# USDA/FDA ANNOUNCEMENT ON NITRITES AND RELATED ISSUES



## HEARING

BEFORE THE

## COMMITTEE ON AGRICULTURE
## HOUSE OF REPRESENTATIVES

NINETY-SIXTH CONGRESS

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# USDA/FDA ANNOUNCEMENT ON NITRITES AND RELATED ISSUES

TUESDAY, SEPTEMBER 16, 1980

HOUSE OF REPRESENTATIVES,
COMMITTEE ON AGRICULTURE,
*Washington, D.C.*

The committee met, pursuant to notice, at 10 a.m., in room 1301, Longworth House Office Building, Hon. Thomas S. Foley (chairman of the committee) presiding.

Present: Representatives Jones of Tennessee, Rose, Richmond, Nolan, Baldus, Harkin, Bedell, Fithian, Panetta, Skelton, Glickman, Whitley, Coelho, Anthony, Stenholm, Wampler, Sebelius, Johnson, Madigan, Grassley, Hagedorn, Marlenee, Hopkins, and Thomas.

Also present: Representative Martin of North Carolina.

Staff present: Fowler C. West, staff director; Robert M. Bor, chief counsel; John E. Hogan, counsel; Robert T. Lowerre, associate counsel; J. Robert Franks, associate counsel; Gary L. Norton, assistant counsel; Glenda L. Temple, clerk; Thomas E. Adams; Stephen T. Adams; Bernard Brenner; Anita Brown, Mori Irvine; and Jerry Jorgensen.

Mr. JONES of Tennessee [acting chairman]. The Committee on Agriculture will come to order.

We are delighted to see our witnesses here this morning. We appreciate very much the fact that the audience is filled with people who are also interested in our subject today.

The purpose of this full committee hearing is to consider the recent Department of Agriculture and Food and Drug Administration announcement on nitrites. We will discuss the issues related to that announcement.

I might mention that the chairman of our committee, Congressman Foley, will be here at a later time this morning. He did ask me to begin the meeting for him.

Our first witness is Congressman James Martin from North Carolina, a colleague of ours and a very able Member of Congress. He is accompanied by Dr. Norman Borlaug.

Mr. Martin, we will be happy to hear from you. Any statement of yours or Dr. Borlaug will be put in the record in their entirety. You may either summarize or read. Then we will hear the other witnesses. We will give the members of the committee an opportunity to question you. I know your time is quite valuable.

Before we hear from you, I want to yield to the ranking member of the full Agriculture Committee, our friend and colleague, Mr. Wampler.

The General Accounting Office and the EPA Enforcement Office will appear before the subcommittee to help us focus on these issues.

Although I am frustrated by the pace of our efforts to resolve this monumental problem, I am heartened by recent activities indicating that there is a general consensus to reach the solutions which this subcommittee has helped devise and will continue to support.

Before I call on the first witness I ask my colleague, Mr. Lent, whether he has any statement.

Mr. LENT. Mr. Chairman, many times in the past I have denounced the EPA for failing to promulgate the RCRA regulations in a timely fashion. Certainly it has been well over a year since my exhortations to EPA to act quickly began.

So I am pleased that today at last we will hear from EPA about some real progress which has been made with respect to the RCRA regulations. They are not yet complete, but a substantial portion has been published in final form, which means we now have most of the essential framework in place for regulating the disposal of hazardous wastes.

However, with these strict new regulations will come different kinds of problems. Foremost among those problems will be the availability of siting. The new regulatory framework sets strict controls over waste dumping. Many who have handled hazardous waste in a careless fashion in the past will be forced to comply with the new regulations if they are to stay in business and avoid stiff civil and criminal penalties. Undoubtedly, many present dumpsite owners will close because of the expense of compliance with the new regulations.

A shortage of legal dump sites coupled with current public opposition to creation of new sites could cause a fresh wave of illegal dumping. That is the last thing we need in light of the tremendous job of cleaning up after past illegal dumping still ahead of us.

I hope that siting and the closely related issue of waste disposal methods are subjects to which EPA and GAO are paying special attention and that we will hear from them today about their efforts in these areas.

Mr. GORE. I would like to express my thanks on the public record for the tremendous work that GAO has done in assisting this subcommittee not just in this hearing but for quite some time.

I believe it has contributed substantially to the public interest.

Mr. Eschwege, you have a prepared statement and please proceed to present it.

**TESTIMONY OF HENRY ESCHWEGE, DIRECTOR, COMMUNITY AND ECONOMIC DEVELOPMENT DIVISION, GENERAL ACCOUNTING OFFICE, ACCOMPANIED BY DANIEL WHITE, TEAM DIRECTOR AND FRANK POLKOWSKI, TEAM LEADER**

Mr. ESCHWEGE. Thank you, Mr. Chairman, I appreciate your kind remarks and I would like to give assurance to you and the members of the subcommittee that we will continue to work with you in this very important area.

We welcome the invitation to be here today to discuss our ongoing review of Environmental Protection Agency programs for the disposal and cleanup of hazardous waste.

A second review dealing with the testing necessary to establish liability for hazards at disposal sites is currently underway and we expect to brief you on this review in September 1980.

We will discuss hazardous waste disposal by land injection into deep wells, and high-temperature burning. Although our discussion today is directed to these three methods, other alternatives short of disposal are available to handle the hazardous waste problem.

We will also discuss the concept of regionalization as a way to establish disposal facilities, the need for additional research and development efforts, the status of cleanup of closed and abandoned sites and, finally, we will touch on the hazardous waste regulations released by EPA last May.

Because our review is still underway, top EPA management has not yet been given an opportunity to comment on the results of our work.

Each of the available methods of disposal has merit. They are all needed to cope with the volume and types of hazardous substances requiring disposal. However, none of the methods is 100 percent safe. Each requires effective control and enforcement procedures. Substantially more analysis is also needed as to their application on an individual site basis.

Land disposal is a method of placing waste substances in or on the land, for purposes of getting rid of them or long-term storage. It is the most commonly used method. For certain States, such as Maryland and Pennsylvania, it is the predominant method in use.

EPA has estimated that nationally, there are about 94,000 landfills and 173,000 surface impoundments—pits, ponds, and lagoons—used for the disposal of wastes.

At the three EPA regional offices and six States we visited, however, only limited data on the extent that land disposal was being used for various hazardous substances, and the locations of disposal sites, had been developed. To date, detailed estimates of the total number of closed and abandoned sites had also not been made.

For the immediate future, land disposal will keep its appeal largely because it is the least expensive method of disposal. Yet, with time we will run out of land on which to develop sites. Depending on location and the substances disposed of, land disposal sites can eventually leach and contaminate groundwater. Its elimination as a disposal method is not practical, however, since land disposal will be required to dispose of solids that otherwise cannot be disposed of, as in the case of residues from incineration and solids that cannot be injected into deep wells.

Where groundwater is used or planned for use as a drinking water source, the land disposal of hazardous substances should be very closely controlled and where possible substantially reduced. Until a greater capacity for other disposal methods is developed for the country, land disposal will remain predominant.

After more specific controls over land disposal operations are put in place by EPA, resulting in increased costs, its use should decline.

There are no published guidelines or Department regulations requiring scientific review of cases such as this at FDA, and at this time any study which that Agency says shows evidence of cancer-causing potential can be used as evidence supporting a ban under the Delaney clause.

Under current Federal policy there could be a hundred studies to the contrary and the one showing a carcinogenic effect could be used to effect a ban. We must create guidelines for review of studies in the context of all previously gathered information. Along with that we need to evaluate the magnitude of risk of a substance.

That is why I have introduced legislation, H.R. 6521, to establish a National Science Council. Such an independent council, made up of a blue-ribbon panel of 15 eminent scientists best qualified as to training and experience, would evaluate all the available evidence of a substance's effect on human health.

The Council would decide purely scientific factual cases such as the nitrite issue by drawing on recommendations of advisory panels which would be required to review the results and validity of a test, the quantity and quality of scientific information, the predictive value of the information in determining harm to human health, and give an opinion as to the level of risk to human health.

The Council would decide issues of concern to all the agencies charged with regulating chemicals and would thus concentrate expertise in one place, as well as give consistency to the current hodgepodge of guidelines throughout the Government.

The Science Council is an idea whose time has come. Recently, similar proposals have been made by the Office of Science and Technology Policy, OSTP, and the American Industrial Health Council.

There are differences between these various proposals, but the important goal we all share is to seek the objective truth in scientific controversies which all too often have become clouded by political and emotional issues.

Only when we have a scientific evaluation of potential risk does it make sense to consider policy options. Twenty-two years after the adoption of the Delaney clause, it is time to reconsider the scientific assumptions on which that law was based.

If we can detect the presence of tiny amounts of a substance that has been found in large-dose tests to be carcinogenic, does this mean that we assume that a few molecules of that substance will give someone cancer?

Although scientists do not yet have answers to all the questions of chemical carcinogenesis, more and more of them, including Government scientists, agree that thresholds will be found below which some substances will not cause cancer. They are also taking about levels of potency of carcinogens—and they are not all equally harmful.

Current food safety law, in general, and the Delaney clause, in particular, reflect outdated scientific assumtpions. That is partly because improved technology in the detection of trace level substances has allowed us to find very small amounts of toxic substances, even in so-called natural foods, such as solanine in potatoes, or, more to the point, nitrites in spinach.

We must come up with a way of evaluating these risks or we will have to ban much of the food supply. I think the National Academy of Sciences report on food safety outlines the kind of answer we should be looking at—defining law, moderate, and high risks and the balancing of benefits with each category. We should use this as a model of the new system we create.

I do not think anyone here could believe in the utopia called a risk-free society. We are creating and discovering new risks daily. Some of the sources of these risks we can eliminate and others, like potatoes, no one would advocate doing away with.

In the case of nitrites, eliminating their use leads to a whole new health hazard, and one with far higher health costs—botulism. In other cases, society is willing to take risks where other kinds of benefits are judged to outweigh the risks. The public outcry in the cases of nitrites and saccharin show that in the food area Americans are willing to take risks to preserve the availability of certain foods.

We in Congress have been responsive in helping them retain those rights by passing the moratorium on the saccharin ban and proposing legislation to head off a nitrite ban. But we must ask ourselves how many times this will have to occur before we take responsibility for changing the laws to insure sensible decisions in the first place.

The close of the current Congress is too near to remedy these problems this year. However, I would hope that today's hearing would serve to lay the groundwork for future hearings in the next Congress to examine comprehensive changes in our food safety system.

It is time we on the Agriculture Committee began to realize the broad impact of food safety decisions on our area, not only in terms of agricultural production, but also in terms of the impact of food safety risk assessment on risk assessment in other areas where chemicals are involved. It is a good time for this committee to become involved in this debate.

I hope this is the beginning of a meaningful dialog that will bring some order out of the chaos and confusion that has reigned.

Thank you, Mr. Chairman.

Mr. JONES of Tennessee. Thank you, Mr. Wampler, for a splendid statement.

Congressman Martin, we are delighted to hear from you now. You and Dr. Borlaug may proceed as you will. Please introduce Dr. Borlaug.

## STATEMENT OF HON. JAMES MARTIN, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF NORTH CAROLINA

Mr. MARTIN. Thank you, Mr. Chairman.

I want to commend you and the chairman of the full committee, Mr. Foley, and Mr. Wampler, as well as all members of this committee for the very effective work that you have done in this committee in focusing attention on the procedures that were used in the crusade to attempt to ban nitrites just recently.

I want, as well, to commend you for calling these hearings so that, as the announcement of the hearings pointed out, we can examine not only the facts and circumstances surrounding this

In 1979, EPA revised its research strategy to emphasize the following six categories: One, hazardous waste identification, two, uncontrolled waste site problems, three, hazardous waste technology, four, hazardous waste risk assessment, five, energy and mineral wastes and, six, nonhazardous wastes.

For fiscal year 1981, EPA has requested $26.4 million for hazardous waste research funds. This amount represents a $21.1 and $15.4 million increase over fiscal years 1979 and 1980 funding levels respectively. Over one-half of the requested funds will be applied to the further development of disposal technologies, including $8.2 million to develop refinements in incineration techniques.

The remaining research funds are to be applied to related hazardous waste problems such as toxicity and health effects studies.

To date, the national problem of what to do about closed and abandoned hazardous waste sites has not been fully confronted by the Federal, State, and local governments or by industry.

EPA continues to consolidate from various sources existing information on closed and abandoned sites, yet it has not been able to complete the type of national inventory and site assessment program that has been recommended by this subcommittee.

We testified before this subcommittee a year ago that there was no accurate and complete information on the total number of closed and abandoned sites, the extent of environmental danger that these sites pose, and the total cost of cleanup. Although EPA has started to expand its efforts to confront the cleanup problem, much more is needed.

EPA has initiated a hazardous waste task force and tracking system and contracted for site investigations and site analyses. To date, EPA has concentrated on the highly visible, emergency cases that have been brought under public scrutiny by the Congress, the general public and the press media.

We continue to believe that there is a need to completely assess the scope and nature of the closed and abandoned site problem and its true economic and environmental cost to the country.

As you know, the recently published hazardous waste regulations are voluminous and complex. A thorough analysis would require much additional time. We would like, however, to make some observations regarding those regulations that apply to owners and operators of hazardous waste treatment, storage, and disposal facilities.

EPA acknowledges that it may take several years to fully develop the data base, and to perform the analyses necessary to resolve the more complex technical issues that may be raised regarding facility operations, before nationally applicable detailed technical standards for facility operations can be promulgated.

The regulations promulgated to date, called phase I, largely deal with prescribed recordkeeping, reporting requirements, and good management practices, which are not highly technical.

The more specific standrads for the operation of hazardous waste facilities are to be promulgated in phases II and III.

Phase II, to be issued in the fall of this year, will provide additional regulations to allow permits to be issued for facilities based on each EPA regional administrator's best engineering judgment of the data the applicant submits and, the technical requirements the

facilities should meet. It will be left to each region to determine what constitutes an adequate facility operation.

Our experience shows that a governmental agency needs to speak with one voice to avoid confusion and the possibility that a facility developed based on requirements for one region may not be acceptable in another.

The phase III regulations, which EPA has stated may take several years to promulgate, will deal with the further resolution of specific technical issues such as site design and engineering requirements. Standards may be established for specific industries as well as for wastes requiring special controls. Throughout the process, the regulations will continue to be changed and revised.

