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# 1978 FOOD AND AGRICULTURAL OUTLOOK

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**FOOD—SUPPLIES, DEMAND,  
AND CONSUMPTION**

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## NATIONAL APPROACH TO CARCINOGENS

(By David W. Huston for Hon. Barbara Hackman Franklin, Commissioner,  
Consumer Product Safety Commission)

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Several weeks ago at a press conference in Harrisburg, Pa., I called for White House leadership in the development and articulation of a national, coordinated effort toward control of possible cancer-causing substances, only one example being Tris, with which I am sure you are familiar. I said at that time that what is needed is open and frank discussion of the causes and control of cancer, the second leading cause of death in the United States, the subject of growing governmental attention, and a source of great concern to the public and to those in business who face decisions about the manufacture and marketability of many chemical compounds in a variety of applications.

The consternation of the American people is understandable. Is nothing safe any more? Are we victims, they ask, of overdramatization by the media? Regulatory overkill? Industrial conspiracies? Is this a necessary price we pay for living in a highly industrialized society? Or, are the dangers all too real and avoidable?

The stark reality, of course, in trying to answer these questions in any final way is that we find ourselves not knowing with certainty all the causes of cancer. And trying to find out is difficult, agonizing and can take years.

What we do know, however, is this: Advances in the basic scientific state of the art clearly indicate that nothing more surely will guarantee wrong answers in this area than neglect or complacency. In other words, we know enough to know that closer focus on carcinogenicity is not misdirected. In fact, we can expect more certainty as science becomes increasingly capable of identifying hazards where none were thought to exist before.

But Federal involvement spans many agencies—each with its own laws, priorities and budgetary limitations. What then constitutes adequate public protection? Are the answers to be found more in terms of the efforts of the individual agencies or the Federal response as a whole? Is attention to many chemical hazards required or a more detailed focus on a few?

There are other questions. Is there need for greater consistency on the ways agencies move from research results to regulation—or will this always boil down to decisions on a case-by-case basis within the parameters of each agency's laws? How do we minimize delay in the regulatory process yet assure an ethically and legally defensible basis for regulation, meaningful public participation and adequate due process? Do we scrap cost/benefit thinking altogether as some have suggested? Or do agencies have the obligation to assure that decisions do not go

beyond the point when regulation—or reluctance to act—may be self-defeating?

As a Nation, we need to better identify tests that are reliable, fast and cheap to screen substances for carcinogenicity. Some short-term testing is being used but no one in or out of Government is sure just yet how conclusive a predictor it is or should be as a basis for regulation. And, animal tests to determine carcinogenicity can take years and cost up to \$250,000 each. At the moment, each agency has or is formulating its own testing guidelines and criteria. So presumably are many companies.

One result is that as companies try to evaluate new chemicals on the theory that safety should be tested in the lab and not in the environment—they find no uniform Federal or scientific position on what tests should be conducted and how the results should be interpreted.

The latest example of the problems we face with the testing of toxic substances surfaced recently with Fyrol. The CPSC held a public meeting with consumer interests, representatives from private industry, and scientists in the testing field to discuss testing methods and results regarding the flame retardant, Fyrol FR-2, which has been used in some cases as a substitute for Tris in children's sleepwear. One consumer group advocated that garments treated with Fyrol be recalled from the marketplace based on a series of short-term tests done by several laboratories while those in the industry who manufacture Fyrol or clothing treated with the chemical claim that their tests, performed separately, and using different methods, did not indicate that a potential hazard exists. These kinds of discrepancies in testing methods and results make it difficult for regulators to know which chemicals may pose potential hazards to the public. Make no mistake, Fyrol and Tris are only two in a long list of chemicals that the Commission will be investigating in the future. And, I am certain that flame retardants will not be the only textile chemicals subjected to this kind of scrutiny.

Therefore all of us in Government, in the private sector, and the general public must get our act together in terms of how suspected mutagens or carcinogens are to be tested and regulated in the future.

