any questions or if you anticipate a delay in submitting the required material, please telephone the Staff Secretary immediately.

K. R. COLE, JR. For the President

THE WHITE HOUSE

ACTION MEMORANDUM

WASHINGTON

LOG NO .:

Date: October 8

Time: 1030am

FOR ACTION: George Humphreys Max Friedersdorf Bobbie Kilberg Glenn Schleede cc (for information): Steve McConahey Ed Schmults Jack Marsh Robert Hartman

FROM THE STAFF SECRETARY

DUE: Date: October 9

Time: noon

SUBJECT:

S.3149-Toxic Substances Control Act

ACTION REQUESTED:

----- For Necessary Action

____ For Your Recommendations

_____ Prepare Agenda and Brief

X For Your Comments

____ Draft Remarks

- dity

_ Draft Reply

REMARKS:

please return to judy johnston, ground floor west wing

day is manday. 10/8/76 3:15 april sent de researche

PLEASE ATTACH THIS COPY TO MATERIAL SUBMITTER

If you have any questions or if you anticipate a delay in submitting the required material, please telephone the Staff Secretary immediately.

10/8 Researched copy atterned.

James M. Cannon For the Presson 1018/76 3:15pm I am today signing S. 3149, the "Toxic Substances Control Act." I believe this legislation may be one of the most important pieces of environmental legislation that has been enacted by the Congress.

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

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

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

2



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

OCT 11976

OFFICE OF THE ADMINISTRATOR

Dear Mr. Lynn:

This letter is in response to your request for the comments of the Environmental Protection Agency on the enrolled bill, "The Toxic Substances Control Act".

The legislation will provide the Federal government with needed authority to protect health and the environment from dangerous chemicals. Under the legislation, the Administrator of EPA is empowered to require the testing of new and existing chemical substances that might present an unreasonable risk of harm to health or the environment. A manufacturer is required to give notice to the Administrator of his intent to manufacture a new chemical substance or a significant new use of an existing chemical ninety days prior to commercial production. The Administrator is provided with the opportunity to evaluate the hazard-causing potential of the new chemical substance or significant new use before it is introduced into commerce.

The Administrator is also empowered both to act against existing harmful chemical substances and new chemical substances and significant new uses before the substance can endanger health and degrade the environment. The legislation provides for the collection of information on all chemicals so that their effect on health and the environment can be monitored and evaluated. The bill also contains the necessary administrative, enforcement, and cooperative and consultation provisions appropriate for implementing this complicated and sophisticated legislation. I strongly recommend that the enrolled bill be signed into law by the President. This legislation has the support of the concerned agencies of government, of labor, industry, and environmentalists, and the public. The House and Senate passed their respective bills by wide margin - (House 319 to 45) (Senate 60 to 13); the conferees swiftly resolved and perfected the several problem areas; and the House and Senate approved the Conference bill and report overwhelmingly by votes of 360 to 35 and 73 to 6, respectively.

This legislation has now been brought substantially in line with that proposed and supported by the Administration in every important respect. The Congress and the conferees responded to strong and persistent objections of the Administration and removed the premarket screening authority without court order if objections are filed by the industry, the OMB budget and legislation by-pass provisions, and the Congressional veto provisions. In light of these accommodations it would be quite unwise to suggest that this most important legislation be delayed any longer in the expectation of ever obtaining a more favorable bill.

The bill is in fact an excellent piece of legislation and though I have frequently criticized the Congress for this long delay of six years in passing it, the delay has been advantageous in some respects. It has insured that every aspect of the bill was studied and debated thoroughly, resulting in a bill that is strong and fair; and adequate to do the job intended, but without over regulation or otherwise placing undue burdens on the government or industry. Having been head of the Council on Environmental Quality which drafted the original Toxic Substances Control Act in late 1970 and early 1971 and having been directly and constantly concerned with its debate in the Congress since that time and with the health and environmental problems of the Nation which it is intended to prevent and correct, I am generally satisfied with the legislation that has finally emerged and I strongly endorse it.

The enrolled bill is similar in many ways and would achieve the same objectives as the original 1971 Administration bill and the Administration supported Toxic Substances Control Act, H.R. 7664, as proposed by the Administration to be amended in November 1975, and in January 1976. The enrolled bill and the Administration-supported bill create a regulatory framework for the testing and regulation of new and existing chemical substances that constitute a threat to health and the environment. In each bill the burden is placed upon the Administrator of EPA to initiate actions against chemicals which may be deleterious, to then promulgate rules requiring testing and regulating such chemicals and ultimately, if such action were necessary, to justify in a U.S. District Court any proposed action to make a ban immediately effective for a chemical substance or to prevent its introduction into the market place. The flow of new chemical substances and proposed significant new uses of existing chemicals to the market place would not be unduly impeded. The Administration supported bill or the enrolled bill does not include, as some previous versions did, the objectionable so-called premarket screening provision whereby the Administrator could unilaterally and without court sanction stop a substance from being produced merely by writing a rule and making it immediately Industry has the opportunity to effectively require effective. a court order before a rule such as this is made immediately effective.

