

*Author*

Date MARCH 17, 1976

INTEROFFICE  
MEMORANDUM

Subject EPA -- TOXIC SUBSTANCES CONTROL

LEGISLATION

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Attached for your information are comments by Russell E. Train, as published in the Environmental News, concerning the testing of chemicals in the fight against cancer and other major diseases.

/mjv  
Attachment

*A. J. Diglio*  
A. J. DIGLIO

(320)

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# Environmental News

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FOR RELEASE AFTER 1:00 P.M., THURSDAY, FEBRUARY 26, 1976

TRAIN URGES PREVENTIVE MEDICINE TO CURE CHEMICAL THREAT

Environmental Protection Agency Administrator Russell E.

Train today told the National Press Club that it's time to start testing chemicals, not people, in the fight against cancer and other major diseases.

He urged the enactment of Toxic Substances Control legislation that would give "the American people not only the opportunity to understand and assess the risks and benefits of these chemicals, but a decisive voice in sorting out these risks and benefits."

Train said that of the more than 2 million known chemicals, only a few thousand have been tested for carcinogenicity and -- aside from those used in food additives, drugs and pesticides -- only a few hundred have been adequately tested.

"Long after they have been loosed upon the world and the public at large," Train said, "we have learned what an appalling wide range of disease and death can be caused by chemicals -- they can attack the liver, the lung, the kidney, the central nervous system; they can cause cancer, infant mortality, and genetic damage. We have learned, for example, that: mercury, lead and cadmium can attack the central nervous system; carbon tetrachloride and chlorinated phenols can destroy the liver; ethylene glycol and cadmium sulfate produce kidney disease; and vinyl chloride and arsenic cause cancer.

We have seen our fish contaminated by phthalates, our cattle poisoned by polybrominated biphenyls, and our horses

(more)

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killed by dioxin. Fluorides have destroyed forest seedlings, chloramines have killed oysters, and zinc has damaged our wheat crops. And now the fluorocarbons may be threatening the ozone belt."

Train emphasized five basic points about chemicals and their effects upon human health:

--Entirely new chemicals have been released into the environment over the past few decades with little or no knowledge of their health effects.

--Enormous benefits have been reaped from chemical use, and those benefits must be measured in health terms as well as economic.

*CIGARETTES  
MAJOR CAUSE*

--An estimated 60 to 90 percent of all cancers are the result of environmental factors. Yet of all the chemical agents in the environment, probably only a very small fraction is responsible for that large share of cancer.

--It may take only limited exposure to contract cancer. It typically takes anywhere from 15 to 40 years after that exposure for the first onset of cancer to occur.

--A large and growing share of the diseases that cripple and kill are caused by "environmental factors."

"Our national health care efforts," Train said, "must increasingly stress the prevention rather than the treatment of disease, and effective measures for the assessment and control of potentially dangerous chemicals and other agents before they enter the environment must be a key element in this new shift toward preventive medicine."

Train said that after five years of congressional consideration of a toxic substances legislation, "We still find ourselves without the authority we need to cope with such longstanding problems as those posed by polychlorinated biphenyls (PCBs)."

"Last week," Train said, "it was announced that for the first time in history, the Hudson River will be closed to commercial fishing because it is contaminated by these chemicals. In the Great Lakes, commercial and sports fisheries that are being restored as the result of massive pollution clean-up efforts are now being threatened by PCB contamination. We remain almost entirely unable to discover how harmful a compound can be until years after it has become a rather commonplace item in our everyday life, even a significant factor in our economy."

(more)

Train refuted "industry spokesmen" who claim that toxic substances legislation "would 'cripple' the chemical industry and give the Administrator of EPA near dictatorial authority over the introduction of new chemical products'."

"The only real 'crippling' that is going on," Train said, "is the kind which this legislation would try to prevent -- the crippling of who knows how many Americans every year who contract cancer or some other affliction after exposure to some hazardous chemical agent. Nor has it been on the 'near-dictatorial authority' of the EPA Administrator that so many such agents are introduced into the environment without any effort to find out what their health effects are, much less let the public have any say about whether or not, or in what circumstances, it is willing to be exposed to them."