Can or should differences in testing be resolved? In my opinion, agreement at least with respect to a battery of short-term tests to be run, standardizing the test methodologies and what that test results mean is crucial. Critical also is a uniform definition of "carcinogen" and the standardizing methodologies for conducting the longer term tests. Adjustments, of course, should be made from time to time to stay in tune with developing scientific knowledge. Then there's the issue of threshold levels—whether or not regulatory agencies can determine levels below which carcinogenic compounds have no adverse effects on humans. If we knew for certain what these levels are for the compounds—or even if they exist, making decisions would be easier. But again certainty does not exist, forcing regulators to act on the basis of the best information available and in keeping with the laws they administer.

Recent efforts to deal with this problem were headlined when the Food and Drug Administration proposed a ban on saccharin in accordance with their Delaney clause, which triggers an automatic ban. The laws administered by CPSC, on the other hand, do not contain a

Delaney-type provision. At our agency, regulation must follow a Commission decision that a substance presents an "unreasonable risk" of injury, illness or death. Still other agencies have a different approach.

In light of the important public policies inherent in this whole issue, the most compelling need, as I see it, is to sharpen, broaden and unify the focus on carcinogens—to pull our act together, expand the cast and shift the spotlight onto arriving at some better answers.

We need more and better scientific information, yes. We need intelligent and informed agency-by-agency action, yes. We need continued close cooperation among the agencies, yes. But we also must move beyond this.

What is needed is a strong, sustained and coordinated national commitment and a plan of action to find better ways to bring the hazards down to size.

With strong leadership and support from the White House, candid dialogue should begin with the scientific, academic and medical communities, the private sector, the public and others. Together, we need to develop a coordinated approach and strategies which balance the need for more consistency in Government policy with the need for flexibility for agencies to perform the jobs that Congress and the President intend.

If we don't move in this direction, I fear we run a great risk of uneven and unfair regulation that seriously shortchanges the public.

The point I am making should not be misunderstood. I am not attacking all forms of Government regulation. Rather, what is at issue is that we cannot blithely continue to mandate requirements if the substantial costs and other adverse side-effects they produce far outweigh the benefits.

A particularly good example of this occurred last week at the Commission. The Commission voted that it is "essential" to propose for the second time in 3 years extensive recordkeeping requirements that would affect over a million companies.

I cast the sole dissenting vote because I believe they are a classic example of regulatory overkill.

If finalized, the rules would compel over a million companies to generate consumer complaint files, establish and maintain an extensive central filing and retrieval system with records of each and every safety-related communication readily accessible and available. The records would have to be kept for 3 years; knowing violators could be subject to penalties up to \$500,000.

At first glance, some may consider this regulation harmless. But consider this: The Commission already can and does obtain this information simply by asking companies for it or if necessary, by issuing a special order, general order or even a subpoena. Beyond this, the Commission made no attempt to estimate the costs for companies in implementing the regulation—costs which, I believe, will be passed on to consumers in the form of higher prices without any corresponding gain in the safety of the products they buy and use. No exemptions for small businesses have been made in the text of the Commission's proposal. And, to make matters worse, the fact is that the Commission proposed substantially the same requirements 3 years ago, with public comment at that time being overwhelmingly negative.



As I see it, the Commission, in proposing these requirements, has ignored the repeated statements of President Carter and former President Ford that Government should move away from paperwork that smothers business people and hands consumers the bill unless there are good reasons. It thwarts the intent of Congress—in this case an intent specifically written into the language and the legislative history of the law CPSC administers. Congress told the Commission that we could “reasonably” mandate requirements only after giving “due consideration” to the costs and benefits. But most onerously, the proposal shortchanges the public in the name of consumer safety when, in reality, about all they will get is another blow to the family budget.

The two issues I have outlined for you tonight provide examples of the daily problems a regulatory agency and regulators face in interpreting the statutes that they are charged with enforcing. As I have outlined, the issues are complex and I am sure, will become even more so in the future. As a regulator and public official I look more and more to the public for their feelings and views on consumer product safety. I have recently established a new program consisting of a series of meetings with a large cross-section of the American public—homemakers, businessmen, women’s groups, farmers, and elderly, consumer advocates—to provide me with a broad and diversified range of views on the crucial issues that face me as a decisionmaker. I am hopeful that these meetings on a regular basis will help me to make the best possible decisions I can.