Other significant similarities between the legislation and the positions that the Administration has taken include: a requirement that the Administrator impose the least burdensome restriction upon a regulated chemical; a requirement that the Administrator consider the economic impact of any proposed restriction; provision for taking action against an imminently hazardous chemical substance; a broad exemption from reporting burdens for small businesses; and procedures to prevent duplication of Federal regulatory efforts by coordinating the regulatory authority contained in this legislation with other laws administered by the Administrator and with laws administered by other Federal agencies.

There are numerous other less significant, though important, provisions in the enrolled bill that follow the original Administration language, or have essentially the same effect. No attempt is being made here to itemize and outline all of these similar provisions.

Several of the more important provisions in the enrolled bill which either differ from the proposal that the Administration supported or do not compare with any provision in the proposal supported by the Administration are outlined below. These differences are primarily procedural in nature and do not alter the overall intent or focus of the legislation. A close analysis of these differences presents no significant reason why this legislation should not be signed by the President. Most of these differences and additions are in fact improvements.

One important difference is the concept in the enrolled bill to provide for premarket notification of new chemical substances and significant new uses. The enrolled bill does not contain the "limiting list" concept as recommended by the Administration. Instead the enrolled bill provides for broad premarket notification but allows a number of exemptions. The scope of premarket notification in the enrolled bill, therefore, is greatly reduced by allowing exemptions for research chemicals, chemicals being used in test marketing, chemicals where only the proportion of inert ingredients have been changed, and no-risk chemicals. Another and perhaps the most significant limitation in the enrolled bill to broad premarket notification is the authority of the Administrator to designate categories of chemicals. This means that when the Administrator designates a category of existing substances, minor variations in the existing chemical substances will not result in such variations being considered new substances and thus subject to premarket notification. As a result of these exemptions in the enrolled bill, its premarket notification provision will reduce the total notifications required in a manner that is similar to the effect that the "limiting list" concept would have had in the Administration supported bill. Importantly, this approach in the enrolled bill permits the Administrator to receive notification of all potentially harmful new chemicals and significant new uses without unduly burdening industry. This approach also has a most important advantage of not providing a serious loophole for a very dangerous chemical to enter the market without prior notice simply because existing knowledge was not available to cause the chemical to be placed on a list. On balance we believe the premarket notification provisions set out in the enrolled bill are superior to those of the Administration supported provisions.

A provision in the enrolled bill not found in the Administration supported bill (and a compromise of the so-called Durkin Amendment) is one that requires the Administrator to publish reasons for not taking action during the premarket notification period for three categories of substances--those where testing is already required, those where the Administrator in his discretion has put on a list as being of a greater risk, and those which the Administrator determines to be significant The provision does not delay the date of the commercial new uses. production of a new chemical substance as the original Durkin amendment in the Senate bill required. In addition the chemical substances to which the provision applies are greatly limited from the original Durkin proposal thereby greatly reducing the burden of this proposal on the Agency. While the Administration strongly opposed this provision in any form, the

conferees had to make some compromise between no publication at all and publication on all premarket chemicals not regulated, and whether delay in production should be required. The required publication of only limited categories of chemicals with no requirement to delay production is an acceptable compromise given the strong support the original Durkin proposal received.

There are some procedural differences between the Administration position and that set out in the enrolled bill with regard to banning or restricting chemical substances during the premarket period and before initial manufacture can begin. The Administration position would allow restriction or banning during the premarket period only if it could be shown in court that an imminent hazard would likely happen. The enrolled bill, on the other hand, provides an improved and more sophisticated process but ultimately requiring court sanction to delay production of a chemical substance beyond the premarket review period. In all cases a court order must be obtained when objections are filed.

Where the Administrator has <u>insufficient</u> information to evaluate health or environmental effects of a new chemical, the enrolled bill, following other preliminary procedures, and the filing of objections, requires the Administrator to go to court and seek an injunction to prohibit or limit manufacture until testing may be completed and evaluated or until a testing rule is promulgated, if necessary. Although the Administration supported bill includes no special provisions for this contingency, the enrolled bill is specific in closing this gap. It will insure that harmful new chemical substances are not released into the environment before their effects can be evaluated. On the other hand, the court review provisions give a manufacturer all reasonable protection from a hasty or an inadequate basis for action by the regulating agency.

A similar procedure is followed where the Administrator has <u>sufficient</u> information that a new chemical substance or significant new use may present an unreasonable risk. Under some circumstances after required findings are made, the Administrator may issue a limited, immediately effective rule to limit use or quantities or to require appropriate labeling or which specifies proper disposal methods. To completely prohibit manufacture where such action is warranted the Administrator must justify his action and seek a court injunction if objections are filed. This procedure again provides the manufacturer with ample procedural protection. These premarket restriction procedures do not allow the regulatory agency to ban a substance from the market merely by drafting a rule and making it immediately effective. With regard to the banning of existing chemicals, when necessary, provisions in the enrolled and Administration supported bills are essentially the same. In neither case could a rule banning a substance be made immediately effective. In both bills the Administrator would have to go to court and show the existence of an imminent hazard. Under the enrolled bill, however, it is possible to provide less than a complete ban by making a rule immediately effective if the substance is likely to cause serious and widespread harm and making it so effective is necessary to protect the public interest. This is an improvement over the Administration position as it allows regulation of less than a complete banning and thus would not delay manufacture. This latter option would not be available under the Administration supported bill.