In the case of the land disposal—specifically landfill—requirements, the regulations provide general operating requirements, including general requirements for waste analysis, surveying and recordkeeping, closure and post closure of the site, and special requirements for liquid and incompatible wastes, and waste containers. Specifics on how to develop a site are not provided.

With regard to the underground injection control program, I understand that EPA issued regulations just a few days ago on June 24.

In summary, in the face of Love Canal and situations such as at the Valley of the Drums and in Toone, Tenn., it is now generally agreed that major new emphasis should be provided for hazardous waste disposal practices in the country.

The continued reliance on land disposal as the predominant disposal method for the long term may need to be significantly reduced in view of the prospect for environmental disasters that it may entail.

Consideration also needs to be given to the further development and application of other methods of disposal, for example, the deep well injection of wastes, and the destruction of hazardous wastes by high temperature incineration.

It appears facilities need to be developed on a regional as opposed to on a local need or individual company basis because environmental and cost impacts can often be reduced. We do not perceive any fundamental basic research needs that would preclude the development of facilities at this time. Substantially more time will be needed before the hazardous waste regulations are fully and effectively promulgated and implemented by EPA.

Finally, Mr. Chairman, legislation which confronts the issue of closed and abandoned dump sites, such as is currently under consideration in the Congress in the so-called super fund bills is essential to solving the cleanup problem facing the country.

This concludes my prepared statement. We will be glad to respond to any questions you may have.

Mr. GORE. I appreciate your statement very much, Mr. Eschwege.

Do either of you gentlemen, Mr. White or Mr. Polkowski, have a statement you wish to make?

Mr. WHITE. No.

Mr. POLKOWSKI. No.

Mr. GORE. Fine.

Let me try to boil down parts of your testimony and go back over some parts of it in a little different form.

and, therefore, high-yield strains of grain, corn, and so forth for which he has been awarded the Nobel Prize in his field.

He and I have discussed these questions previously. I was delighted to learn just yesterday that he was in town on other business and I invited him to come with me.

He has a statement which is being typed and will be presented for the record. I would ask that the committee accept that statement as part of the record and hear from him as to whatever informal remarks he may want to make before this committee at this time.

Mr. JONES of Tennessee. Without objection, the entire contents of the statement of Dr. Borlaug will become part of the record.

As I announced at the beginning of the meeting, for the benefit of those members who arrived a little bit late, we will question Dr. Borlaug and Congressman Martin before we hear from the other witnesses following Dr. Borlaug's statement.

Dr. Borlaug, we are delighted that you are here.

## STATEMENT OF DR. NORMAN E. BORLAUG, AGRONOMIST

Dr. BORLAUG. Thank you, Mr. Chairman.

Chairman Jones and distinguished members of the committee, I have looked for the last 10 years as I have seen the confusion, emotion, and lawsuits raised around these various issues. These issues have been involved in not just the food additives, but I think, in part, are an outgrowth from the confusion that began there and spread to more general issues of pollution of the environment, whether it be water or air.

Let it be perfectly clear that I am all for trying to keep the environment, including our food supply and water supply, as pure as possible within reasonable limits.

You must remember that for the last 36 years of my life, I have lived outside the United States in food-deficit nations struggling with food production problems from quite a different point of view than is viewed by the general public of the United States who are blessed by the abundance that is produced on our land and taken from our waters in the form of marine products.

I think, as I see the general issues, there is a great deal of confusion that results from a lack of recognizing what has been contained in life expectancy from time of birth. If you go back to the beginning of this century and compare it to life expectancy now of the average for both sexes on something on the order of 73 years, it is a great increase in the numbers of years that one is expected to live and survive, based on the time of birth.

Not only is it so, but also the quality of life has improved. We enjoy, I think, a more pleasant life than our grandfathers' and fathers' generations. I think we fail to recognize there are certain limits beyond which we will not be able to achieve, at least very rapidly, further perfection.

It seems there is an unusual amount of fear of increasing incidents of cancer. Yet, when one examines the record and makes adjustment for age, you must remember that it is not as clear as is generally put forward in the general press that we are having an epidemic of cancer. With the exception of noncancer, this does not generally seem to hold.

Then we further ignore the general idea that in the real biological world there is no zero biological risk. Any number of accidents along the way, most of which we cannot explain at this time, can take place.

I happen to have been a lucky individual, I think, relatively speaking, because from the time of conception—that is a long number of years ago—I happened to have evolved into an individual who has 10 fingers and 10 toes and more or less an acceptable body and some kind of mental process that perhaps is average. But many things could have happened along the way from the time of conception until birth and from then on also.

We have made great progress in overcoming the infectious diseases through antibiotics, sulfa drugs, and the improved vaccines that reflect in longer life expectancy from the time of birth on.

But we seem to still be searching for that fountain of perpetual youth which will never be achieved. Were it to be achieved, imagine the chaos in this world with the population pressures we already have on the land from the standpoint of even producing that first basic necessity, essential food.

We seem to ignore the fact that there is a growing body of evidence that indicates aging human cells in culture apparently in the absence of carcinogens begin in produce chromosome aberrations. This has been observed in the last 10 years, especially at many different medical schools.

These chromosome aberrations give rise also to abnormal cells, some of which have the appearance of becoming somewhat like cancer cells. The only way that a cell can be perpetuated beyond the 50th generation of reproduction in tissue culture is to infect it with some kind of a virus. There is a great deal of confusion going on across all these complex fronts.

It is my belief that we will need to explore the feasibility of incorporating into a new amendment to the Delaney clause which will give flexibility to the Administrator of the Food and Drug Administration Act to use his judgment, weigh benefits against risks across all the different types of experiments that have been conducted or are now being conducted.

In closing I would like to say that much of this confusion comes about from the fact that we use inbred lines of animals so that we can get nice bits of data that are reproducible, 28 generations of inbreeding. Look at us as a human species and we are all different. In this room I see no two individuals who are alike even in physical makeup. There may be a pair of identical twins, but I have not seen them.

That being the case, even in physical differences, imagine all the complications and differences that exist in psychological, in pathological resistance, grades of tolerance. Yet, we want it to be absolute. It has never been so in the biological world and it will never be so long as life remains on this earth.

As a matter of fact, it is the only mechanism by which we can improve our crop varieties or our animal species and, for that matter, I think if you look back in the history of early man, I think we have made some progress there, too.

Thank you very much for allowing me to participate in this presentation.

Mr. GORE. I can see the CMA lawyers on that point right now. What do you think about that?

Mr. POLKOWSKI. I want to stress, Mr. Chairman, we did not analyze the types of substances that are acceptable for landfilling. That was something that was beyond the scope of our initial review.

Mr. ESCHWEGE. I think—Mr. Polkowski may correct me on this—this is the first phase only and I think EPA is planning to come out with more detailed regulations on the issue. This may take some time to work out. I think they are probably in a better position to know when that will happen.

Mr. GORE. Let's distinguish between interim status regulations and the best engineering judgment system. Clearly there are severe problems with the interim status regulations. They are ludicrous in my judgment. Maybe that is too strong a word. Who is going to be making the decisions on the BEJ?

Mr. ESCHWEGE. That is going to be your regional administrators and what you are faced with as we point out in our statement is different judgments in different regions. Not everybody is going to have the same judgment. In this case that is a problem. It is going to give industry a problem, too.

Mr. GORE. This is a structural problem with EPA's management plan. They haven't been able to make up their minds about where key decisions are made, and you get a shuffling back and forth between the central office and the regional offices.

In the regional offices the role of the States is varied and unclear. Are State officials going to be interpreting or playing a role in the BEJ system as well?

Mr. ESCHWEGE. I would think they would help furnish some of the information which then EPA regional administration would use to make the judgment but there would also be the information from industry, of course.

Mr. GORE. On what basis are the BEJ determinations going to be made? Do they have any basis? Have they clearly set out the basis on which those judgments are supposed to be made?

Mr. ESCHWEGE. I don't think EPA has clearly set out yet as to what basis it will use. I would suspect they would use the information from industry and information they might gather themselves plus the State information to make this judgment.

Mr. GORE. What are the common health and environmental problems characteristic of landfills? If you had to give a short list, what would be the common set of problems associated with landfills?

Mr. ESCHWEGE. One which we have already mentioned is that they will generally leach. If it is located to potable groundwater, aquifers, drinking water can be contaminated. Also, once you use land for a landfill its use for general urban purposes such as for housing development would not appear to be possible without exposing residents to health and environmental dangers.

It would probably be best, if you had to use this land, to devote these areas to industrial uses such as developing a tank farm for petroleum storage. In other words, it would be very restricted as to what you could use the land for.

Mr. GORE. We are going to continue to see landfills used as a primary disposal method for the foreseeable method. Is that a fair prediction?

Mr. ESCHWEGE. Yes.

Mr. GORE. Should we continue to rely on them?

Mr. ESCHWEGE. It is not something you can change overnight but everything indicates we ought to start deemphasizing landfills. We ought to be using where we can—and you can't use it everywhere—deep well injection. There have not been any really bad experiences if it is done properly, and certainly incineration which in many cases can completely destroy the hazardous wastes.

In other cases there will be residues and you may need some landfills to take care of that residue but it would be a much smaller volume involved.

Mr. GORE. You speak well of the deep well injection technique. Wasn't there a serious problem in Ohio with a geyser of hazardous wastes coming back up out of the ground?

Mr. POLKOWSKI. I am not familiar with the Ohio example but there have been instances where there were problems with deep well. I am emphasizing deep well disposal. That type of example generally was attributed to improper technology or special blowout prevention equipment was lacking or the technical application of the process was not adequate largely rather than the process itself being inadequate.

We emphasized the need for continued control of the process in the well development and operating phases as an alternative to solving that difficulty.

Mr. GORE. I recognize now Mr. Lent.

Mr. LENT. Thank you, Mr. Chairman.

I have been told, Mr. Eschwege, that in Europe, the burning of garbage is far more common than it is in the United States. Do you have any information on that?

Mr. ESCHWEGE. We have done some research on what other countries are doing.

Mr. POLKOWSKI. They do burn substantially more, but they do not have the strict limits on burning that we do with regard to the air pollution problem.

Mr. LENT. One of my local public officials up in Long Island recently returned from a European trip where he looked at some of the garbage-burning facilities in Switzerland, Germany, and the Netherlands.

He tells me with the escalation in fossil fuel costs some of the local municipalities are looking forward to the day in the not too distant future where they will be able to sell their garbage and get a pretty good return on it.

Mr. ESCHWEGE. Mr. Lent, we have done some work in this area and issued some reports on this which may be of interest where we feel more can be done to utilize the wastes to extract minerals, to use it for converting it to energy and to also codispose sludge with garbage, and use one to burn the other.

I think we are not nearly as far along in that area as we should be. It may come to a point where this is going to be cost effective and then more will be done to utilize this kind of waste disposal

some theoretical idea that it is somehow possible to arrive at a zero risk situation.

Our witnesses have told us in graphic terms this morning that it is impossible. We have to balance the various factors against one another and arrive at a rational approach and not the type of emotional one that I think is included in the Delaney clause.

Thank you very much.

Mr. MARTIN. That is the nub of the whole problem.

Mr. JONES of Tennessee. Mr. Anthony?

Mr. ANTHONY. No questions.

Mr. JONES of Tennessee. Mr. Stenholm?

Mr. STENHOLM. No questions.

Mr. JONES of Tennessee. Mr. Grassley?

Mr. GRASSLEY. I think all this discussion we have had for the last 2 years on the nitrite issue points out some very serious deficiencies in the whole Federal regulatory process. I think we lose sight of a greater problem if we look at just the nitrite process. We have had 2 years of confusion, doubt, and uncertainty and bureaucratic muddling so far as this issue is concerned.

I hope it does not all end with just a whimper. I have yet to see that there are many changes made in any of the procedures in the Government agencies involved as a result of this fiasco.

So, I think we have to look just beyond the nitrite issue and at some of the greater issues confronting us as policymakers in the Federal Government to see that we do not lose sight of the real problem. The real problem is just the procedure by which regulation writing and processes can escape congressional review adequately.

Mr. MARTIN. It even managed to escape scientific review for awhile. That is part of the problem as Mr. Wampler has also pointed out. There has to be an insistence on scientific peer review process in arriving at these kinds of rational decisions as to the nature of risk and the magnitude of risk.

Thank you very much for the opportunity, Mr. Chairman.

Mr. JONES of Tennessee. Thank you.

The Chair recognizes Mr. Nolan for any comments he might have.

Mr. NOLAN. Mr. Chairman, I do not have any questions, but I do want to thank our colleague, Mr. Martin, for his testimony here, and a special welcome and a special thanks to Dr. Borlaug. I particularly thank you for your lifetime of dedication to food and agricultural research. I think I can speak for all this committee and a lot of other people when I say we are very, very grateful and thankful. It is a pleasure to have you before the committee here this morning.

Mr. MARTIN. A graduate of the University of Minnesota also.

Mr. NOLAN. That is correct.

Mr. JONES of Tennessee. The Chair recognizes Mr. Fithian.

Mr. FITHIAN. No questions.

Mr. JONES of Tennessee. I believe we have given all the members of the committee an opportunity to question the witnesses.

I want to say to you that I appreciate very much the fact that you are here, Mr. Martin. We do know that you are quite well

qualified to appear on this subject. We appreciate the fact that you are here.

Thank you, Dr. Borlaug, for the statements that you have given this full committee. If you do have a printed statement, it will be a part of the record.

Thank you very much for being here.

[The prepared statement of Dr. Borlaug may be found at the conclusion of the hearing.]

Mr. JONES of Tennessee. The Chair will call Dr. Jere Goyan, Commissioner of the Food and Drug Administration, Washington, D.C. He is accompanied by Mr. Robert Brady, Dr. Sanford Miller, and Mrs. Carol Tucker Foreman, Assistant Secretary for Food and Consumer Services, U.S. Department of Agriculture.

I am going to give you people the opportunity to proceed in whatever method that you like. I do not know who wants to be first, but we will hear all of you before we question this panel. Carol, I will say to you that you can make the decision as to who is first.

Ms. FOREMAN. Thank you. I think we have decided among ourselves that I should go first.