"I do not think any of us is under the illusion that there is, or is ever going to be," Train said, "any such thing as a simon-pure, antiseptically safe world. I do not think any of us imagines that there is, or ever going to be, a real world without very real risks. But there is absolutely no reason why we cannot -- there is, in fact, every reason why we must -- take sensible steps to exercise some intelligent and effective control over the risks that we ourselves create. The basic aim of the toxic substances control legislation before the Congress is to help us gain that kind of control -- to help us protect human health by bringing down to reasonable levels the risks that chemicals pose while preserving their benefits. We are not talking, in other words, of getting rid of all risks from chemicals, but rather of finding out what the risks are and, eventually, of removing "unreasonable" risks. We are saying that, whatever we do with these chemicals, we ought to know what we're doing before we do it, and we ought to do it with our eyes wide open."

Train said that, had the Toxic Substances Act been enacted five years ago when it was first proposed, "we would be a lot farther ahead in dealing with some potentially very serious hazards;

--We would have begun to reverse the spread of polychlorinated biphenyls which are now destroying some of our valuable fisheries;

--We would already have, as we now do not, reliable test information concerning the effects of vinylidene chl. ride which is widely used throughout the plastics industry;

--We would have a greatly improved data base for determining the extent to which benzidine-derived dyes reconvert to free benzidine, a well-known human carcinogen, when these widely-used dyes are accidentally ingested or absorbed;

(more)

--We would have taken a number of steps to clarify the chronic effects and, as necessary, to limit exposure to tris 2,3-dibromopropyl phosphate, which has mutagenic effects in microbial systems and is widely used as a fire retardant in textile products, including children's pajamas."

"Most Americans had no idea, until relatively recently, that they were living so dangerously. They had no idea that when they went to work in the morning, or when they ate their breakfast -- that when they did the things they had to do to earn a living and keep themselves alive and well -- that when they did things as ordinary, as innocent and as essential to life as eat, drink, breathe or touch they could, in fact, be laying their lives on the line. They had no idea that, without their knowledge or consent, they were often engaging in a grim game of chemical roulette whose result they would not know until many years later."

"It is time we started putting chemicals to the test, not people. It is time we gave the people of this country some reason to believe that, everytime they breathe or eat or drink or touch, they are not taking their life into their own hands," Train said. "It is time that, down here on earth, we took a couple of small, sensible steps on behalf of human health and life."

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*Author*

INTEROFFICE  
MEMORANDUM

Date MARCH 2, 1976

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Attached for your information is the MCA's "Special Issue on Toxic Substances" pending bills (S. 776 and H.R. 10318). S. 776 is now out of the Senate Committee. This issue states the Manufacturing Chemist's position on the legislation and calls for assistance in communicating these views to congressmen and representatives.

We are preparing a draft of a letter on the subject. Its purpose is for possible use by chemicals group plant managers for mailing to their respective congressmen and senators.

  
A. J. DIGLIO

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## Special Issue

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## Toxic Substances

Fast Action Needed  
To Gain Moderate Bill

## MCA NEWS

Published by Manufacturing Chemists Association

February 1976

## Industry Position on Toxic Substances

1. The chemical industry shares the public's concern with toxic materials and the determination to have adequate protection through industry programs and governmental regulation.

2. The chemical industry, over the years, has developed the capability of producing and handling hazardous chemicals safely and is committed to the principle that its products, when handled responsibly, must be safe for manufacture, use and disposal.

3. The chemical industry believes it should be responsible for adequately screening and conducting safety tests on its new products and the chemical industry accepts this responsibility.

4. A number of companies recently joined to form the independent Chemical Industry Institute of Toxicology to screen large-volume chemicals for safety, including their long-term effects at low-dose exposures.

5. The chemical industry realizes that more can and should be done, and to this end supports additional constructive federal legislation on toxic substances that will close the gaps in present law and offer greater protection to workers, consumers and the general public.

6. The industry opposes unnecessary testing requirements for all new and existing chemical substances without adequate regard to the relative level of risk which may be involved.

7. The industry opposes administrative authority that could ban the production of a chemical, shut down the plants making it or using it and terminate the jobs involved based on a possible finding that a substance is merely likely to constitute an unreasonable risk to health and the environment without requiring the preparation of economic impact and risk/benefit analyses.