Another provision not found in the Administration supported bill gives a citizen the right to petition the Administrator to make, amend or repeal a rule. The burden this section imposes upon the Administrator was significantly lessened by its limitation to petitions concerning rules authorized under sections 4, 5, 6, and 8 of the bill rather than authorizing petitions for any action possible under the Act as provided in the Senate bill. More importantly, the enrolled bill requires a court where there is an appeal to review the Administration's denial of a petition to take into account Agency resources, priorities, and other relevant factors. Where priorities dictate, and resources permit, the Administration will want to implement the Act. Thus, this citizen petition provision, while strongly opposed by the Administration, is not expected to be burdensome, given the requirement that priorities and resources must be considered by the court in reviewing a petition.

Finally, a provision in the enrolled bill creates an interagency committee to develop a priority list of harmful chemical substances that should be tested. For the top fifty chemical substances on the list, the Administrator is required to either initiate testing rules or publish the reasons why rules are not being initiated. This provision ensures that testing rules will be proposed or the reasons published why no proposed rules are necessary for only 50 designated substances on the list. With this limitation the publication burden should not be great and certainly not so in relation to the original requirement that such publication had to be made on all substances on the entire list (not just the designated 50) where testing rules are not proposed. It is important to note that the total annual cost estimates of the chemical industry to meet the requirements of the legislation range from \$70 to \$140 million by EPA to \$1.4 billion by industry with GAO estimating that it should not exceed \$200 million. Whatever the actual cost will be it will not be excessive when compared to the industry's annual sales of \$120 billion of products that could come under the provisions of the legislation.

Since 1971, when the first toxic substance legislation was sent to Congress by the Administration, Congress has been considering various versions of the legislation. The enrolled bill has the same objectives as the original Administration bill. It provides the same basic regulatory framework to come to grips with any problems toxic substances are inflicting upon the environment while not containing the most undesirable features of some intervening versions of the legislation which might have created substantial administrative burdens for both government and industry. The enrolled bill is thoughtful and thorough and has been developed into what I believe is a much more effective and manageable bill than any prior versions. The Congress, the Administration, the industry, and others can all share credit for this improved legislation.

The list of chemical substances causing health and environmental problems continues to grow. The urgency and severity of the toxic chemical problem have been underscored many times in recent months. In light of the severity of this problem and of the increasing public awareness and demands for action, any further delay in making effective this legislation cannot be justified or explained. The support that this legislation has received from the public at large, labor, environmentalists, major segments of the chemical industry, and concerned government regulatory agencies evidences this fact. This may well be the most important environmental legislation which has been proposed by any Administration or enacted by any Congress.

I, therefore, strongly recommend that the Toxic Substances Control Act be signed into law by the President.

Sincerely yours, : Main Administrator

Honorable James T. Lynn Director, Office of Management and Budget Washington, D.C. 20503



GENERAL COUNSEL OF THE UNITED STATES DEPARTMENT OF COMMERCE Washington, D.C. 20230

OCT 4 1976

Honorable James T. Lynn Director, Office of Management and Budget Washington, D. C. 20503

Attention: Assistant Director for Legislative Reference

Dear Mr. Lynn:

This is in reply to your request for the views of this Department concerning S. 3149, an enrolled enactment

"To regulate commerce and protect human health and the environment by requiring testing and necessary use restrictions on certain substances, and for other purposes."

This legislation, to be cited as the "Toxic Substances Control Act", sets forth a comprehensive system for testing, evaluation and control of chemical substances in order to protect human health and the environment from unreasonable risk of injury.

The Department of Commerce recommends approval of S. 3149 by the President.

Enactment of this legislation will not involve additional budgetary requirements for the Department.

Sincerely, Counsel



U.S. DEPARTMENT OF LABOR

OFFICE OF THE SECRETARY WASHINGTON

OCT 5 1976

Honorable James T. Lynn Director Office of Management and Budget Washington, D.C. 20503

Dear Mr. Lynn:

This is in response to your request for our comments on an enrolled enactment, S. 3149, the "Toxic Substances Control Act." We strongly endorse Presidential signature of this legislation.

As you know, this Department has a mandate to protect employee safety and health. Most chemical substances are used in the workplace, and exposure in a workplace situation is usually much more concentrated than elsewhere. We therefore welcome legislation which will provide the Federal Government with new information about the potential health effects, as well as environmental effects, of chemical substances. We also anticipate that this bill will provide new and efficient means of regulating those substances having dangerous properties.