Mr. JONES of Tennessee. Please proceed.

## STATEMENT OF CAROL T. FOREMAN, ASSISTANT SECRETARY FOR FOOD AND CONSUMER SERVICES, U.S. DEPARTMENT OF AGRICULTURE

Ms. FOREMAN. Thank you, Mr. Chairman.

I have a fairly lengthy statement, Mr. Chairman. I will try to cut out parts of it, but I would like to proceed with major parts of it, if I may, please.

Mr. Chairman, I welcome this opportunity to discuss the FDA and USDA actions on the problem of nitrite and to examine some of the issues of food safety policy that have been raised by this experience. For 3½ years now I have been Assistant Secretary of Agriculture with responsibilities for enforcing the health and safety provisions of the Federal Meat and Poultry Inspection Acts. During this period, the evidence on the potentially adverse health effects of nitrite has posed some of the most difficult and controversial questions that food regulatory agencies have ever had to face. I sympathize with Commissioner Goyan who had the misfortune of entering the drama in midstream.

I can assure you that FDA and USDA have not sought the limelight on this particular issue. From the outset it has been a regulator's nightmare—with bacon and breakfast, hotdogs and baseball on one side, and the potential risk of cancer on the other. The last thing we wanted was to turn nitrite into a cause celebre. We have attempted to steer a calm, open, and rational course. Much of the heat has come from other quarters, including some Members of Congress. In today's hearing, I hope that we will have the reasoned and constructive discussion that the question of nitrite deserves.

Two years ago, I testified with Donald Kennedy, who was then FDA Commissioner, before Agriculture Committees in both the House and the Senate on the subject of nitrite. A month earlier, our Departments had announced the results of an animal feeding

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We have not independently tried to find out what the various costs are. There is very little incineration going on today. I have seen figures that people have estimated that right now incineration is 10 times as expensive as landfill.

I wouldn't want to vouch for those figures because land can be more expensive in one place than another and depending on how you dispose of it on the land has a lot to do with the costs.

Mr. MAGUIRE. Can we get better projections of what those cost relationships are likely to be in the future if we are not talking about initial costs but overall or life cycle costs?

Mr. ESCHWEGE. Offhand, I don't know of a good way of doing it other than it would be my hope if incineration caught on more we would find some very effective but cheaper ways of incinerating.

As I indicated earlier, with EPA's regulations if they take hold, restricting how you go about landfilling, economics would take care of it at some point. But I don't know where.

Mr. MAGUIRE. I think it is very important for us to try to make some projections on precisely that point in order to make intelligent decisions now about which way we ought to be going. If we are only talking about 2 or 3 percent being disposed of through high temperature burning, it is clear there is going to be a need for incentives to be developed.

In the absence of data that show the cost curve of landfill moving up and possibly economies to be gained with better technology or greater scale on high temperature burning, we are going to have continued recitations of this enormous gap in initial costs. This will discourage people who don't look into it with care, and we will not be able to assess the high costs of the leaching process that you have alluded to and the problems then of cancer or genetic damage that might ensue.

Mr. Chairman, I hope this is something the subcommittee can look into a bit more and perhaps get some expert assistance because I think it is the key to the economics of this.

Mr. ESCHWEGE. Sir, it is not a simple either/or. It is an important issue, one which I think we can look at more because there are other things that come into play, recycling, using this waste for energy and so on, which could help alleviate the whole problem of having to either choose landfill or incineration.

Mr. MAGUIRE. Except that you have also indicated that as landfill sites become more scarce we are going to have to shift a percentage of that to other methods and yet we are always going to have a certain amount of solid waste and residues from the burning which, as I undertand it, have to be put into land disposal sites.

It would seem the premium, therefore, would be on reserving those sites for those purposes.

The specifics of the proposed and final regulations you haven't spent a lot of time on in your statement. Do you have any comments on facts like the exemption on generators being raised from 100 to 1,000 kilograms or the toxicity characteristics of being raised from 10 to 100 times the drinking water standards?

Mr. POLKOWSKI. We have no comments on those issues.

Mr. MAGUIRE. What about the exclusion of the utility wastes at this point? Do you have any comment on that?

Mr. POLKOWSKI. We have not analyzed the appropriateness of certain ones versus others.

Mr. MAGUIRE. We will have an opportunity to talk with EPA about that.

Mr. GORE. Thank you, Mr. Maguire.

We have a vote on a conference report on the floor. So we will, with your indulgence, return with this panel in about 8 minutes.

[Brief recess.]

Mr. GORE. The subcommittee will come to order.

I recognize now my colleague from California, Mr. Dannemeyer.

Mr. DANNEMEYER. Thank you.

I am interested in your treatment of the high temperature waste incinerator possibility. We had a gentleman from Kentucky, I think it was last year, before our subcommittee who made the observation that he believed that the private sector was in a position to provide the basis for disposal of much of the waste, industrial waste, in the country if we would just establish some guidelines so that the private sector would know where it stands on the issue.

I would like to know, from your investigation, how many of these high temperature incinerators—1,000° C. or more—we have operating in the country today? Did you discover that?

Mr. ESCHWEGE. We asked that same question. Very few. We have gotten the range, anywhere from 6 to about 20, less than 20. That is all we have.

Mr. DANNEMEYER. Currently operating in the United States?

Mr. ESCHWEGE. Yes, sir.

Mr. DANNEMEYER. In private hands?

Mr. POLKOWSKI. Yes, sir, in private hands.

Mr. DANNEMEYER. How are they being fueled?

Mr. POLKOWSKI. It depends on the substance that you burn. In some instances you need fossil fuel; in others you do not. One of the cost factors that is important to burning is whether you do need to use auxilliary fuel or not, and also the volume you would be burning.

Mr. DANNEMEYER. This witness stated that much of the waste we have to dispose of is hydrocarbon based, which means it will burn in high temperature incinerators.

Mr. POLKOWSKI. Yes, sir.

Mr. DANNEMEYER. The impression I got from the gentleman was that the process would be power productive and that the waste would provide the energy with which to burn itself, and also as a plus factor, produce power which could be sold to the power grid. Did you discover anything about that?

Mr. ESCHWEGE. I think this would be an ideal situation. There is waste like that. I can't tell you how much of it is that way and how much of it is like Mr. Polkowski was saying which actually would require additional fossil fuels and which would make it a lot more expensive.

Mr. DANNEMEYER. For instance, these 5,790 potential hazardous waste sites, how many of them contain hydrocarbon based waste within them, do we know?

Mr. ESCHWEGE. No.

Mr. POLKOWSKI. That type of information wasn't readily available either in the States or in the regional offices we visited.

The same substance can fall under different categories depending upon its use. Nitrite can be considered a "food additive," a "color additive," or a "prior sanctioned substance" depending upon the product in which it is used and the function it serves.

I turn now to food additives and color additives.

In everyday speech, anything added to a food may be called a food additive. Under the law, however, the term "food additive" has a narrow and more precise meaning. The Food, Drug, and Cosmetic Act defines food additives as "any substance the intended use of which results or may reasonably be expected to result, directly or indirectly, in its becoming a component or otherwise affecting the characteristics of any food. . . ." The act then goes on to state that the term does not include pesticides, new animal drugs, color additives, or prior sanctioned substances.

The Food, Drug, and Cosmetic Act defines the term "color additive" to mean "a material which is a dye, pigment, or other substance . . . and when added to a food . . . is capable . . . of imparting color thereto." The act then goes on to state that a color additive does not include any material which the Secretary, by regulation, determines is used solely for a purpose or purposes other than coloring, even if it colors the food.

I turn now to prior sanctioned substances. A "prior sanctioned substance" is one that is used in accordance with a sanction or approval granted prior to September 6, 1958. The existence of a prior sanction depends upon the specific use of the substance.

If a specific use was approved before September 6, 1958, then prior sanction would apply. An example would be the use of nitrite as a preservative in certain red meat products. But if that same substances were put to a new use, which was not approved before September 6, 1958, then prior sanction would not apply.

In its most common use today—as a curing agent in bacon, hotdogs, ham, corned beef, pastrami, and other red meat products—nitrite is considered a prior sanctioned substance. The agencies have determined that this use in red meat was approved by USDA many years ago.

As early as 1925, USDA had regulations limiting the residual quantity of sodium nitrite in meat in quantities up to 200 parts per million. However, there are other current uses of nitrite in which the substance is regulated not as a prior sanctioned substance but as a food additive. These include its use in fish, pet food, home curing mixes, and certain imported cheese. The question of whether nitrite is a food additive or a prior sanctioned substance in poultry products is now being reviewed by USDA.

Any possible color additive status for nitrite is now being considered by FDA as the result of a court action. A suit was brought against USDA and FDA contending that when used in bacon, nitrite is a color additive or a food additive, and not a prior sanctioned substance. Color additives are food additives and are subject to a separate FDA approval system which places the burden on manufacturers to establish the safety of a substance before it can be used. According to an argument made in the lawsuit, the present use of nitrite is illegal because it has not been through the FDA approval process for additives. USDA and FDA argued, however, that nitrite sanctioned by USDA for use as a preservative in

red meat products, including bacon, prior to September 6, 1958, and was not a color additive.

Both the U.S. district court and the court of appeals upheld the Government's position regarding food additives. The question of whether nitrite might be regarded as a color additive as well as remanded to FDA for administrative consideration.

I would now like to talk about the Delaney clause.

When nitrite is regulated as a food additive or a color additive, it is subject to the Delaney clause, a well-known and much discussed provision of the Food Additive Amendments of 1958 and the Color Additives Amendment of 1962.

The Delaney clause prohibits the use of any food additive or color additive shown "to induce cancer when ingested by man or animals or shown to induce cancer when man or animals are exposed to it by any appropriate test."

One of the frequent criticisms of the Delaney clause has been its lack of flexibility. Once it has been concluded on the basis of adequate scientific analysis that an additive has been shown to induce cancer in animals, that substance must be banned. There is little room for administrative discretion.

The Delaney clause does not permit any consideration of the benefits of substances classified as food additives or color additives. It sets a strict, risk-based standard. In this respect it differs from the provisions in the law that govern other categories of food substances, such as pesticides, unavoidable contaminants, and naturally occurring substances.

In regulating a pesticide such as dieldrin or an unavoidable contaminant such as PCB, the FDA is permitted to weigh the benefits of different regulatory approaches and then decide what level of these substances to allow in food before it is considered adulterated. An unavoidable contaminant is one that has become so ubiquitous in the environment that there are no feasible short-term means of keeping it out of the food supply.

An example would be the contamination of the streams, lakes, and oceans that results in low levels of potentially toxic substances in fish. But when a substance is deliberately added to food, the Congress has created a different standard. When a substance is a food additive or a color additive, the Delaney clause applies, and there is no flexibility. There is no provision in this law for the weighing of benefits.

Further, no amount of a substance, however small, can be permitted once it has been found to cause cancer in animals. Congress established this zero-tolerance because of the scientific assumption that there is no safe level of exposure to a cancer-causing substance.

I turn now to the Federal Meat Inspection Act.

In its most common use—as a curing agent in red meats—nitrite is not subject to the Delaney clause. I believe that this has been the most misunderstood aspect of the whole controversy over nitrite.

Because the use of nitrite in red meat was approved before September 6, 1958, it is excluded from the Delaney clause as a prior sanctioned substance. However, nitrite use in red meat is subject to the adulteration provisions of the Federal Meat Inspec-

Mr. ESCHWEGE. They don't specify, no.

Mr. GORE. As far as the rest are concerned, anything can be dumped in a landfill, right?

Mr. POLKOWSKI. Assuming it is an EPA defined hazardous waste.

Mr. GORE. Sections 265.312 and 313 are the relevant sections, as I read the regulations, on that point.

Now also I want to revisit your response on deep well injection. Do these figures sound correct that there are 400,000 injection wells currently in operation with 5,000 new ones each year and 7,500 directly injecting hazardous wastes into underground drinking water?

Mr. POLKOWSKI. I don't know whether the figures are correct, but there are a great many other wells other than deep wells. What we are talking about are the ones below the aquifer. There is a whole range of wells.

Mr. GORE. So you are talking about deep well injection instead of the other?

Mr. POLKOWSKI. Right.

Mr. GORE. Maybe there is a problem with definition, but if we have 7,500 injection wells putting hazardous wastes directly into drinking water supplies, that is a problem, isn't it?

Mr. POLKOWSKI. I think the new regulations are going to address that in that area.

Mr. GORE. I hope so. They don't, the new regulations don't address that. That would seem to be an oversight or deficiency, wouldn't it?

Mr. POLKOWSKI. I am not familiar with it.

Mr. GORE. If we have 7,500 wells directly putting hazardous waste into drinking water, that is something that any reasonable set of regulations ought to be directed at.

Mr. WHITE. I think that should probably be part of their fall regulations that they plan to come out later in the fall.

Mr. GORE. Well, I would hope so.

Now in light of these figures, do you want to qualify your response on deep well injection at all? I will allow you to do so for the record if you wish.

Mr. ESCHWEGE. Well, we would have to look at those figures. We have not seen them. All we were saying really is that the deep well injections that have occurred with some exception have not created any major problems and we have gone back to Texas where this was first started in 1938.

Mr. GORE. Would you gentlemen be willing to answer additional questions in writing? Mr. Maguire has several additional questions.

Mr. ESCHWEGE. Certainly.

Mr. GORE. And I have a couple here.

Mr. ESCHWEGE. We will be glad to do that.

Mr. GORE. With regard to regional waste facilities, did State and local officials have criticisms of the EPA's role in the development of regional waste facilities? If you could give a brief response.

Mr. ESCHWEGE. Now?

Mr. GORE. Yes.

Mr. POLKOWSKI. I didn't have any indication of any special criticism on the part of regional State officials with regard to EPA's participation in regional facilities. EPA has encouraged the devel-

opment of regional facilities. The limits, of course, are in the amount of grant money that was available to them.

Mr. ESCHWEGE. One problem with regional facilities that perhaps we should mention is that you may have to transport the waste over fairly long distances in some cases and this could be a problem to the communities through which you transport it.

Mr. GORE. Well, we have another vote on the floor. This is a good point to change panels.

Let me again express my appreciation to GAO and to you gentlemen in particular for the work you have done on this issue. It has really benefited us and I think the public interest.