8. The industry opposes rulemaking authority for testing, notification, screening, banning or restricting unless based on findings justifying the required action which have been developed in accordance with fair procedures and which are subject to adequate judicial review.

9. The industry opposes any authority to disclose trade secrets and confidential information beyond what is necessary for carrying out responsibilities under the act and judicial enforcement proceedings.

10. The industry opposes the uncertainty which would be created by the passage of the pending bills by encouraging duplicative action by different federal agencies and which would permit the Environmental Protection Agency (EPA) to pick and choose among potentially applicable laws (overlapping legislation).

11. The industry opposes both pending bills (S. 776 and H.R. 10318) as unnecessarily broad and unduly burdensome legislation that would not serve the national interest, is not necessary to protect human health and the environment, is economically wasteful, and would retard innovative research and development for new products.

12. The McCollister bill, H.R. 7664, as introduced would correct many of the defects cited above, and we endorse the principles of this bill. The Administration has now endorsed H.R. 7664 with certain amendments and the industry is actively working for the enactment of this legislation.

"We have a very difficult job at hand to achieve moderate, constructive toxic substances control legislation at this late hour in the legislative process," Richard E. Heckert of Du Pont, chairman of MCA's Special Committee on Toxic Substances Legislation, wrote to MCA member companies on February 16.

"To succeed we need an extraordinarily effective effort by member companies of the Association in communicating to members of Congress support for moderate legislation and opposition to the present onerous bills in the Senate and House."

In the same memorandum, Mr. Heckert addressed the smaller member companies of MCA, urging them to waste no time in communicating directly with their senators and representatives relative to the potential adverse impact of the Tunney and Eckhardt bills.

Mr. Heckert and other chemical industry representatives have been meeting with congressional delegations from various states and with individual senators and representatives to present industry's position.

The purpose of this edition, therefore, is to provide background articles and papers that you and your firm can use in the effort to amend such legislation constructively.

For example, all of the material can be shaped for use in:

- Talks with congressmen and senators.
- Letters to congressmen and senators.
- Employee publications and bulletin boards.
- Talks with suppliers, dealers and customers.
- News releases to local newspapers, newsweeklies and radio and television stations.
- Speeches to local groups such as service organizations.
- Enlisting the aid of other groups you feel would or should be interested in the subject, such as local or state trade and business associations.

The material in this publication is fully approved as the chemical industry position reflected through the Manufacturing Chemists Association. We urge that you use it promptly as you see fit. There are no restrictions on reproduction.

For additional free copies, please telephone John Slavick, editor of MCA News, Washington, D.C. The number is 202-483-6126.

AP00037045

# Legislators Hear MCA Special Committee Chairman

I'm pleased to appear before you today to state unequivocally the Manufacturing Chemists Association's views on toxic substances legislation, views which are embraced by most of the industry.

1. The chemical industry shares the public's concern with toxic materials and the determination to have adequate protection through industry programs and governmental regulations.

2. The chemical industry realizes that more can and should be done and to this end supports additional federal legislation on toxic substances that will close the gaps in present laws and offer greater protection to workers, consumers and the general public.

3. The industry is committed to the principle that its products, when handled responsibly, must be capable of safe manufacture, use and disposal.

4. The chemical industry, over the years, has developed and clearly demonstrated its capability of producing and handling hazardous chemicals safely. There have, of course, been mistakes and instances of unsatisfactory performance, and such situations must be corrected and avoided in the future. No matter what federal law is involved, industry must fulfill its responsibility for the safety of its products.

*Summary of remarks by Richard E. Heckert, chairman of MCA's Special Committee on Toxic Substances Legislation, before a recent New Jersey Congressional breakfast.*

5. Of concern to us at the moment is the current allegation that industrial chemicals represent a major factor in recently reported large increases in cancer within the population. This is simply not the case. When adjusted for age and lung or respiratory cancer, the data show no such increase.

Before specifying the type of legislation which we believe would provide added public protection from toxic substances, I would like to emphasize several principles which we think should guide your deliberations on toxic substances.

First, the chemical industry has always handled and will continue to handle hazardous substances in the normal course of its commerce; legislation will not eliminate all toxic substances in our industry such as hydrogen cyanide, vinyl chloride, sulfuric

acid. They are the building blocks for other industrial activities and important consumer products.