Industrial testing of new chemical substances pursuant to this legislation should encourage industry to look for safe product substitutes prior to substantial investment of production resources, and halt the flow of potentially dangerous substances into the marketplace. Industrial testing and reporting of existing substances will provide the more complete information which all Federal, State and local authorities need in administering existing regulatory programs. A data system to absorb and disseminate this information to concerned Federal agencies, and which will assist to minimize duplicatory Federal information requirements, is to be developed through the cooperative efforts of those agencies. Government research pursuant to this legislation will promote the development of new and inexpensive chemical testing methods for the swift and reliable determination of health and environmental effects. These are just a few of the benefits of the legislation before the President for consideration.

As you know, this Department has been actively involved in the development of Administration policy with respect to the detailed provisions of this legislation, and we are satisfied that the enrolled enactment is generally in accord with that policy.

We expect to continue our active involvement with this new legislation during implementation, taking advantage of the many consultation and coordination provisions it contains, and fulfilling a specific statutory obligation to assist the Environmental Protection Agency in the establishment of testing priorities. In our view, the only viable way to undertake government regulation in this area is through participation by all concerned agencies in efforts to evaluate and, where necessary, to regulate chemical substances, accompanied by recognition of the unique and special expertise which each agency has to offer.

Again, we strongly endorse Presidential signature of this legislation.

Sincerel Secretary of Labor
DEPARTMENT OF HEALTH, EDUCATION. AND WELFARE



OCT 5 1976

The Honorable James T. Lynn Director, Office of Management and Budget Washington, D. C. 20503

Dear Mr. Lynn:

This is in response to your request for a report on S. 3149, an enrolled bill "To regulate commerce and protect human health and the environment by requiring testing and necessary use restrictions on certain chemical substances, and for other purposes."

In summary, we strongly support the goals of this legislation and believe enactment of the enrolled bill would materially assist in protecting the health of the American people. We defer to the Environmental Protection Agency (EPA), the agency charged with administering S. 3149, as to comments on provisions of the enrolled bill relating to specific environmental regulatory matters.

S. 3149 would, among other things, require manufacturers to give advance notice of intent to manufacture a new chemical or to manufacture a chemical for a significant new use, require manufacturers to report information about their chemicals, empower the Administrator of EPA to require the testing of chemicals that might present an unreasonable risk of injury to health or the environment, and enable the Administrator to initiate procedures for restricting or if necessary prohibiting the manufacture of harmful chemicals. The enrolled bill would authorize the Secretary of this Department to develop and evaluate methods for testing the health and environmental effects of chemicals.

The Public Health Service of this Department is charged with responsibility for Federal efforts in the health area. As a result, this Department has undertaken significant initiatives in toxicology and environmental health. Moreover, we have become increasingly concerned with the need The Honorable James T. Lynn

to anticipate and prevent dangerous contacts between man and chemical agents, rather than to attempt to cope with the resulting problems once irreparable harm has been inflicted.

The enrolled bill would greatly facilitate such preventative efforts, as it would not only better protect the health of the American people, but also result in long-term savings in respect to reduced overall costs for medical care and reduced absence from the labor force. If the enrolled bill becomes law, this Department will closely collaborate with EPA in its implementation of the bill since the formulation of regulatory policy will often be based upon health considerations.

We recommend that the President sign the enrolled bill.

Sincerely,

William A. Marsill

Acting Secretary



United States Department of the Interior

OFFICE OF THE SECRETARY WASHINGTON, D.C. 20240

OCT 5 - 1976

Dear Mr. Lynn:

This responds to your request for the views of this Department concerning enrolled bill S. 3149, the Toxic Substances Control Act, which is before the President for approval.

We recommend that the President approve the bill.

The Bill

S. 3149 would require EPA to test chemical substances and mixtures where (1) insufficient information about such chemicals exists and tests are necessary to develop information about their effects on health or the environment and (2) either (a) the chemical may present an unreasonable risk of injury to health or the environment or (b) the chemical will enter the environment in substantial quantities or there will be significant or substantial human exposure to it. The testing requirement would be imposed by rule specifying the chemical, testing standards and, for existing chemicals, a reasonable period for submission of data to EPA. Testing standards and periods would be required to take into consideration relative costs and availability of testing facilities and personnel. A rule could require the submission of preliminary data before the conclusion of testing. The bill provides that standards in rules must be reviewed at least annually and adjusted where appropriate. Rules are to be promulgated under 5 U.S.C. 553. Persons required to submit test data may apply for exemptions, which would be granted where the chemical is equivalent to one already tested or a test would duplicate data already available. Public notice about test data after it is received would be required. A priority list of chemicals (not more than fifty) to be tested must be drawn up by a committee of representatives from specified Executive Branch agencies. In establishing the list, the Committee must give priority attention to chemicals known as or suspected of causing or contributing to cancer, gene mutations or birth defects. Upon receipt of information indicating that a chemical presents a significant risk of harm to human beings from cancer, gene mutations or birth defects, EPA must initiate action under the bill within 180 days (subject to a 90 day extension for cause) to prevent or reduce the risk. Persons



intending to process or manufacture chemicals (for which notice is required under the bill) could petition EPA for standards for the development of test data.