When we return in about 8 to 10 minutes, we will have Mr. Steffen Plehn.

[Brief recess.]

Mr. GORE. The subcommittee will come back to order.

At this point, without objection, I would like to enter into the record correspondence between the subcommittee and the Environmental Protection Agency which is pertinent to today's hearing.

[The following was received for the record:]

As a result, other reporters from the general press were expressing interest. We believed and believe that the worst possible outcome would have been for news of the study to leak out in a distorted fashion. The only thing worse than having the report was to have press and television spread the alarm that the Government was suppressing evidence that hotdogs and bacon caused cancer.

The root of our dilemma was legal: The strict adulteration standard of the Federal Meat Inspection Act and the Food, Drug, and Cosmetic Act. So we turned to our lawyers to see if there was some way around that standard. We needed a legal alternative to an outright ban or to tossing the entire matter back into the hands of Congress. The course we finally decided upon was to propose an eventual phaseout of nitrite.

In view of its health benefits, nitrite would continue to be used until alternative substances were developed. We believe that this course gave us some breathing space, gave public notice of the action that might eventually might be necessary, and avoided the untenable position of doing nothing to protect the food supply.

We believed we could rely upon the administrative process to give us some of the time we needed. I discussed this aspect of our plan in the hearings 2 years ago:

"We believe, if fact, that the administrative process provides an excellent opportunity for a considered, sensible, and useful analysis and debate, both of the Newberne study and of a proposed course of action on nitrite. "It will also stimulate intelligent public consideration of the important issues involved in dealing with the safety of our food supply in general."

I turn now to the Attorney General's opinion.

We recognized, however, that our tentative course of action rested on an untested interpretation of the law. So in August 1978, we wrote to the Attorney General requesting an opinion of our legal position. We proposed two theories.

First, USDA aruged that since the general intent of the law is protection of the public health, we should be allowed to balance the health benefits of nitrite—prevention of botulism—against their potential harm.

Second, USDA argued that even though there was no discretion in the law as to whether to ban a cancer inducing additive, the law does not specify when a ban must take effect. Therefore, FDA had the discretion to permit the use of nitrite until alternatives were developed.

The Attorney General rejected both arguments, stating that the wording of the statutes, the legislative history, and existing case law all demanded that, upon finding that nitrite is carcinogenic, the agencies had no alternative but to proceed with orderly removal of this substance from commerce.

At this point, Mr. Chairman, I would like to have the memorandum of the Attorney General's opinion placed in the record.

Mr. JONES of Tennessee. Without objection, so ordered.

[The Attorney General's opinion follows. Other attachments are held in the committee file.]

Office of the Attorney General
Washington, D. C. 20530

March 30, 1979

Honorable Joseph A. Califano, Jr.
Secretary, Department of Health,
Education and Welfare
200 Independence Avenue, S.W.
Washington, D.C. 20201

Honorable Bob Bergland
Secretary, Department of Agriculture
14th and Independence Avenue, S.W.
Washington, D.C. 20250

Gentlemen:

This letter responds to your requests for the opinion of the Department of Justice with respect to the continued presence of sodium and potassium nitrite in food products regulated by your Departments. You advised me that certain private studies indicate that nitrites have been found to cause cancer in laboratory animals. I understand that neither Department has yet concluded that these studies are in fact accurate, and that, in advance of making any such finding, both Departments would undertake a thorough, independent examination of the question and would provide ample opportunity for public comment by interested parties. The responsibility and the authority to decide whether nitrites are in fact carcinogenic rest exclusively with your two Departments. The question you have posed is whether -- assuming that you eventually find that nitrites do induce cancer in man or animal -- you are authorized under applicable law to adopt an extended procedure for phasing out the use of nitrites over whatever time period may be necessary to develop a feasible substitute.

As you know, I have asked the Office of Legal Counsel for its views on this question. Enclosed you will find a memorandum to me from John Harmon, the Assistant Attorney General in charge of that Office, in which he examines the relevant statutes in some detail. He has carefully considered your written submissions and your comments in the meetings we have had on this question. His conclusion, with which I agree, is that at bottom

state, and local files and to use that data to establish priorities for on-site inspection and sampling. (We have attached both the initial and follow-up site prioritization guidance provided to the EPA Regional offices).

Where the evidence indicates a high priority for on-site inspections, inspections are conducted by EPA Regional staff or by state officials and documented on the attached forms. Information from on-site inspections is then used in making a "tentative disposition" indicating that a site appears to represent "no hazard" or is to be pursued as a possible enforcement case or as an emergency cleanup and containment action under Section 311 of the Clean Water Act.

At the time that the Subcommittee on Oversight and Investigation revealed the results of its Waste Disposal Survey, EPA Regional offices already had some 1536 potential hazardous waste sites on their Regional investigation logs. Regions were instructed to add all non-duplicative Subcommittee sites to their Regional investigation logs and to review those sites for priority site inspections using the established prioritization criteria (i.e., toxicity of pollutants, pathways to the environment, population potentially at risk, etc.). Additionally, all non-published Committee data which was made available to the Task Force was forwarded to appropriate Regional offices with additional copies to be made available to the states.

This data proved to be extremely useful in augmenting the existing site inventory, and highlighted the usefulness of the industrial survey approach --- particularly when backed by subpoena power. (As you know, there is currently no EPA subpoena power under the Resource Conservation and Recovery Act --- although that power is granted in the Senate version of the currently pending RCRA reauthorization.)

As of May 31, 1980, the EPA Site Tracking System listed 5,790 potential hazardous waste sites on Regional investigation logs. (As indicated on our forms and in all of our communications concerning the system, the mere listing of a locale as a "potential" hazardous waste site does not represent a finding that the site presents an actual hazard or that any illegal activity has occurred. Rather, it indicates that the site has been identified for further investigation.) This total has been growing at approximately 200 sites per month. Of this 5,790 total, 3,126 sites have had a "preliminary assessment" and 1,001 sites have had on-site inspections by Federal or state officials. 151 sites are currently under investigation for potential enforcement actions and 23 hazardous waste cases have been filed in Federal court (see attached case summarries). We anticipate filing 50 Federal enforcement actions before the end of Calendar Year 1980.

RESPONSE TO SPECIFIC RECOMMENDATIONS

Against this background, I would summarize my response to the specific recommendations listed on pages XI and XII of the Subcommittees' Report of October 1979 as follows:

Recommendation #1

> Undertake, in conjunction with the states, a comprehensive national inventory of disposal sites utilized by principal waste-producing industry groups.

The process of identifying and characterizing hazardous waste disposal sites is underway. While we have used site identification tools --- like EPA's recently completed Surface Impoundments Assessment --- to focus our attention on particular industrial classifications, we have generally emphasized our site prioritization criteria rather than emphasizing particular waste-producing groups.

Obviously, EPA and the states face a major problem in tracking the results of decades of careless and often undocumented waste disposal practices. To augment EPA's existing site identification and site inspection resources, the Agency has recently executed a $12,000,000 national contract which will place contractor teams in each Region. A total of 180 contract investigators will be allocated to our Regional Offices and will operate under Regional supervision. Additionally, this contract will allow us to quickly subcontract for additional assistance. The contract is already in partial operation and approximately 100 site inspectors are already in-place in the Regions.

Recommendation #2

> Conduct appropriate investigation with respect to all haulers identified in the survey who transported wastes to locations unknown to the waste generators to determine where such wastes were taken and the manner in which they were disposed.

While Subcommittee data on haulers has been provided to Regional Offices, the Agency will be unable to conduct a comprehensive "haulers" study until the additional field inspection resources referenced above are in place.

Recommendation #3

> Conduct, where warranted, a follow-up study of the disposal sites identified in the survey, particularly those known to be closed and on private lands, to determine whether there is reason to suspect that any of those sites pose threats to the public health or the environment.

the scientific community as well as the general public so that the process of criticism and evaluation could begin.

In addition to seeking peer review, we formed an interagency working group for nitrite research. This group was given the responsibility of arranging for an independent pathology review of the tissue slides from Dr. Newberne's study.

Even though the Newberne findings could only be considered tentative, there were several reasons why they had to be taken seriously. These reasons include the well-established evidence on nitrosamines, Dr. Newberne's previous study on nitrite, the scope of the Newberne study, the reputation of the researcher and the institution, and FDA's initial review of the findings.

I turn now to the problem of nitrosamines.

Scientists have been aware of potential problems with nitrite for many years. In the early sixties, they discovered that fish treated with nitrite and dried at high temperatures contained substances known as nitrosamines. Many nitrosamines, which can be formed at high temperatures when nitrites combine with amines and amides, have been shown to cause cancer in laboratory animals.

The discovery of nitrosamines in fish led the scientific community to investigate the possibility that nitrosamines might also be present in cured meat products. When studies revealed that the risk of nitrosamine formation was especially great in bacon, USDA had to take regulatory action to reduce the amount of nitrite used in curing bacon.

This regulatory program for eliminating nitrosamines from bacon has been successful. We have been able to reduce nitrosamines in bacon to below detectable levels and, contrary to fears once expressed by the meat industry, no manufacturers have been forced out of business. However, nitrosamines also occur in a variety of consumer products, and there have been indications that they can be formed in the stomach and intestinal tract through the action of nitrite with amines or amides.

This body of scientific evidence formed the background to Dr. Newberne's study. His findings simply added a new dimension to already serious questions about nitrite in the food supply.

I turn now to Dr. Newberne's earlier study.

The findings we announced in August 1978 were not the first indication that there might be a direct link between nitrite and cancer. In 1975, FDA had contracted with Dr. Newberne to study the possibility that nitrites might react with amines and amides in food to produce nitrosamines in the digestive tract.

In the course of that study, evidence developed suggesting that nitrite, when fed alone—that is, without any amines or amides—to rats,. induces a form of cancer called malignant lymphoma—cancer of the spleen, lymph nodes, and cells that make white blood cells. This evidence led FDA to contract with Dr. Newberne for a much larger study to determine whether continuous lifetime exposure of laboratory rats to nitrite causes cancer.

The scope of the Newberne study is as follows: The second Newberne study was one of the largest and most comprehensive of its kind ever undertaken. It involved 1,381 rats that were fed nitrite in varying amounts and in a variety of diets. It involved an additional 573 rats used in control groups. The study was designed to show

the relationship between dose—the amount of nitrite fed—and response—the occurrence of cancer in the aminals fed nitrite.

Although it is often misunderstood by the general public, the use of large doses in an animal study is a scientifically accepted method of determining whether a substance causes cancer. Cancer researchers understand that high doses are not representative of human exposure, and are not intended to be. High doses are used so that enough cancers will be produced to make the effects of a substances identifiable. The results of the experiment then provide a basis for estimating, by statistical means, how many cancers might result from the lower doses to which humans might be exposed.

The results of the study indicated that nitrite produced a statistically significant increase of cancer of the lymphatic system. The combined incidence of lymphatic cancer in the groups that were not fed nitrite was 7.9 percent, and the incidence in groups fed nitrite was 12.5 percent—or 50 percent greater than the control groups. The pattern of the turmors appeared to rule out the possibility that the carcinogenic effect of nitrite occurred by the formation of nitrosamines.

Nitrosamines typically produce cancers at multiple sites—in the lungs, digestive tract, liver, and nervous sytem—and have not been known to produce lymphatic cancer exclusively.

In addition to the evidence of lymphatic cancer, the study pointed to other potential toxic effects from nitrite, including enlargement of the heart and alterations in various parts of the immune system.

I would now like to talk about the reputation of the researcher.

Our concern over the possible adverse health effects of nitrite was reinforced by the reputation of the researcher. Dr. Newberne and his laboratory are well-regarded within the scientific community, and he has had a strong track record as a cancer researcher. The Massachusetts Institute of Technology, where the study was conducted, is one of the Nation's preeminent centers of scientific research. Moreover, Dr. Newberne is known to be conservative in his interpretation of data that suggest carcinogenicity. In the Senate hearings on nitrite in September 1978, Newberne was described by another cancer researcher as a highly respected and very able toxicologist and pathologist who is an objective scientist and is not known as an alarmist or an extremist.

I turn now to FDA's preliminary evaluation.

Although scientific confirmation of Dr. Newberne's findings had to await a rather lengthy process of peer review, his study did not go unscrutinized. Before Dr. Newberne was awarded the contract, he had to submit a set of protocols describing in some detail the scope of his study and how he planned to proceed. During the course of his experiments, he was required to submit regular progress reports. Once the study was completed, it was reviewed by a contracting officer to determine whether the protocols had been fulfilled.

As part of FDA's good laboratory practices survey, an FDA official visited Newberne's laboratory to observe whether proper procedures were being followed. When questions arose, Dr. Newberne worked to resolve them to FDA's satisfaction.

We have to develop the regulations under phase II and phase III of our program, and I know you will be asking questions about that so we can explain that in more detail at that time.

We have the problem of putting this program into operation. We believe that over 100,000 firms in this country will be affected and will be required to notify us. That is just initially, because we believe there are close to three-quarters of a million generators of some amount of hazardous waste in this country.

We have the problem of receiving applications from the States to operate this program and dealing with those. Then we will have the problem of the issuance of permits to the close to 30,000 facilities that store, dispose or treat hazardous waste.

We also have the very fundamental and extremely difficult problem of securing sites in this country where the best technology for the management of hazardous waste can be applied and, as was discussed this morning, that is an extraordinarily difficult political and social problem.

So that I think it fair to say that while we are reasonably proud of the extensive work we have done in developing these regulations to date, we recognize that there are difficulties in them and points that will need elaboration, refinement, and improvement. We are truly humbled by the task still ahead of us in trying to bring some better control over hazardous waste in our society.

Thank you.

Mr. GORE. Thanks for your statement.

You mentioned the subcommittee's pursuit of this issue. I assure you we are going to continue to pursue it because it looks like the public interest is being defeated in the trenches where the hand-to-hand combat is taking place on this issue. The industry lobbyists are winning.

Let me just ask you about this BEJ. Who is assisting EPA in the development of BEJ?

Mr. PLEHN. We are doing that as part of the rulemaking process. We proposed regulations in December of 1979 and we received extensive commentary on those. We will be considering all of those comments in the development of phase——

Mr. GORE. Who is assisting you in the development of BEJ? Is Monsanto assisting you in the development of BEJ?

Mr. DIETRICH. We retain Monsanto to help write a set of guidelines.