Second, zero risk in industrial operations or any other phase of our lives is unattainable. No one can guarantee that a specific substance is totally safe. Even after extensive testing, one more test may develop knowledge of a hazardous situation that previous tests failed to disclose. Society has established certain risk-benefit relationships for products—for example, with regard to the continued use of cigarettes, automobiles and airplanes—that also apply to decisions on hazardous chemicals. The question is not how to achieve zero risk; but what risks must society accept in order to enjoy the benefits of a particular product, and how may these risks be managed satisfactorily? Our nation has progressed through its ability and intelligence to accept and manage risks, and I am sure it will continue to do so.

Third, regulation of this sort represents added cost to the public whether it is added taxes or higher prices. No one is suggesting that some cost should not be incurred, but rather that these costs should be accompanied by comparable benefits.

## Support McCollister Bill

We support, with some modification, the principles embodied in the McCollister bill, H.R. 7664, which represents constructive legislation. (The Administration has now endorsed H.R. 7664 with certain amendments and the industry is actively working for enactment of this legislation.) This bill was in fact passed by the House of Representatives in the 93rd Session. To this effect, we support authority to require testing of selected chemicals, premarket notification or screening of new chemicals and significant new uses of established chemicals. We also support authority to restrict or limit uses or ban production of chemical substances.

But these are not new principles. They have been embodied in legislation passed by both the House and the Senate in the 92nd and 93rd Sessions of Congress.

The new bills (H.R. 10318 and S. 776) differ from McCollister's as to the scope of discretionary authority that should be granted EPA. Fundamental differences apply to granting and exercising authority for premarket notification or screening and the authority to restrict or limit uses or ban production.

For example, one or the other of these bills would permit:

1. Testing and screening requirements for all new chemical substances and significant new uses of existing chemical substances *without adequate regard* to the relative level of risk which may be involved (S. 776).

2. Standards for testing such as, that a substance may *merely contribute* to an unreasonable risk (H.R. 10318).

3. EPA authority to ban the production of a chemical, shut down the plants making it or using it and terminate the jobs involved based on the vague and uncertain finding that a substance is *merely likely* to contribute to an unreasonable risk to the environment (H.R. 10318) and without requiring the preparation of economic impact and risk/benefit analysis (H.R. 10318 and S. 776).

4. Broad rule-making authority for testing, notification, screening, banning or restricting the use of a chemical *without adequate procedural rights*.

Currently, the McCollister bill does not contain many of the objectionable provisions that are found in H.R. 10318 and S. 776, and is considerably more reasonable in many areas, such as testing, premarket notification and regulatory control. Yet McCollister imposes significant new testing requirements and controls on industry. Let's focus on just a few provisions of the McCollister bill.

## Testing Required

The McCollister bill requires testing of a chemical if the administrator finds that testing is necessary to protect against an unreasonable risk to health or the environment.

The McCollister bill requires premarket notification of those chemicals likely to pose a substantial danger to health or the environment.

The McCollister test does not require a showing of an actual danger, but only that a chemical is likely to pose such a danger or that there is a probability and not a mere possibility.

McCollister also requires that the least burdensome controls be imposed to prevent or sufficiently reduce the risk and expressly proposes a hierarchical level of controls including banning but only if necessary.

## Selected MCA Position Papers Negative Burden of Proof

### The Issue:

Should a negative burden of proof be imposed on the defendant in this legislation? Traditionally, a plaintiff must make some demonstrable proof that harm exists or will result. How can a defendant maintain any defense if there is no such need? In effect, he would have to prove a negative—that is, complete absence of risk, or zero risk. Such a burden is scientifically impossible and totally unreasonable.

The Senate Toxic Substances bill (S. 776), section 13(e) explicitly reverses the burden of proof in all judicial proceedings requesting equitable relief brought under any statute administered by the EPA administrator.

This subsection provides that "where a risk to public health is . . . established, the failure . . . to prove that demonstrable harm to health exists or will result shall not . . . constitute a permissible basis to deny . . . relief." The key question, of course, is what is meant by "establishing" a "risk?" Without further statutory qualification it could readily mean "slight" or mere "speculative" risk. And, if the plaintiff cannot have its relief denied because of a failure to prove any

harm, what must the defendant do to prevail? Even the most convincing case proving lack of injury might be held insufficient, under the act, to warrant denial of the injunctive relief sought by the plaintiff. It may well be that no defense would suffice, since even proof that no demonstrable harm would result might not permit the court to dismiss the case in defendant's favor.