S. 3149 would prohibit (a) the manufacture of any new chemical substance on or after the 30th day after EPA publishes a required inventory of existing chemicals and (b) the manufacture or processing of any chemical for a significant new use (determined by rule) unless EPA is notified 90 days in advance and required test data is submitted. EPA could extend the notice period up to 90 additional days. It would also be authorized to compile a list of chemicals presenting an unreasonable risk of injury to health or the environment. Within 5 days after EPA receives a manufacturing or processing notice or required data, it must in turn publish a notice containing specified information in the Federal Register. Should EPA determine that insufficient information is available to evaluate health and environmental effects but that there may be either an unreasonable risk of injury to health or the environment or significant or substantial human exposure to a chemical, then EPA may issue a proposed order limiting or prohibiting activities involving the chemical. If the manufacturer or processor objects to the proposed order, however, EPA must seek relief in a U.S. District Court, unless the agency decides on the basis of the objections that it cannot make the 'insufficient information' and 'risk of harm' determinations. The injunction must be dissolved after submission of test data sufficient to evaluate health and environmental effects, unless EPA proceeds administratively with the issuance of a rule prohibiting or limiting activities relating to the chemical. Should EPA determine that sufficient information does exist to provide a reasonable basis for concluding that an unreasonable risk of injury to health or the environment would be presented by a chemical, EPA could also issue proposed orders and seek injunctions. Whenever EPA determines not to initiate action either by proposed order, injunction or rule, to a prohibit or limit activity with respect to a chemical, the bill would require EPA to make and publish in the Federal Register a statement of reasons for not taking action. Exemptions from the notice or data submission requirements are provided for test marketing, equivalent chemicals, duplicative data, manufacturing or processing small quantities for scientific purposes after notice of risk to persons engaged in the scientific work, where no unreasonable risk of injury to health or the environment is presented, and for chemicals to which there is no human or environmental exposure and which exist only in the manufacture or processing of another chemical.

If an unreasonable risk of injury to health or the environment is determined by EPA to exist with respect to any chemical, the agency must apply by rule one or more of the following requirements to the extent necessary to protect adequately against such risk, using the least burdensome requirements: 1. Prohibition or limitation of the amount manufactured, processed or distributed.

2. Prohibition or limitation for a particular use or use in excess of specified concentration levels.

3. Marking the chemical.

4. Record-keeping, monitoring and testing.

5. Prohibition or regulation of any manner or method of commercial use.

6. Prohibition or regulation of disposal.

7. Requirement directing manufacturers or processors to give notice of unreasonable risk of injury to distributors or other persons, to give public notice and to replace or repurchase substances presenting unreasonable risks, as elected by the person to whom a requirement is directed.

EPA may impose quality control requirements on chemical manufacturers or processors where the agency determines that inadequate quality control is presenting an unreasonable health or environmental risk, after hearing on the record under 5 U.S.C. 554. In promulgating rules, EPA must consider and publish a statement concerning effects on health and the environment and the magnitude of human and environmental exposure, benefits of the chemical, availability of substitutes, the reasonably ascertainable economic consequences of the rule after consideration of the effect on the national economy, small business, technological innovation, the environment and public health. If the risk could be reduced through application of other laws, EPA would be precluded from issuing a rule under the Toxic Substances Control Act unless it is in the public interest to proceed under that Act. In promulgating a rule, EPA must proceed under 5 U.S.C. 553 (without regard to any reference to sections 556 and 557). It must also publish notice of proposed rulemaking, allow and make publicly available written submissions, provide opportunity for an informal hearing, and promulgate a final rule with specified findings. Provisions are included with respect to management of hearings and support for participation in rulemaking proceedings. A rule may be declared effective prior to final promulgation if (i) the chemical involved is likely to result in an unreasonable risk of serious or widespread injury to health or the environment before final promulgation and making the proposed rule so effective is necessary to protect the public interest, and (ii) a court has granted relief with respect to the risk under the Act's imminent hazard provisions. In such circumstances, expedited procedures are required.

S. 3149 requires that within six months after its effective date, EPA must promulgate a rule to (A) prescribe methods for the disposal of polychlorinated biphenyls (PCBs) and (B) require marking PCBs with adequate warnings and instructions. One year after the effective date of the Act, no person could manufacture, process or distribute PCBs, except in a totally enclosed manner. Exceptions from the "totally enclosed' requirement could be granted where no unreasonable risk of injury to health or the environment would be presented. Two years after the Act's effective date no further PCBs could be manufactured. Two and one-half years after the effective date no person could process or distribute PCBs. Exceptions would be allowed where the 'no unreasonable risk' test is met and good faith attempts to develop acceptable substitutes have failed.

EPA would be authorized by S. 3149 to commence an action in an appropriate U.S. District Court for (A) seizure of an imminently hazardous chemical, (B) specified relief with respect to imminently hazardous chemicals or (C) both seizure and relief.