Mr. GORE. You have hired Monsanto Chemical Co. to write the guidelines for the BEJ?

Mr. DIETRICH. No. Monsanto Research Corp.

Mr. GORE. Monsanto Research Corp.

Mr. DIETRICH. Which is a subsidiary of——

Mr. GORE. Subsidiary of Monsanto Chemicals.

Mr. DIETRICH. They are developing a set of guidelines. They are not working on the development of the BEJ regulation. We will come out with a regulation and there will also be some guidance material that will accompany that.

The guidance material does a number of things. It reviews the state of the art of incineration; it provides methodologies in order to make certain calculations with regard to the incinerator facility.

It is more of an engineering manual than anything else. And, yes, we did retain Monsanto Research to help develop that guideline.

Mr. GORE. Do you think they might have a conflict of interest?

Mr. DIETRICH. We very definitely went into that before we awarded that because we were mindful.

Mr. GORE. Did you decide there wasn't a conflict of interest?

Mr. DIETRICH. We decided there was not a conflict of interest.

Mr. GORE. On what basis did you make that decision? I mean, they are——

Mr. DIETRICH. First of all, what they were doing would not have any effect on the BEJ regulation.

Mr. GORE. What do you mean, it won't have any effect on it? They are writing the engineering manual for it, aren't they?

Mr. DIETRICH. They are writing the manual with regard to what is the state of the art out there, basically collecting information.

Mr. GORE. What is possible and what is not possible? Do you think their determination of what is possible might be influenced by their judgment as to what is expensive?

Mr. DIETRICH. I think not in this particular case. We are, however, being very, very careful about that contract. That guidance, by the way, is currently being reviewed by a number of other peer level people.

We will have a second draft toward the summer. Then it will be made publicly available for comment by the public at large with regard to that. So the ultimate product is going to have critical review by the world, if you will.

Mr. GORE. Well, it is going to have critical review by this subcommittee. I mean, what we have here is the public interest on the one side and a special interest, largely that of the chemical industry, on the other side.

Now in passing this law—RCRA—the Congress balanced those two interests in a general way. Laws are blunt instruments and imperfect. But in passing that law we decided that the public interest demands closer scrutiny of hazardous waste disposal.

We then turned over the job of putting that law into effect in the form of regulations to the Environmental Protection Agency.

Unfortunately, what has happened is the public interest has, evidently, been trampled by the special interests involved in the design and implementation of these regulations.

We have asked a series of questions about the first phase of regulations and the general response is later regulations will improve them. With specific regard to the interim site regulations, we are told that the BEJ or best engineering judgment standards will supplant them and improve them.

Now we find that Monsanto Chemical Co., a subsidiary of Monsanto Chemical Co., has been asked to compile the data which will form the basis of the BEJ standards. Again, the conclusion is inescapable that the public interest is losing out to the special interests and what we want to find out in these hearings is why, why?

Let me turn to the injection wells.

Mr. PLEHN. I could add one point, Mr. Chairman.

Mr. GORE. Yes, you can respond to that.

cluded that there were no faults in the laboratory practices serious enough to jeopardize the results of the study.

The third area of criticism—concerning scientific methodology and interpretation—was the most worrisome. Some people questioned the statistical appropriateness of aggregating the results from different groups that had been fed different diets. Others noted that the results of the study might be overstated because of the tendency of animals from the same litter to respond more alike to a test substance.

The high incidence of spotaneous lymphomas in the control groups—rats on a nitrite-free diet—also troubled some scientists, leading to speculation that the tissue slides had been misdiagnosed.

They were all valid concerns, but they could be resolved only through the lengthy process of peer review. This was particularly true of the question of the pathological diagnosis.

Pathology is by no means an exact, quantifiable science. It involves difficult questions of judgment and interpretation by experienced observers, who have been known to disagree over what they see through a microscope. It was in this area that other pathologists later disagreed with Dr. Newberne.

I think it should be emphasized that back in August 1978, we had no way of knowing that several other pathologists would disagree with Dr. Newberne's interpretation of the tissue slides. We know that the slides would have to be reviewed, but considering Dr. Newberne's outstanding reputation the possibility of significant disagreement seemed remote. It should further be emphasized that almost all the initial criticism concerned other matters, which for the reasons I have mentioned were not considered compelling.

One must conclude that there is no easy answer to the question: What went wrong?

Given the laws under which we must operate and the apparent strength of the Newberne study, the agencies took what they believed to be the only rational—and legal—course of action.

It was unacceptable to suppress the existence of the report and it was unacceptable to acknowledge its existence and do nothing. With human health at stake, it was imperative to act conservatively. However, there are still some lessons to be learned from our experience with the nitrite study. The whole episode illuminates some significant public policy issues.

I turn now to the third area of my statement which are the policy issues.

In announcing today's hearing, Mr. Chairman, you stated that the committee would go beyond the immediate question of how the nitrite matter was handled, and would discuss the broader issues surrounding our present laws on food additives. I fully agree that the experience with nitrite raises some significant policy questions, and that this is a good occasion to examine them.

In my view, there are two broad policy issues that emerge from our recent experience. First, have the legal categories governing added substances grown too complex? Second, is the present risk-based standard for added substances too inflexible?

In examining the present laws on food additives, one is immediately struck by their complexity. Nitrite offers a good case in point. Depending upon its use, nitrite can fall under either the Food,

Drug, and Cosmetic Act, or the Meat and Poultry Inspection Acts. It can be regarded as a food additive, a color additive, or a prior-sanctioned substance. It can be subject to the Delaney clause or not subject to the Delaney clause. Over the years the food additive provisions of the law have grown so complex that sometimes I am not sure that even the lawyers understand them.

There can be little disagreement that the present scheme should be simplified and clarified. At the same time, we must recognize that the present law may reflect a number of sound policy decisions that are worth preserving.

For example, it makes sense that the safety standard for added food substances is higher than the standard for traditional food commodities, such as potatoes.

When the Congress set these standards it considered the need for an abundant food supply, and took into account the fact that naturally occurring substances, unlike additives, may not be subject to deliberate control.

We, therefore, would be wise to resist the understandable impulse to scrap the present scheme and start all over again. But there are some areas where changes may be considered.

One such area is the lack of flexibility in the present standard for food additives. As we have seen, the Delaney clause, as well as the adulteration provisions of the Federal Meat Inspection Act, the Poultry Products Inspection Act, and the Food, Drug, and Cosmetic Act, all set a strict, risk-based standard for food additives.

There is no provision in the law as enacted by Congress for the executive branch to consider the benefits of a substance. Added poisonous or deleterious substances that may cause harm to humans are prohibited in food regardless of any benefit they may confer.

In the case of nitrite, there was a well-established, health benefit—the prevention of botulism—and we believed that it should be considered in fashioning a rational regulatory approach that would protect the general public. But we were told by the Attorney General that the law did not permit us to take benefits into account—not even health benefits.

There would appear to be an easy solution to the type of dilemma that confronted us on nitrite: Simply allow the agencies to balance risks against benefits.

However, again I believe it wise to proceed carefully. Proponents of full-scale risk-benefit analysis often overlook the fact that current categories of substances already reflect social benefit judgments about various classes of food substances.

For example, it is extremely difficult to ban a basic food commodity under the present law because Congress has judged the benefits of the substances to be very high. This is less true of additives. It is entirely appropriate that the Congress should make these fundamental decisions.

A stronger case can be made for having Congress set certain broad guidelines and then permitting the agencies to weigh benefits against risks. But risk-benefit analysis on even a limited basis may not be the panacea it is often cracked up to be.

The possible problems include: The increased administrative burdens, and bottlenecks in decisionmaking; the erosion of public con-

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PREPARATION OF PERMIT WRITER GUIDANCE FOR HAZARDOUS WASTE INCINERATION

BACKGROUND

On December 7, 1979 the EPA Office of Solid Waste (OSW) requested the Office of Research and Development (ORD) to prepare a guidance document on hazardous waste incineration to be used by the Agency in implementing the permit program under the Resource Conservation and Recovery Act (RCRA). At that time, the OSW was under pressure to meet a court ordered deadline. This deadline was subsequently established as October 30, 1980, but in order to meet this deadline, delivery of the first draft of the guidance document was necessary by April 1, 1980, so that adequate review of and appropriate corrections could be made to the document.

The quest for assistance from ORD was a direct result of the Agency's decision to promulgate the final RCRA regulations on the basis of a "best engineering judgement (BEJ)" concept for issuing hazardous waste management permits. The incineration guidance manual was to outline clearly the current state-of-the-art in the design and operation of hazardous waste incinerators and to delineate the factors the permit writers would consider in reviewing and issuing permits for such incinerators. Mr. Louis Lefke, Deputy Director, Municipal Environmental Research Laboratory, was requested to direct a group effort dedicated to the preparation of the guidance document. A draft for review had to be available by April 1, 1980 in order that the review could be completed to coincide with the court ordered RCRA deadline.

Because of the short deadline for preparing a draft document, its development could not be accomplished solely with EPA personnel. The tight deadline also meant that initiating a specific competitive procurement would not be possible. EPA therefore decided it would be necessary and appropriate to use the Technical Engineering and Service Contract (TESC) contract mechanism available to the Industrial Environmental Research Laboratory (IERL)-Cincinnati. Under this mechanism, eight contractors have been prequalified to perform engineering and analytical services for EPA on a task order basis. The contractors available under this mechanism are listed in attachment #1.

The procedure for determining the most appropriate contractor under the TESC system is strict, and specific guidelines must be followed. Standard areas of capability are listed in the scope of work and are required of all eligible contractors who qualified for the TESC. Different contractors possess these qualifications in various combinations. The procedure involves the development of a weighted profile of the capabilities required for a specific effort. At no time are those involved in making the selection aware of the identity of the contractors.

Accordingly, Mr. Lefke asked Mr. Warren A. Schwartz, a senior engineer in the Office of the Director of the Municipal Environmental Research Laboratory, to prepare a set of weighted qualifications keyed to the requirements of the job at hand. Mr. Schwartz was asked to do this because he was a well qualified third party not otherwise involved in this effort. His work was reviewed and approved by Mr. Lefke. Mr. Schwartz's weighted job qualifications were also reviewed and evaluated by Mr. Ivars Licis, the TESC project officer for IERL-Cincinnati. The results of this purely mechanical evaluation indicated that Monsanto Research Corporation was the most appropriate contractor for the job.

ISSUE

The selection of Monsanto Research Corporation as the contractor raised several obvious questions of conflict of interest. Monsanto Research Corporation is a wholly owned subsidiary of Monsanto Company, a chemical company and hazardous waste generator. Monsanto Company also has expressed commercial interest in hazardous waste incineration technology. The Assistant Administrator for Water and Waste Management and the Associate Deputy Assistant Administrator for the Office of Solid Waste requested EPA's General Counsel to address these issues. The General Counsel defined two sources of conflict of interest --- Monsanto Company might benefit from advanced knowledge of the regulations that EPA is developing and will promulgate for hazardous waste incinerators, and Monsanto Company might benefit from the guidance document's influence on EPA's development of these regulations.

In summary, EPA addressed these questions of conflict of interest in several ways. First, Monsanto Research Corporation was chosen only because it was the most qualified organization from among the eight firms available. Second, the conflicts of interests of the contractor were recognized and measures were taken to assure that Monsanto Company would not benefit from prior knowledge of the incinerator regulations. Specifically, EPA adopted two procedural safeguards to assure that Monsanto Research Corporation would not be able to bias the guidance document for the benefit of Monsanto Company. The first procedure was the development of a sixty-page, detailed outline of the document and the very close supervision of the contractor's work in assembling the information comprising each section of the document. The second procedure was the requirement that the draft document be extensively reviewed by a number of knowledgeable organizations and individuals to see that the report was of high technical quality and did not show a bias toward Monsanto Company's single point of view.

MONSANTO COMPANY ADVANCED KNOWLEDGE

The subject of conflict of interest was first openly addressed by ORD after receiving Mr. Michael Dworkin's memorandum to Mr. Lefke on March 13, 1980 (attachment #2). Mr. Dworkin, an attorney in the EPA Office of General Counsel, expressed concern about a potential conflict of interest in using Monsanto Research Corporation for preparing the guidance document. His concern evolved from the fact that the Monsanto Research Corporation is a wholly owned subsidiary of Monsanto

believe, a good example of the problems that can arise when you make important regulatory judgments without the benefit of extensive peer review of the data upon which those judgments are based.

Consequently, I believe it is essential that your agencies undertake a study to find alternate ways to improve your peer review mechanisms. I know that the American Industrial Health Council has recently recommended a study of the alternative institutional means for making sure that scientific regulatory agencies have the best and most objective system of scientific evaluation. I would appreciate your consideration of these ideas and any others that you might propose.

Your response to this letter, including an estimate of the cost of any proposed study, would be appreciated at the earliest possible time.

Yours very truly,

Tom Eagleton

THOMAS F. EAGLETON, Chairman
Subcommittee on Agriculture, Rural
Development and Related Agencies

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DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION
ROCKVILLE, MARYLAND 20857

September 10, 1980

The Honorable Thomas F. Eagleton
Chairman, Subcommittee on Agriculture
and Related Agencies
Committee on Appropriations
United States Senate
Washington, D. C. 20510

Dear Senator Eagleton:

This is in response to your letter of August 28, 1980, requesting that FDA and USDA consider ideas for making sure that scientific regulatory agencies have the best and most objective system for evaluating scientific data on which regulatory judgments are based. You suggest specifically that we study alternate ways to improve our peer review mechanisms, stressing your concern that important regulatory judgments not be made "without the benefit of extensive peer review of the data upon which those judgments are based." Finally, you ask that we provide an estimate of the cost of any proposed study.

We agree that it would be extremely useful to have an appropriate organization conduct for us under competitive contract a study that would do the following:

1. Assess the procedures now in place at FDA and USDA for sponsoring and monitoring the progress of research examining the toxicity of substances.

2. Assess the procedures now used by FDA and USDA to evaluate for regulatory purposes scientific data on the toxicity of substances, including existing procedures for obtaining external peer review of such data.

3. Consider whether changes are needed in the manner in which FDA and USDA review scientific data for regulatory purposes, including whether, and under what circumstances, additional external peer review mechanisms are needed.