### The Chemical Industry Supports:

- Deletion of section 13(e).

### The Chemical Industry Opposes:

- Any proposal relieving a plaintiff of the burden of proving at least some demonstrable harm and which shifts to the defendant the negative burden of proving no harm under all possible conditions.

### Brief Analysis of the Negative Burden of Proof Aspect of Proposed Legislation:

#### S. 776 (Tunney):

- See above.

#### H.R. 10318 (Eckhardt):

- No provision.

#### H.R. 7664 (McCollister):

- No provision.

## Testing Requirements

### The Issue:

The key issue is the scope of discretionary authority that should be granted in requiring testing and under what conditions such authority should be exercised.

The industry is committed to the principle that its products must be adequately tested so that when they are handled responsibly, they will be safe for manufacture, use and disposal.

### The Chemical Industry Supports:

- Allowing the administrator to require testing of selected chemicals when necessary to protect against an unreasonable risk.

### The Chemical Industry Opposes:

- Broad selective testing requirements which would require testing based on merely possibilities as opposed to probabilities and without adequate consideration of relative levels of risk.

- Use of the nation's limited toxicological testing capabilities for evaluation of low-risk chemicals, thus preempting

needed facilities for evaluation of significant risks.

- The added cost of extensively broad testing requirements and incremental research and development costs which may lead to drastically curtailed new product development and selection of candidates for such development.

### Brief Analysis of the Testing Aspect of Proposed Legislation:

#### S. 776 (Tunney):

- Testing of chemicals is required whenever the administrator determines that "there is reason to believe that a substance may present an unreasonable risk." While testing is further subject to the requirement that testing would be necessary to make a determination whether or not the risk exists, the basic standard is so broad and uncertain as to subject a large number of chemicals to test programs which may not be necessary.

#### H.R. 10318 (Eckhardt):

- Requires the testing of existing chem-

*continued on page 4*

## Confidentiality

### The Issue:

In enforcing or administering any toxic substances law which requires the testing and premarket notification and screening of chemicals, it is reasonable that the administrator of EPA have access to data and information that is relevant to his statutory duties. Such data may involve trade secrets and other confidential material not otherwise available to government and the public. The issue is to what extent can such information be protected from public disclosure.

### The Chemical Industry Supports:

- Legislation which protects the confidentiality of trade secrets and other information by limiting use of the data to enforcement proceedings or other regulatory proceedings.

### The Chemical Industry Opposes:

- Legislation which threatens the confidential status of trade secrets or other information by granting access to the data to persons not associated with the enforcement or administration of the toxic substances law.

### Brief Analysis of the Confidentiality Aspect of Proposed Legislation:

#### S. 776 (Tunney):

- Allows disclosure of confidential information if the administrator "determines it is necessary to protect human health and the environment."

- Provides for disclosure of confidential information to "qualified scientists" if the administrator determines it is in the public interest.

#### H.R. 10318 (Eckhardt):

- Provides adequate protection.
- If the administrator determines that public disclosure is necessary, the owner of the data is notified in writing 30 days in advance of disclosure so he may protest to the administrator or seek relief in the courts.

#### H.R. 7664 (McCollister):

- Provides adequate protection.
- Limits disclosure to rule-making proceedings and court actions.

# MCA Position Paper: Procedural Fairness

## The Issue:

The administrator is authorized to make regulations which can limit or prohibit the manufacture and distribution of a chemical substance. This regulatory power is the core of the proposed legislation and must be exercised pursuant to fair and objective procedures. Disputed issues of fact must be identified and resolved, the administrator's conclusions must rest on findings supported by a complete hearing record, and the regulations must be subject to review in federal court. In a similar vein, the right of an interested citizen to ensure that the administrator is fulfilling his duties must be balanced against the need to protect the administrator from constant second-guessing.