The bill would also require EPA to establish rules for reporting and retention of information necessary for the effective enforcement of the Act. The nature of information for which record-keeping and reporting may be required is specified and subject to the limitation that it is required "insofar as known to the person making the report or insofar as reasonably ascertainable". After consultation with the Small Business Administration, EPA would promulgate special rules for "small manufacturers and processors". EPA must develop a list of each chemical substance manufactured or processed in the United States to be published not later than 315 days after the Act's effective date. EPA may also require health and safety studies by persons using chemicals. Any person who manufactures, processes or distributes a chemical and who obtains information which reasonably supports the conclusion that the chemical presents a substantial risk of injury to health or the environment would be required to inform EPA immediately unless such person has actual knowledge that EPA has been adequately informed.

Provision is made for EPA to determine that dangerous chemicals may better be dealt with under a Federal law not administered by E.P.A. and to report on the risk of such chemical to the administering agency. If such agency responds to the report by either determining that the risk does not exist or that the agency will act under the laws administered by it, EPA would be prohibited from instituting proceedings to control such chemical. Coordination between agencies administering laws controlling toxic substances is required and in administering the Act EPA would not be deemed to be exercising statutory authority to prescribe or enforce standards or regulations affecting occuptional safety and health for purposes of the Occupational Safety and Health Act of 1970. Under authority granted by S. 3149, EPA would be given certain research, development, training and data collection, dissemination and utilization functions, to be carried out in conjunction with other Federal agencies. Inspection and subpoena authority to carry out the Act would be conferred on EPA and civil and criminal enforcement is provided for. Discharge and discrimination protection is provided for employees participating in proceedings under the Act. Controls and exemptions are specified for the disclosure of data and for imports and exports. S. 3149 would not pre-empt State law except with respect to required testing and regulatory rules or orders under the Act. Even where a Federal rule or order has been promulgated, however, a State could prescribe requirements: (i) identical to EPA standards, (ii) to carry out the Clean Air Act or other Federal law, (iii) to prohibit use of a chemical (except in manufacture or processing of another chemical) or (iv) if EPA determines that a more protective State requirement would not unduly burden interstate commerce. The President would be authorized to waive any requirement of the Act in the interests of national defense.

Judicial review of administrative actions would be provided in U.S. Courts of Appeals. Citizen suits are authorized, as are citizen petitions for EPA to initiate proceedings for issuance, amendment or repeal of a rule or order under the Act, subject to de novo review by a U.S. District Court.

Potential employment effects of actions under the toxic substances program would be subject to continuous investigation and evaluation. EPA would also be required to conduct a study to determine the desirability of providing indemnification as a result of EPA actions under any law administered by it. Other specific study and reporting requirements are imposed on EPA and the agency is also authorized to support complementary State programs with grants up to 75 percent of establishment and operation costs.

To defray the costs of administering the Act, EPA would be permitted to establish by rule and collect fees of up to \$2,500 (but not over \$100 for any "small business concern"). Other Federal agencies are authorized to cooperate with EPA in carrying out the Act. For fiscal year 1977, the bill authorizes \$10.1 million to carry out the regulatory programs, \$12.625 million in FY 1978 and \$16.2 million in FY 1979. The effective date of the Act is January 1, 1977 (except for section 4(f) restraining actions based on receipt of information of serious or widespread harm to human beings from cancer, gene mutations or birth defects).

Discussion

The need for a general Federal toxic substances control law is widely recognized. As human beings and the environment are opposed to increasing quantities of new and existing chemicals, direct governmental action is essential to protect the public interest. In view of this, the Administration has supported legislation to provide appropriate controls without inflicting undue economic or other injury. While S. 3149 does not conform entirely with Administration positions, in major outline it is substantially in accord with Administration goals.

More specifically, the bill addresses the problem of health and environmental hazards from chemicals with a preventive, rather than a rehabilitative, approach. It seeks to ascertain danger in advance without imposing undue costs or discouraging inventiveness and economic progress. Moreover, it provides a vehicle for the development of more authoritative information than exists at the present time for toxic substances. A major benefit of S. 3149 is that it would force the Government to coordinate and rationalize its regulatory and research programs dealing with toxic substances. Finally, and of major importance, the bill adopts the principle of weighing costs and benefits of specific governmental actions, so that these actions will serve the broad public interest.

This Department has major responsibilities which are directly affected by the measure—the economic development functions related to mineral resource use and the environmental protection functions relating to fish, wildlife, recreation and land resources. In implementing S. 3149, it will be essential for both responsibilities to be closely involved with the Environmental Protection Agency. We look to the establishment of arrangements to coordinate with EPA in implementing the law at an early date.

Sincerely yours, ary of the Interior ecret

Honorable James T. Lynn Director Office of Management and Budget Washington, D. C. 20503

EXECUTIVE OFFICE OF THE PRESIDENT COUNCIL ON ENVIRONMENTAL QUALITY

722 JACKSON PLACE, N. W. WASHINGTON, D. C. 20006

October 4, 1976

Dear Mr. Frey:

The Toxic Substances Control Act (S.3149 currently enrolled) fills a critical gap in existing Federal authority to control the use and distribution of hazardous chemicals. S. 3149 represents virtually all of the Administration inputs since it was first introduced as an Administration proposal in 1971 and has nearly universal support, from environmentalists, labor, and the Manufacturing Chemists Association.