4. To the extent additional peer review mechanisms are needed, consider what those mechanisms should be.

being selected. The final version of the Incinerator Permit Guidance Manual is now being prepared by Mitre Corporation. Both the Permit Guidance Manual and the Handbook will be noticed for public comment and circulated for scientific review.

SUMMARY

EPA contracted to obtain technical skills in the preparation of a detailed guidance document for permit writers charged with exercising "best engineering judgement" in the review of hazardous waste incinerator permits.

The very restrictive time schedule and the intense demand of EPA personnel meant that EPA could not develop the document in-house and had to rely on contractors to help prepare the document. The time schedules also meant that a full competitive process for contracting was impossible. EPA selected the most highly qualified contractor from the eight available. This was Monsanto Research Corporation. EPA recognized the conflict of interest between the parent corporation Monsanto Company and the regulation of hazardous waste.

Pollution control is a highly specialized technical art. Organizations and individuals processing detailed knowledge in the area are almost never free of interest or proa association with a regulatory or regulated organization. The project manager and senior EPA management felt, and continue to feel, that the potential for bias would be disclosed and could be managed. Tney therefore felt that the best course of action was to continue the project with Monsanto Research Corporation.

Controlling the opportunity for bias meant an enormously detailed specification of the tasks to be performed, extremely intensive EPA supervision of contractor activities, and multiple review of the draft reports.

EPA believes the Monsanto draft is an objective report of excellent technical quality.

ATTACHMENT #1

TESC CONTRACTOR INFORMATION Rev. 9/15/78

(18 - MONSANTO RESEARCH CORPORATION - 68-03-2550)
Dr. William H. Hedley
Dayton Laboratory
1515 Nicholas Road
Dayton, Ohio 45407
8-774-2700, ask for 268-3411

(17 - BATTELLE MEMORIAL INSTITUTE - 68-03-2552)
G. Ray Smithson, Jr.
Columbus Laboratories
505 King Avenue
Columbus, Ohio 43201
Battelle - 8-976-6424
Smithson - 8-976-7814/6

(19 - HITTMAN ASSOCIATES, INC. - 68-03-2566)
Dr. C. Leon Parker
Dwight B. Emerson
9190 Red Branch Rd.
Columbia, Maryland 21045
Phone: 8-920-3311, ask for 730-7800

(31 - ACUREX CORPORATION - 68-03-2567)
Larry Cooper - ext. 3471
Aerotherm Division
485 Clyde Avenue
Mountain View, California 94042
Phone: 8-(415)-964-3200

(60 - TRW, INC. - 68-03-2560)
Irving Zuckerman
Energy Resources Group
One Space Park
Redondo Beach, California 90278
Phone: 8-(213)-536-1413
Home: xxxxxxxxxxxxxx

(56 - MIDWEST RESEARCH INSTITUTE - 68-03-2563)
Dr. A. D. McElroy
425 Volker Blvd.
Kansas City, Missouri 64110
Phone: 8-758-7212, ask for (816)-753-7600

(41 - THE DOW CHEMICAL COMPANY - 68-03-2568)
Mohamed A. Zeitoun
Freeport, Texas 77541
8-749-1011, ask for (713)-238-4807

(1 - JACOBS ENGINEERING CO. - 68-03-2569)
Henry Cruse
Lucille Page -ext. 419
Krishnan (P.O.)
251 South Lake
Pasadena, California 91101
Phone: 8-(213)-449-2171

For this reason, we welcome Senator Eagleton's suggestion that our agencies undertake a study to find alternative ways to improve our peer review mechanisms. Last week, we sent him a reply stating that we will seek competitive bids for the type of study he has proposed. We will use fiscal year 1981 funds to carry out this study.

This study will assess the procedures now used by FDA and USDA to evaluate scientific data on the toxicity of substances, and consider what changes are needed, including what additional peer review measures should be instituted.

Because the study will involve complex, scientific, legal, and philosophical questions, we hope to receive innovative and imaginative proposals. We believe the results will have Government-wide importance.

I want to next turn to the public's right to know.

I have left the issue of the public's right to know until the end because it was of central concern to us when we first learned of the results of the Newberne study back in May 1978.

The public's right to know is a loaded phrase, and I do not wish to invoke it as any sort of moral justification for our decision to announce the Newberne findings. What I wish to emphasize is a simple matter of fact: Regulatory agencies must now go about their work in an environment of total openness.

In a recent editorial on the subject of the nitrite study and freedom of information, the Washington Post referred to this bias as "our let-it-all-hang-out style of government."

The Post attributes this open style to the effect of the Freedom of Information Act and to post-Watergate sensitivities about coverups. We could probably spend several days on this subject. For right now, however, the question worth examining is the effect that all this had on our decision in August 1978 to go public with the Newberne study.

There was never really any question about having to release the results of the study. Once an agency has contracted for a study and then accepted it, it is virtually impossible under the Freedom of Information Act to withhold its release.

Given the rather widespread knowledge that the Newberne study was underway, and the intense interest in any study that concerns a potential carcinogen, we inevitably would have been faced with a Freedom of Information request. We were certain that, at some point, we would be legally required to release the Newberne findings.

The real questions were when to announce the findings, and in what manner. In hindsight, it is clear that the ideal time to release the study would have been after the thorough review of the pathology of the tissue slides. But back in the summer of 1978 this choice was not available. We could not predict that the review of the pathology would undermine the results of study. The best indications were just the reverse.

Given the significant scope of the study and the previous record of the researcher, the safest prediction was that the results would be confirmed. We would then have been faced with the question of why we had kept the study under wraps for such a lengthy period.

On the matter of timing, it also was unrealistic to expect that we could keep the results secret for any period of time. All of us must live with that time-honored Washington institution known as the news leak.

When we began to develop a plan for releasing the study, we knew that it was only a matter of time before reports on the study would begin appearing in the media. This knowledge gave our deliberations some sense of urgency.

As I have mentioned, Food Chemical News carried a story on the findings almost as soon as they were reported to us. We felt there was the greatest potential for alarm, both to consumers and to industry, if reports of the study were leaked out to the public in piecemeal and distorted fashion.

Therefore, we believed that the manner in which the Newberne findings were released were critical. It is always difficult to decide the best way to inform the public about a potential health risk.

But the evidence on nitrite presented an even more difficult situation because it involved competing health risks: The potential of causing cancer, and the potential risks of botulism.

It was important to adopt a public information strategy that attempted to explain as fully as possible the complexity of the issue. We had to present the Newberne findings for what they were, but at the same time make it clear that they still had to be confirmed.

We also had to point out that there might be competing health risks. We had to assure consumers that we were proceeding in a manner that would protect the public health, but at the same time allay the fears of consumers and industry that we would take action that might create another risk to public health and that could cause severe economic hardships.

These concerns lay behind our decision to announce a tentative regulatory plan for dealing with the problem of nitrite. We felt it important to let both consumers and industry know where we were headed.

The most alarming action we could have taken would have been to announce the Newberne study without any explanation of what we planned to do about it. Consumers would have feared that the Government was doing nothing to protect the safety of the food supply, and industry would have feared that the Government would suddenly do too much.

Under the circumstances, I think we took the only sensible course.

I turn now to the future.

As we look back on the difficult decisions that confronted us 2 years ago, we can only be grateful that the original Newberne findings were not borne out by the later review. But it would be a grave mistake for us now to be lulled into a false sense of security.

As I mentioned earlier, the scientific community remains concerned over the possibility that nitrite can combine with other substances in the human digestive tract to form the powerful carcinogen known as nitrosamines.

The inescapable lesson to be drawn from our recent experience is the folly of becoming excessively dependent on the use of one substance. There is little wisdom in having an entire industry and

directive for an (Est.) 8,000 hour/$320,000 effort to produce "Permit Writer Guidelines - Hazardous Waste Incineration" during the period between January 10, 1980, and April 1, 1980. MRC has already submitted an 1100 page draft version of this report to EPA. A final version is due on March 28. It is expected to be rewritten by September 1, 1980.

MRC is a wholly owned subsidiary of Monsanto Company. High Monsanto Company officers, including the Chairman of its Finance Committee, hold four of the five seats on MRC's Board of Directors. The fifth director, MRC's President, reports functionally to Monsanto Company's Vice President for Technology Development and, through him, to J.W. Hanley, Chairman-Board of Directors and Chief Excutive Officer of Monsanto Company. The manufacturing groups owned by Monsanto Company report to Mr. Hanley through separate chains of command. The existing TESC contract contains no relevant restrictions on MRC's or Monsanto Company's use of data generated from or for this project. 2/

Clearly, there is a potential for a conflict of interest in this situation. It takes two forms. Monsanto Company could benefit from advanced knowledge of incineration regulatory development; and Monsanto Company could benefit from the manual's influence on permit writer decisions. Even if this conflict is never acted upon, its mere appearance is disturbing.

The ideal solution to the problem would be to terminate this contract and to replace it with one for a manual to be created by experts who will not be members of the regulated community. 3/ This may not be practical. Most consultants with the necessary expertise are tied to members of the regulated community; other TESC contractors evaluated included, for example, Dow Chemical, also a hazardous waste incinerator. On the other hand, non-operators such as Accurex or Battelle could have performed this work under TESC; and sources other than the TESC "stable" might have been explored at the cost of a slight delay.

That decision has already been made. We are now in a situation where MRC is about to complete a major piece of work on this project.

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2/ Art. VIII, §C requires that the Contractor protect confidential information of other companies and that it not use such information to compete with such companies. This does not cover information relevant to regulatory development and is totally irrelevant to issue of influence by MRC upon EPA's decision-making process.

3/ I have previously suggested that this could be done by the West Germans who prepared NATO's CCMS study on hazardous waste incineration.

The start-up cost and delay of diverting the manual to another contractor would be great. If we can avoid that transfer cost by minimizing the problems with the present contract we should do so.

The danger of undue influence upon EPA can be checked if we really do have the technical capability to analyze the completed manual for "tilt" and if we ensure that permit-writers do not view this reference work as the functional equivalent of a regulation. The danger of improper advantage to Monsanto company can be checked by contractual revisions to prevent improper distribution of information. Such a contractual revision, enforcing MRC's separation from Monsanto's production and financial operations, would reduce to a tolerable level, the present appearance of, and potentiality for, impropriety. April 1 is the obvious date for this. Mike Hennessey and Rick Anderson should be able to help with this. If these corrections cannot be made, we should terminate this contract and obtain an independent assessment of the work thus far produced.

One, more general point remains. This contract allows the government to unilaterally increase the level of effort to a maximum of 60,000 hours at a rate of $401,500 for each 10,000 hour increment; a grand total cost of more than $2,400,000. Yet it does not include a standard "Organizational Conflict of Interest Clause." Even small contracts dealing with policy issues should have such a clause. When a contract of this magnitude is used for work that is directly entangled with the creation of a regulation - especially a proposed one with a closed comment period - such a provision and a review for conflict of interest should be automatic. Future work should take this into account. See E.P.A. Procurement Information Notice No. 78-23, April 20, 1978.

cc: Eckhardt C. Beck (WH-556)
Steffen Plehn (WH-562)
Gary Dietrich (WH-562)
Jack Lehman (WH-565)
Tim Fields (WH-565)
Anne Allen (WH-565)
Lisa Friedman (A-131)
Donnell Nantkes (A-134)
Mike Hennessey - CMD Cincinnati
Rick Anderson - Grants & Contracts
Cincinnati

the approval and thereby ban the substance. The process involves publication of a proposal in the Federal Register for public comment, evaluation of the comments, publication of a final regulation, receipt of objections to the final regulation, receipt of objections to the final regulation, evaluation of the objections, a formal evidentiary hearing before an administrative law judge if justified by the objections, a decision by the administrative law judge, appeals to the Commissioner, a final decision by the Commissioner based on the entire record, and finally, judicial review of the final decision in a Federal court of appeals.

This process takes—not weeks or months—but years to complete. Its virtue, however, is that it gives the scientific community and the public-at-large opportunities at both the proposal and hearing stages to review, criticize, and challenge the basis for a proposed action, including the scientific evidence.

Although the process is elaborate, the substantive showing FDA must make to trigger a banning procedure is not difficult. Even after a food additive has been approved, the burden remains on the manufacturer to demonstrate its safety should questions about its safety subsequently arise.

Thus, to initiate a banning procedure FDA need not be able to prove that the food additive is unsafe, but only that new evidence raises a substantial unresolved question about the safety of the additive such that there is no longer a reasonable certainty of no harm resulting from use of the substance.

When FDA makes that showing in a proposal to withdraw approval of a food additive, the burden shifts to the manufacturer to prove that the additive is, in fact, safe.

Prior-sanctioned substances are subject to a substantially different regulatory scheme than food additives. There is no premarket approval requirement, and, in order to remove a prior-sanctioned substance from the food supply, the burden rests on FDA to prove that the presence of the substance in food may render it injurious to health.

The Delaney clause does not apply, but an intentionally added substance shown conclusively to cause cancer in a valid animal study would most likely fail this safety standard and thus be subject to removal from the food supply.

Were it to become necessary to remove a widely used prior-sanctioned substance from the food supply, FDA would use an administrative rulemaking process that provides for a proposal published in the Federal Register for public comment, evaluation of the comments, and judicial review of the final regulation in Federal court. Although not as elaborate as the process applicable to food additives, this process also affords a full opportunity for public review and critique of the scientific evidence.

In the case of a prior-sanctioned substance used in meat or poultry products, the responsibility for taking any necessary action to ban the substance rests with USDA under the Meat Inspection Act and the Poultry Products Inspection Act, but the applicable safety standard, burden of proof, and administrative procedures are the same as those FDA would use.

With this statutory framework as a background, it is now appropriate to turn our attention to FDA's handling of nitrite.

I would like to discuss the Newberne study of nitrites and FDA's response.

In 1974, an FDA-sponsored study of nitrosamines developed evidence suggesting that nitrite, when fed alone, that is, without amines or amides, to rats, induces a form of cancer called malignant lymphomas—cancer of the spleen, lymph nodes, and the cells that make white blood cells.

This evidence led FDA to contract with a leading expert in the study of nutrition-induced disease, Dr. Paul Newberne of MIT, to explore the possibility in a large and thorough study. Dr. Newberne's research was quite extensive. It involved 1,381 rats that were fed nitrite, plus 573 controls.