## The Chemical Industry Supports:

- Legislation granting the administrator the authority to issue binding regulations governing toxic chemical substances, even including the power to ban such chemicals as are found to pose an unreasonable risk to human health.
- Legislation requiring such regulations to be based on findings developed from the record of rule-making hearings.
- Legislation specifying that the administrator must allow cross-examination and hear rebuttal evidence with respect to disputed factual issues relevant to a proposed rule, as Congress required in the recent Warranty-Federal Trade Commission Improvement Act of 1975.
- Legislation denying the administrator the power to ban a product from the market without either providing a hearing or seeking a court injunction.
- Legislation providing normal judicial review of the administrator's denial of a citizen's petition.

## The Chemical Industry Opposes:

- Legislation subjecting industry to the power to ban its products without having the right to rebut and cross-examine the facts upon which the administrator may have relied.
- Legislation allowing the administrator to rely on information not introduced at the hearing, and thus not subject to examination or rebuttal.
- Legislation permitting the administrator to ban or restrict a product, or to issue rules regarding the testing or screening of products, without requiring him to make findings regarding relevant factors.
- Legislation authorizing the administrator to ban any substance without a hear-

ing or without applying for a court injunction, based upon his "determination" that a hazard is imminent.

- Legislation permitting any citizen whose petition for issuance of a rule has been rejected by the administrator to go to court and have a full-fledged trial second-guessing the administrator's expertise.

- Legislation authorizing citizens to sue manufacturers for alleged violations of the administrator's regulations, rather than suing the administrator for alleged nonenforcement of his orders.

## Brief Analysis of Procedural Fairness Aspect of Proposed Legislation:

S. 776 (Tunney):

- Grants no cross-examination rights, other than what the administrator in his discretion deems appropriate.
- Contains no requirement that the administrator make findings regarding relevant factors.
- Does not require that the "record" on which a regulation is based be limited to written submissions, oral testimony, and other information which the administrator has specifically designated as relevant in the Federal Register.
- Permits the administrator under certain circumstances to ban a product without a hearing or seeking an injunction.
- Allows a citizen whose petition the administrator has denied to have a *de novo* trial in federal court, thereby turning the court into a mini-EPA required to hear whatever evidence the citizen may wish to offer.

- Allows a citizen to press his views regarding whether a manufacturer has complied with the administrator's regulations by suing the manufacturer in court, rather than seeking redress against the administrator for failing to enforce his regulations.

H.R. 10318 (Eckhardt):

- Grants the right to cross-examination only if there is a single interested party, or if the administrator determines that all who want to cross-examine are of one view and can be represented by a single person.
- Contains no requirement that the administrator make findings regarding relevant factors.
- Permits the administrator under certain circumstances to ban a product without a hearing or seeking an injunction.
- Allows a citizen whose petition the administrator has denied to have a *de novo* trial in federal court, thereby turning the court into a mini-EPA required to hear

whatever evidence the citizen may wish to offer.

- Allows a citizen to press his views regarding whether a manufacturer has complied with the administrator's regulations by suing the manufacturer in court, rather than seeking redress against the administrator for failing to enforce his regulations.

H.R. 7664 (McCollister):

- Grants the right to cross-examination only if there is a single interested party, or if the administrator determines that all who want to cross-examine are of one view and can be represented by a single person.
- Contains no requirement that the administrator make findings regarding relevant factors.
- Does not require that the "record" on which a regulation is based be limited to written submissions, oral testimony and other information which the administrator has specifically designated as relevant in the Federal Register.
- Requires the administrator to seek a court injunction if he believes an imminent hazard requires the banning of a product without an administrative hearing.
- Does not permit any person to litigate in federal court the correctness of the administrator's exercise of his discretion in deciding not to issue a rule.
- Does not permit any citizen to sue any manufacturer for alleged failure to comply with the act or regulations issued thereunder.

## Position on Testing

*continued from page 3*

icals which "may cause or contribute to an unreasonable risk to health or the environment." While testing is limited to a finding of necessity to determine whether or not such risk exists, the basic standard is so broad and uncertain as to subject a large number of chemicals to test programs which may not be necessary.

- An independent, interdepartmental agency is established to recommend testing priorities which are mandatory unless the administrator publishes his reasons for refusing to require such testing. Such establishment of testing priorities that for all practical purposes are mandatory deprives the administrator of discretionary judgment.

H.R. 7664 (McCollister):

- This bill limits testing to where necessary to protect against an unreasonable risk to health and the environment.