Among the most important provisions of this toxic substances legislation is the ability

- -- to identify and prevent problems with as yet unintroduced chemicals
- -- to selectively limit chemical usage so as to minimize the economic impacts of regulation without sacrificing environmental protections
- -- to selectively require testing of only those substances which are most likely to pose problems
- -- to address problems at their source rather than through media controls (e.g., only uses of chemicals leading to fish contamination need be limited rather than the harvesting, sale, and consumption of all fish). Regulations must be the least burdensome feasible consistent with protection of society.
- -- to obtain information on chemical characterization, effects, and use to improve decisionmaking on chemicals throughout the Federal Government.

S. 3149 offers the opportunity for industry, government, and society as a whole to get out of its current reactive posture toward hazardous chemical substances. An effective preventive approach to chemical hazards is not only sound from an environmental and public health perspective; it also makes economic sense. The Council, therefore, urges strongly that S. 3149 be signed into law.

Sincerely, Sundberg for censia Gary Widman

General Counsel

Mr. James Frey
Assistant Director
for Legislative Reference
Office of Management and Budget
Washington, D.C. 20503

Attention: Ms. Ramsey Room 7201 NEOB



OFFICE OF THE DIRECTOR

October 4, 1976

Mr. James M. Frey Assistant Director for Legislative Reference Office of Management and Budget Washington, D. C. 20503

Dear Mr. Frey:

This is in reply to your communication of September 30, 1976, requesting the comments of the National Science Foundation on Enrolled Bill S. 3149, the "Toxic Substances Control Act".

The Foundation supports approval of the bill by the President.

Sincerely yours,

R.C. Att Kunisan

Richard C. Atkinson Acting Director

EXECUTIVE OFFICE OF THE PRESIDENT OFFICE OF SCIENCE AND TECHNOLOGY POLICY

WASHINGTON, D.C. 20500

October 4, 1976

MEMORANDUM FOR JAMES FRY Assistant Director for Legislative Reference Office of Management and Budget

SUBJECT: Enrolled Bill S. 3149, "Toxic Substances Control Act"

This is in response to your request for OSTP to review and comment on S. 3149, "Toxic Substances Control Act" Bill. I have no major objections to this bill and urge that the President sign it.

There are currently several million man-made chemicals in existence. New ones are coming on the market every day. Many have known adverse effects on man, other biological systems, and/or the environment. There are a number of products not covered by existing regulatory authorities, and this proposed bill appears to take care of the jurisdictional gap. While most human exposures to toxic substances can be covered by the regulatory authority through the indirect control of other legislation (e.g., air, the water, occupational health, foods, drugs and cosmetics), such an approach tends to be inefficient because it attacks the problem after the contamination has already occurred. When regulation occurs after the problem develops rather than before, economic hardships tend to be compounded -- wrong industries are punished because sectors other than the original producer of the chemical have become dependent upon the use of the product in many cases.

This bill gives EPA major discretionary power to take control measures, allowing for selective regulation based on chemical type, usage, and amount produced. In this regard I believe that the safeguards built into the legislation ggainst any overzealous action are most important. For example, under Section 2(a), "The administrator shall consider the environmental, economic, and social impacts of any action the administrator takes or proposes to take under this act."

S. 3149 also requires interagency coordination and consultation which I believe will result in improved decision-making about the impact of chemicals on the environment. I am also pleased to note that it calls for regulation of Polychlorinated Byphenyls (PCB) within six months of enactment. Control of PCBs has been a major problem since existing regulations do not cover a majority of uses.

H. Guyford Stever

Director



October 5, 1976

Honorable James T. Lynn Director, Office of Management and Budget Old Executive Office Building, Room 252 17th St. and Pennsylvania Ave. N. W. Washington, D. C. 20503

Dear Mr. Lynn:

In reply to the request of your office, the following report is submitted on the enrolled enactment S.3149, "To regulate commerce and protect human health and the environment by requiring testing and necessary use restrictions on certain chemical substances, and for other purposes."

This Department recommends that the President approve the bill.

The bill provides for Federal regulation of chemical substances and mixtures during manufacturing, processing and distribution in commerce. The bill specifically provides that the Administrator of the U. S. Environmental Protection Agency shall have authority to effectuate the provisions of the Act.

This legislation is the result of a long period of fact-finding, expert consultation, and concerted efforts to reconcile many diverse viewpoints and concerns. The Department agrees that greater accountability in the manufacture, processing and distribution of chemical substances and mixtures is consistent with United States goals of improving the quality of the environment and protecting human health. It must be recognized, however, that proper and efficient administration of the Act is essential to minimizing incremented costs to the manufacturing, processing and distribution system of the United States, and also to supporting the continuing dynamic role of the country as a world leader in providing and developing chemicals important to mankind.