After a careful but preliminary review by FDA scientists, the Newberne study was made public by FDA and USDA in August 1978, so that it could be reviewed by the scientific community at large. In it, Dr. Newberne reported that the nitrite-fed rats had an increased rate of cancer of the lymph system.

Among the rats fed nitrite, 12.5 percent were reported to have been found with lymphomas, compared to 7.9 percent of the control rats. Dr. Newberne later revised these figures to 10.5 percent and 5.75 percent, respectively.

When the MIT study was received in 1978, FDA and USDA reached the tentative conclusion that nitrite might cause cancer. They, therefore, initiated two courses of action:

First, they tentatively decided that, if nitrite were shown to cause cancer, it could not be abruptly eliminated from food processing, unless an alternative preservation method was available to protect against botulism. Therefore, the agencies began developing a proposed series of steps that might be taken to reduce and ultimately eliminate nitrite, as the research might justify.

The agencies asked the Department of Justice whether the proposed plan was possible under current law. The Department of Justice said the proposed phase-out plan would not be possible under current law, and that if nitrite were found to be carcinogenic, an immediate prohibition of its use as a food additive would have to be proposed. The agencies subsequently developed legislation that would have tied a phase-out of nitrite, if justified by the research, to development of an alternative preservation method.

Second, after questions were raised first by Government and subsequently by nongovernment scientists about the validity of the MIT study, the agencies concluded there was need for a thorough outside review of it.

FDA, therefore, formed the Interagency Working Group on Nitrite Research, with scientists from FDA, USDA, the National Cancer Institute, and the National Institute of Environmental Health Sciences.

A preliminary evaluation by the pathologists in the working group of a random sample of tissue slides revealed significant differences of opinion as to diagnoses. Therefore, the group recommended a full-scale pathology review of the MIT study.

FDA then contracted with a consortium of medical school-based pathologists known as Universities Associated for Research and Education in Pathology, UAREP, for a slide-by-slide review of the

On Page 3 under Discussion, you write about a "potential" for conflict of interest. I have to readily agree with you but I think it is only that. It is my opinion that the potential for conflict of interest exists in many aspects of Agency business. It is correct for you to be concerned about the potential for conflict of interest. I can assure you that the professional people working on this effort are well aware of this, not only on this contract but in all of their duties, and I feel equally sure that they will do everything possible to prevent such an occurrence.

I have had extensive discussions with Messrs. Anderson and Hennessey and they are in agreement about the items discussed above.

I trust your concerns have been addressed and that the "potentials" that "could" occur remain just that.

If you have any further questions concerning any other items, I would be pleased to hear from you.

Louis W. Lefke

Attachments
cc: Eckhardt Beck
Steffen Plehn
Gary Dietrich
Jack Lehman
Tim Fields
Anne Allen
Lisa Friedman
Donnell Nantkes
Rick Anderson
Mike Hennessey
Chapter Project Officers:
Harry Freeman
Robert Olexsey
Richard Carnes
Leo Weitzman
Dale Harmon
Carlton Wiles
Don Oberacker
George Huffman
Steven Reznek
William Rosenkranz
Gary Foley
Francis Mayo
John Burchard
David Stephan
Warren Schwartz

ATTACHMENT #4

CLAUSE NO. 52 Contract No. 68-03-2550 (Mod. #17)

ORGANIZATIONAL CONFLICTS OF INTEREST

(a) The Contractor warrants that, to the best of his knowledge and belief, and except as otherwise set forth in the contract, he does not have any organizational conflict of interest, as defined in paragraph (b) of this clause.

(b) The term "organizational conflict of interest" means that a relationship exists whereby an offeror or a contractor (including his chief executives, directors, proposed consultants or subcontractors) has interests which (1) may diminish his capacity to give impartial, technically sound, objective assistance and advice or may otherwise result in a biased work product or, (2) may result in an unfair competitive advantage. Such interests include, but are not limited to, present or proposed contractual arrangements with an industry to be studied, present or proposed contractual arrangements with a firm which manufactures or sells any item or substance to be studied, present or proposed manufacture or sale of any item or substance to be studied, and present or proposed manufacture or sale of any item or substance in competition with an item or substance to be studied under the proposed contract with EPA. It is not relevant that the offeror has either the reputation of being able to resist the temptation to give biased advice or the ability to resist such temptation.

(c) The Contractor agrees that, if after award he discovers an organizational conflict of interest with respect to this contract, he shall make an immediate and full disclosure in writing to the Contracting Officer which shall include a description of the action which the Contractor has taken or proposes to take to avoid, eliminate or neutralize the conflict. The Government may, however, terminate the contract for the convenience of the Government if it would be in the best interests of the Government.

(d) The Contractor agrees further that, if the award follows formally advertised solicitation and a conflict of interest was identified prior to award, he will adequately avoid, eliminate or neutralize the conflict in a manner satisfactory to the Contracting Officer.

(e) In the event that the Contractor was aware of an organizational conflict of interest anytime prior to or after the award of this contract and intentionally did not disclose the conflict to the Contracting Officer, the Government may terminate the contract for default or invoke such other remedies as may be authorized by law.

provides a full opportunity for external review and criticism of the data underlying the proposal before any proposed action becomes final.

To postpone even beginning the administrative process in such a case until all possible questions about a study are resolved through external peer review or other means would only delay a final decision on the substance in question and thus possibly delay unnecessarily an important public health protection measure.

Moreover, the suggestion that FDA routinely obtain external peer review prior to the issuance of all regulatory proposals ignores the very purpose of the statutorily established administrative process, which is to allow public comment and resolve any issues that arise.

As I explained earlier, the applicable administrative processes allow for the widest possible public involvement in evaluating the scientific evidence underlying a proposed regulatory action. In contrast to normal peer review, which ordinarily involves only a small number of independent scientists, the administrative process opens the issue up to all who wish to participate.

This involves all of our concerned public, including the concerned industry. An attempt to resolve ahead of time all possible questions about the scientific evidence underlying a proposed regulatory action through a peer review process undermines the public's opportunity for early widespread involvement in reviewing the Agency's data and could tend to make the statutorily mandated administrative process a meaningless exercise. Indeed, to some degree, it could exclude the industry scientists most concerned.

Finally, it is important to remember that, in the case of food additives, the evidence required to justify proposing a ban need not be conclusive about the lack of safety of the additive, but, as I discussed earlier, need only raise a substantial unresolved safety question. Thus, when FDA has evidence affirmatively linking an additive with a health risk, it may well be appropriate to propose a ban without undergoing beforehand the external peer review of the evidence that might help determine whether the evidence conclusively resolves the safety question.

Once a substantial question is raised, the law appropriately places the burden on the proponent of the additive to provide the evidence necessary to resolve definitely whether the substance is safe.

It is easy to see how the foregoing considerations influenced the steps FDA and USDA took in 1978 with respect to nitrite. In the Newberne study, we had evidence strongly suggesting that nitrite causes cancer.

After a preliminary review of the study seemed to confirm Dr. Newberne's conclusions, we quite appropriately released the study, thereby allowing the scientific community to review the results reported by Dr. Newberne; and we began planning the administrative processes that would be necessary to determine what, if any, regulatory action would be needed.

FDA and USDA never announced a ban, or even a phaseout, of nitrite but only their intention to consider what regulatory steps would be appropriate should the results of the Newberne study be

confirmed. A copy of the August 11, 1978, press release is submitted for the record.

The CHAIRMAN. Without objection, so ordered.

[The press release appears at the conclusion of Dr. Goyan's testimony.]

Dr. GOYAN. In my judgment, what we did in 1978 was the least we could do under the circumstances; and I believe that the process of open public review and questionning of scientific evidence operated just as it should have. Apparently sound data were presented to the public, reviewed with an intensity justified by their potential significance, and, when found wanting, were declared by FDA and USDA not to justify further consideration of regulatory action.

It is important to note that the questions about the Newberne study—that is substantial disagreement regarding the diagnoses of the pathology—is of the kind that would not be caught by the normal peer review process. It is thus difficult to imagine how any different handling of the study by FDA and USDA could have altered the basic sequence of events that occurred.

Although peer review of the normal kind, involving review of the protocols, study execution, and statistical analyses, would likely not have affected our handling of the Newberne study, FDA recognizes that in certain special circumstances preproposal, external peer review may be an appropriate step to take.

FDA's Bureau of Foods recently has adopted a policy that assigns to a Bureau Executive Committee the responsibility to identify the special cases that warrant scientific review outside the normal Bureau review channels.

The factors that might justify a special level of review include:

One, a lack of the requisite expertise within the Bureau;

Two, insufficient Bureau resources to handle the workload;

Three, the need for outside scrutiny of a study the Bureau itself has conducted; and,

Four, the need for a broader base of recognized scientific input to develop a public consensus on a controversial scientific issue.

The special level of review these factors might justify include review of the study by Government scientists from outside the Bureau or FDA, interagency committees, private consultants, and public advisory committees.

Although we believe the Bureau's new policy will help us deal more effectively with the special case, it is important for the committee to understand that the additional level of review would only supplement the already well-established scientific review processes that exist in the Bureau of Foods for evaluating scientific studies.

For each study that comes before the Bureau, senior Bureau officials make a determination, based on the nature and subject of the study, as to the appropriate level of review.

For example, routine scientific studies are reviewed at the staff level. If the study has regulatory implications, it is reviewed by the staff of the appropriate regulatory branch in the Division of Toxicology and, where appropriate, by responsible scientific directors in the Division of Toxicology or associated staffs.

Other mechanisms used to assure multidisciplinary reviews are the Bureau of Foods' Cancer Assessment Committee, which reviews all cancer studies having potential regulatory significance, and

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Mr. GORE. In 1982, regulations under the Safe Drinking Water Act will affect many of these wells. Is that part of your answer?

Mr. PLEHN. No; I am saying that what the regulations say is that 6 months after a State is delegated responsibility for the operation of an underground injection program, that practice must cease. If a State chooses not to take the program or if we determine they are not capable of taking it, then the responsibility under the program lies with EPA and we would then be responsible for promulgating regulations that would have effect in that State and that ban would become effective 6 months after that.

Mr. GORE. I will pursue this later.

I will recognize Mr. Rinaldo.

Mr. RINALDO. Thank you, Mr. Chairman.

I would like to direct a number of questions to Mr. Plehn. I want to begin by making an assumption. I assume you are familiar with the fire and explosion which occurred April 21 at the Chemical Control Corp., Elizabeth, N.J., which is in my congressional district.

Mr. PLEHN. Yes.

Mr. RINALDO. To give you a little background, our subcommittee investigated the site at which more than 50,000 drums of toxic chemical waste had been stored illegally. I was certainly the first Congressman and probably one of the first officials at any level of government to visit the site. I visited it numerous times, a week ago being the last time that I was there.

The State of New Jersey had been in the process of removing drums from the site for about a year when the fire and explosion occurred 2 months ago.

My first question is, If the RCRA regulations had been in place last year, how would the Chemical Control Corp. have been affected? How would the EPA role have been affected? Would there have been greater EPA involvement in the cleanup and would this have resulted in a speedier removal of the drums?

Mr. PLEHN. I think the answer to your question, if it is posed——

Mr. RINALDO. It is more than one question.

Mr. PLEHN. Yes; if the question is whether a year ago, if these RCRA regulations had been in effect, would that have affected the situation of Chemical Control, I think the answer is no, because at that point the facility was, as I understand it, in a bankrupt status, and the State of New Jersey had custody of the facility. What would have really helped a year ago would have been if superfund was in existence, because that would have provided the immediately available authority and resources necessary to let the State of New Jersey go in and clean that situation up.

Mr. RINALDO. I know that. I am going to get to the point in a minute. I am sick and tired—absolutely disgusted with the excuses from EPA that if superfund had been in effect we would have done this and we would have done that.

People in my district, the firemen who were injured, the policemen, the people who are in the hospital, really could not care less about whether or not superfund would have been in effect. They know that New Jersey had the funds in its spill fund. They know that New Jersey had legislation that enabled it to use those funds and they know New Jersey didn't move fast enough.

I don't think there should be any denying of that by EPA. I have a stack of letters here and documents that indicate to me time and time again that throughout this entire fiasco EPA had just been defending the State of New Jersey.

I don't understand your taking this attitude. The State had adequate funds, and that can be attested to by legislators from the State, to proceed with the cleanup on a faster basis.

Let me tell you why I am so upset. In January 1978, the president and officers of Chemical Control were convicted. We knew then there was a serious problem. EPA region 2 officials visited the site and got involved about November 1978.

In March of 1979, two drums exploded. Our subcommittee was involved then and we held hearings. We sent a telegram, the chairman of the subcommittee and myself, to the Governor of the State, urging him to use those State funds for an immediate cleanup.

We started in early 1979. Back in June of 1979, we sent another telegram to the Governor: "Please speed it up: it has been labeled a chemical time bomb."

Nobody was speeding anything up. I was told these are all the workers we can allow here. It is too dangerous a site. They had about five workers there not working more than a full shift. All I was asking for all along was a few more workers from the State, and you could have had more than five at that site, working a little longer hours, maybe two shifts. I saw nothing wrong in an emergency situation with working on Saturdays and Sundays. But this action was not taken.

I got absolutly not one iota of support from EPA. In fact, EPA was taking almost the opposite point of view, that the State is doing the best it could.

Let me go on and tell you how bad the situation was. Finally, we had the big explosion on April 21, 1980. It was so bad all the schools in the city of Elizabeth were closed, many factories were closed. Everyone in the city was given a temporary warning to stay inside. A fishing ban was imposed. A number of firemen were hospitalized. A mushroom cloud of smoke rose over the area. People were concerned. Phone calls indicated some people were in a state of panic.

After the fire was over I asked EPA to investigate the cause of the fire. I said maybe now we can have a speedup. Finally, there was enough pressure, and we got more people there.

On my last visit there were about 20 workers there. I observed them carefully. They are finally doing the best possible job they could. But why did it have to take an explosion? Why did people have to end up in a hospital? Why did it take over a year to get more than a handful of workers there?

You can answer by saying, well, EPA maybe didn't have the funds and that is a legitimate answer, but the State did. If that is so, why am I upset? I will tell you why I am upset.