Sincerely,

Acting Secretary

Bepartment of Justice

Washington, D.C. 20530

October 5, 1976

Honorable James T. Lynn Director Office of Management and Budget Washington, D.C. 20503

Dear Mr. Lynn:

In compliance with your request, I have examined a facsimile of the enrolled bill S. 3149, "To regulate commerce and protect human health and the environment by requiring testing and necessary use restrictions on certain chemical substances, and for other purposes."

The enrolled bill would authorize the Administrator of the Environmental Protection Agency to regulate chemical substances which present an unreasonable risk of injury to health or the environment.

The enrolled bill contains four provisions which would authorize attorneys of the Environmental Protection Agency to represent the Administrator in civil litigation arising under the enrolled bill. Sections 4(e)(2)(C)(iii); 5(e)(2)(A)(i); 5(f)(3)(A)(ii); 7(e).

Subparagraph (e) of Section 4 would establish a committee to make recommendations to the Administrator respecting those chemical substances which the Administrator should give priority consideration for the promulgation of a rule under subparagraph (a). The prerequisites for appointment to the committee are set forth in subparagraph (e). In particular, "no person, while serving as a member of the committee, or designee of such member, may own stocks or bonds, or have any pecuniary interest, or substantial value in any person engaged in the manufacture, processing, or distribution in commerce of any chemical substance or mixture subject to any requirement of this Act or of any rule promulgated or order issued thereunder." Section 4(e)(2)(C)(ii). The Administrator, acting through attorneys of the Environmental Protection Agency, or the Attorney General may bring an action in the appropriate district court of the United States to restrain any violation of this subparagraph. Section 4(e)(2)(C)(iii).

Section 5 would prohibit the manufacture of new chemical substances or existing chemical substances intended for a significant new use unless the manufacturer of such substance makes a showing to the satisfaction of the Administrator that the manufacture, processing, distribution, use, or disposal of said substance does not present an unreasonable risk of injury to health or the environment. Section 5(a). The manufacturer of any such substance would be required to give the Administrator at least 90 days notice of the persons's intention to manufacture or process the substance. The Administrator would be authorized to make a determination that the use of the chemical substance is a significant new use by the promulgation of a rule after notice and opportunity for comment. Section 5(a)(2). Moreover, the Administrator would be authorized to issue a proposed order which would prohibit the manufacture, processing, distribution, use, or disposal of any chemical substances pending the promulgation of a rule. Section 5(e). If the 90 days notice required by subparagraph (a) is not given, the Administrator, through attorneys of the Environmental Protection Agency, shall apply to the United States district court for an injunction prohibiting the manufacture, processing, distribution, use, or disposal of any such sub-Section 5(e)(2)(A)(i). Moreover, if the Adminisstance. trator finds that there is reasonable basis to conclude that the manufacture, processing, distribution, use or disposal of a chemical substance for which notice is required will present an unreasonable risk of injury to health or the environment before a rule can be promulgated, the Administrator may issue an order prohibiting the manufacture, processing, distribution, use or disposal of the chemical substance or apply, through attorneys of the Environmental Protection Agency, to a United States district court for an injunction. Section 5(f)(3)(A)(ii).

Section 7 would authorize the Administrator to commence a civil action in an appropriate district court in situations involving the manufacture, processing, distribution, use or disposal of imminently hazardous chemical substances. The Administrator may direct attorneys of the Environmental Protection Agency to appear and represent the Administrator in such actions. Section 7(e). We are particularly concerned with the provisions on civil litigating authority due to the fact that neither S. 3149 nor its House counterpart, H.R. 14032, contained the provisions set forth in section 5 above when these bills initially passed the respective House of Congress. Thus, the conferees added significant provisions relating to the authority to conduct civil litigation to the instant bill which were not initially considered by either House of Congress. The bill does, however, retain the authority of the Attorney General to conduct litigation in several enumerated areas: petitions for review in appellate courts, citizen suits, criminal actions, civil penalty collection actions, and certain seizures and suits for injunctive relief.

The Department of Justice recommends that should this bill not receive Executive approval, one reason for its disapproval should be that it significantly encroaches upon the authority of the Attorney General to conduct litigation on behalf of the United States and certain of its agencies.

Siderely, Alichael M. Uklima

Michael M. Uhlmann Assistant Attorney General

THE WHITE HOUSE

ACTION MEMORANDUM

WASHINGTON

LOG NO.:

Date: October 8

Time: 1030am

FOR ACTION: George Humphreys Max Friedersdorf Bobbie Kilberg Glenn Schleede cc (for information):

Steve McConahey Ed Schmults Jack Marsh

FROM THE STAFF SECRETARY

DUE: Date: October 9

Time: noon

SUBJECT:

S.3149-Toxic Substances Control Act

ACTION REQUESTED:

____ For Necessary Action

____ For Your Recommendations

_____ Prepare Agenda and Brief

X For Your Comments

____ Draft Remarks

_ Draft Reply

REMARKS:

please return to judy johnston, ground floor west wing



PLEASE ATTACH THIS COPY TO MATERIAL SUBMITTED.

If you have

testions or if you anticipate a the required material, please ecretary immediately.

James M. Cannob For the President