I received a letter from Charles Warren, the regional administrator of EPA, and when I asked him in the telegram shortly after the explosion to investigate the cause of the fire and see to it that the cleanup could be accelerated, I got this kind of crappy answer. That is how I like to characterize it.

HEW NEWS

U.S. DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

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FOR IMMEDIATE RELEASE
August 11, 1978

(Food and Drug Administration)
WALDEN--(301) 443-4177
(Home)--[redacted]

STATEMENT ON NITRITES

by

Food and Drug Administration
Department of Health, Education and Welfare

and

U.S. Department of Agriculture

August 11, 1978

The use of nitrite to preserve and to color and flavor cured meats, poultry and fish has been the source of scientific debate and public controversy for a decade.

Since the early 1960's, scientists have known that nitrite combined with certain chemicals can form nitrosamines, a family of chemicals known to produce cancer in test animals.

We are now confronted with new concerns about nitrite. A study recently completed for FDA by the Massachusetts Institute of Technology strongly suggests that nitrite produces cancer of the lymphatic system in test animals. The mechanism is clearly distinct from that of nitrosamines.

Almost thirteen percent of the test animals receiving nitrite contracted cancer of the lymph system, whereas about eight percent of those receiving no nitrite contracted cancer. The difference is significant statistically and leads us to the concern that nitrite may increase the incidence of human cancer.

About 20 percent of the average human dietary exposure to nitrites

now comes from cured food products. The remaining 80 percent comes from nitrate in other sources of human food. Nitrate exists, for example, in substantial quantities in spinach and other leafy vegetables and in drinking water. Bacteria in our mouths and digestive tracts convert nitrate and other nitrogen-containing compounds into nitrite.

The results of the MIT experiments nevertheless indicate that the use of nitrite as a deliberate additive to food may pose a hazard to human health. However, nitrite also protects against the formation of botulinum toxin, a deadly food poison. We thus are presented with a difficult balance of risks.

We must weigh the risk associated with nitrite added to food against the health risk from not adding it. On the one hand, nitrite makes it possible for cured meats, poultry and fish to be processed, transported, stored and sold without careful attention to refrigeration. On the other hand, nitrite may pose a potential cancer risk to humans.

In the past we have moved without hesitation to ban outright a number of food additives when they pose a hazard to human health. In such cases FDA is bound by law to eliminate these substances, and has always done so in the past with the firm conviction that this action is sound law, responsible regulation and wise health policy. Similarly, USDA is bound by law to eliminate from the foods under their jurisdiction substances which are harmful.

In this case the need to balance two kinds of health risks -- one by taking nitrite out of food and the other by leaving it in -- creates a difficult challenge. We are now assessing several options, with the goal of providing maximum public protection consistent with the law. As soon as this effort has been completed, an announcement of our decision will be made. In the meantime, the MIT study is being placed in the public record so that the process of external scientific scrutiny can commence.

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Mr. MARKEY. It is my understanding that the desire of RCRA is to establish a cradle-to-grave system for monitoring hazardous wastes.

It is also my understanding that the act excludes the so-called small generators of waste, those producing under 2,200 pounds per month, from the requirements.

Would you agree that 2,200 pounds of waste per month is a large amount of waste which represents a threat to health and to the environment? Especially in view of the fact that in many areas of the country, as in New England, over 50 percent of the generators are those that are by definition small generators? Isn't that a serious problem?

Mr. PLEHN. I think you have put your finger on one of the transitional issues as we attempt to move from a situation of no control and no resources to one of more complete control.

Our regulations, as you said, provide that at the outset any generator that produces less than a thousand kilograms a month is not included in the system provided that his or her wastes go to either a hazardous waste facility or to a facility which is licensed by the State.

Our regulations also commit the agency within 2 to 5 years to move that restriction to a level in the area of 100 kilograms a month. The regulations also provide that for particular acutely hazardous wastes, the levels are currently set at either 1 kilogram, 10 or 100, depending on the waste.

Mr. MARKEY. Why can't you make all of the generators subject to the more stringent requirements right now? Why do we have to wait?

Mr. PLEHN. Here is our problem. Our best data is that there are 765,000 generators of hazardous wastes in this country. Our data also indicate that 99 percent of those wastes are generated by the 9 percent of the generators that generate more than 1,000 kilograms a month.

In other words, by structuring the regulatory program as we have, we need only deal initially with 9 percent of the generators—which is still 68,000 of them—and we are catching 99 percent of the waste by doing that.

Mr. MARKEY. Wouldn't it be possible for several of these small generators to be in the same pickup group? Individually, none of them is large enough to constitute what you consider a significant problem. In the aggregate, however, as each load is picked up by a truck, finally becomes a massive chemical cocktail to be deposited at some point. The waste is exempt from the rules and regulations, and escapes the protections of the act.

Isn't that a theoretical possibility?

Mr. PLEHN. I think it probably is. Importantly, though, this exemption is conditional on those wastes going to either a hazardous waste facility or to a facility which is licensed or permitted by the State.

I am not here to say at all that EPA believes that this initial structuring of the program is ideal. We believe that waste below 1,000 kilograms should properly get included in the system but what we are trying to do is to structure a program that can work in these early stages.

I think it is relevant that the Washington Post, in its editorial on our regulations, specifically commended us on this exemption in which they say we—

> Avoided getting ourselves bogged down in the paperwork and bureaucratic nit-picking that weakened so many other health and safety programs that were rushed into action without any sense of priorities. It chose to concentrate on the 9 percent who generate 99 percent of the wastes and to leave aside, at least until the program is well established, the much larger number of small producers.

That is basically what we are trying to do. It is not that we don't want to get there. But we believe if we move to that level at that first step we would hopelessly bog down the system and jeopardize our chance of controlling the 9 percent of the generators that generate 99 percent of the wastes.

Mr. MARKEY. My problem is that this condition exists in New England and other parts of the country with small generators. To monitor it at licensed or unlicensed sites is an impossible task. To remove small generators from these regulations significantly reduces the effectiveness of this program for the New England area.

Mr. PLEHN. I have to add one other point to this. Only 11 percent of those 700,000 generators that we are exempting are in the manufacturing sector. All the others are in the service industries. Just to give you some data, 152,000 of them are painters, plumbers, and electricians. That is 22 percent; 130,000 of them are gasoline service stations; 55,000 are auto repair body and paint shops; 40,000 are dry cleaners; 21,000 are secondary schools; and 221,000 are other service industries, including barbers and beauty shops.

So we are not excluding manufacturers. Only 11 percent of these are manufacturers.

Mr. MARKEY. 11 percent?

Mr. PLEHN. That is right.

Mr. MARKEY. Why can't we include that 11 percent? Why don't we exempt the body shops but try to bring in the balance of the primary contributors to the problem? Why can't we do that?

Mr. PLEHN. We do want to do that.

Mr. MARKEY. Why don't we?

Mr. PLEHN. We have committed to doing that over time but in terms of the initial bite of the apple, we want to get 99 percent of the waste and very substantial number of people, close to 70,000 generators that generate those wastes. Do you want to add anything?

Mr. DIETRICH. No. To bring in the 11 percent, and we are going to work on that—is a definitional problem. How do we find what that 11 percent is?

Mr. MARKEY. You tell me that 1,000 kilograms is your present goal.

Mr. PLEHN. That is our general cutoff.

Mr. MARKEY. General cutoff?

Mr. PLEHN. I want to emphasize again that we have cutoffs down to 1 kilogram for acutely toxic wastes.

Mr. MARKEY. And you will reduce it to 100?

Mr. PLEHN. As a general level.

Mr. MARKEY. When will that occur?

Mr. PLEHN. We have committed to do that somewhere between 2 and 5 years from now, as rapidly as we can within that time period.

Mr. WAMPLER. I thank the chairman.

Ms. Foreman, remembering the earlier experiences that we have had on this nitrite issue before this committee, and perhaps other committees of Congress, what have you learned from this experience?

Ms. FOREMAN. I have learned as I pointed out in my testimony, that I think we do need some changes in the food safety laws; that we have no mechanism at all for dealing with a substance that confers certain health benefits and perhaps certain health risks.

And, I think that we clearly know that we need improvements in our peer review process and, as we pointed out in our testimony once again, we are contracting with, that is, putting out a contract to try to help improve this peer review study procedure.

I think that those are clearly the two major implications of this experience. There is another implication of it, but it is one for which I do not have an answer.

That is, when you have a subject like nitrite which is of concern not only to an industry but of a rather large concern of the public, it is impossible to deal with it behind closed doors. We have to deal with it openly. We have attempted to deal with it openly.

We attempted to deal with it with as many qualifiers as we could possibly attach at the time: Tentative, maybe, appears to be, and every phrase that could possibly be used.

Frequently those phrases were not repeated when the Government's announcement was reprinted in various newspapers. I thought that it was rather well repeated in the major newspapers.

The Wall Street Journal, for example, used the word cautiously. "The Government moves cautiously in dealing with the nitrite study."

But that was not true across the country. Clearly many people were alarmed.

I do not have a solution to offer the committee on how a Government agency can issue a press release with appropriate qualifiers and then guarantee that those follow into statements in the press and in statements, in fact, by Members of Congress. We have no ability to control those statements and never will have.

Mr. WAMPLER. Of course, that dilemma is not limited to members of the executive branch.

As a result of this experience on nitrite, what steps have you, as Assistant Secretary of Agriculture, taken officially to preclude a reoccurrence of this? Have you taken any action?

Ms. FOREMAN. I think the most important action is going to be our contract for a study on conducting peer review. But I think, in part, you have a unique situation.

The Department of Agriculture performs or contracts for very, very few detailed scientific studies. The study in question is an FDA study, for example.

FDA and the Environmental Protection Agency, by and large, set the standards which we then enforce in the meat and poultry inspection program. It is only in this very limited area where we have jurisdiction over prior-sanctioned substances that we have an initial and beginning regulatory responsibility.

Generally speaking, we are adhering now to the standards set by the other two agencies. However, we have found that it is very

important to try and improve our peer review process should we ever get into this situation again and also because over the past few years we are beginning to find more and more difficulty in the chemicals area.

Traditionally, meat and poultry inspection have been somewhat mechanical functions. As we begin to deal with a society that is full of chemicals and we begin to deal with chemical residues, we are having to improve our science.

We have been doing this in a cooperative arrangement with the Science and Education Administration, a relationship that really did not exist until a couple of years ago when we began a joint effort on nitrite research and which we are now extending into a variety of other areas.

SEA is performing specific scientific research to help us carry out the regulatory programs of the Department of Agriculture. This is an area that had been largely ignored before and where I feel we made very substantial progress as a result of cooperation between Dr. Bertrand and Dr. Houston within the last 2 years.

Mr. WAMPLER. Thank you, Mr. Chairman.

The CHAIRMAN. Mr. Rose?

Mr. ROSE. Thank you, Mr. Chairman.

I want to observe that we probably have a day from 2 o'clock on where people will search the ashes for various signs of what this all means and pursue various purposes.

It will be said that this whole nitrite controversy means different things.

I think the process has worked fairly well. I think you have been saddled with some pretty strict laws from the Congress. I think they probably need to be rewritten and that you probably need to suggest to the Congress as clearly as you can how they should be rewritten.

I would hope that all the various institutions and agencies, both public and private, especially the private ones that have been somewhat impacted with this would not go overboard in trying to say what this proves or what this does not prove.

Ms. Foreman, you and I have learned a lot. We have all learned a lot by this process. I am glad it is over. I am glad the results have come out as they have.

I know nobody is more relieved than Ms. Carol Tucker Foreman and you, Dr. Goyan. You were dealing with a subject that was potentially very harmful to the American public. When confronted with that information, although it proved on second look to be something different, you had to come forward with it.

Having been in the Dairy and Poultry Subcommittee and now in the Livestock and Grains Subcommittee, and having heard from meat processors who are anguished over this, I know how they have felt. I hope they will resist the temptation to throw stones. I hope they will patiently work with you and with me to rewrite the law so that this does not happen again.

Thank you, Mr. Chairman.

The CHAIRMAN. Mr. Grassley?

Mr. GRASSLEY. Ms. Foreman, on page 24 of your statement you state: "I think it should be emphasized that back in August 1978,

I have to say generally that accidental insurance—insurance against explosion or fires, things of that sort, is quite available generally for these facilities. What has been the question is, What is called nonsudden insurance, which is for damages caused by leaching from the facility? We have been quite encouraged that domestic insurance companies have been indicating an increasing interest in participating in this area. They almost without exception see their role as insuring those facilities that are permitted. In other words, they want the assurance that the facility meets the standards of the regulatory agency.

We also think their participation will be very useful because they will be additional policemen in assuring that the sites operate well. But what are generally accepted as good hazardous waste management facilities in this country presently have been able to secure and have insurance for both sudden and nonsudden accidents.

Mr. CORCORAN. Thank you, Mr. Chairman.

Mr. GORE. Mr. Plehn, a lot of your responses have been directed at what the Agency expects to do in the future to improve the regulations that are in this current phase. I have here a memorandum from an EPA attorney charged with the drafting of RCRA, the General Counsel's Office. She is commenting on the preamble to the report.

> Often the preamble directly promises we will be doing certain things in the phase II and phase III standards. Please try to give us as much leeway as possible. Say, for example, that we expect—or use something equally mushy—certain standards will be part of the phase II regulations rather than that they will be.

Now, against the background of the 4-year period that developed these regulations, and bearing in mind that we are hesitant to put too much faith in EPA's expectation that these regulations will be improved in the future, I think it is fair to focus pretty intently on the regulations that we have before us and what they accomplish and what they don't accomplish. So I want to ask you a series of detailed questions about these regulations.

I want to begin with a memorandum by the Chief of the Hazardous Wastes Implementation Branch, Mr. William Sanjour, dated June 16, 1980, and I would ask the staff to provide a copy of that memorandum to Mr. Plehn. Are you familiar with it?

Mr. PLEHN. I have seen that memorandum.

Mr. GORE. The title of it is "Impotence of Hazardous Wastes Regulations" prepared by the Chief of the Hazardous Wastes Implementation Branch. [See p. 66.]

Now, in this memo he reviewed the nine hazardous waste damage cases which were specifically cited by EPA in its arguments to Congress in favor of passing RCRA back in 1976. In other words, when the Resource Conservation and Recovery Act was pending before the Congress 4 years ago and EPA pressed its case in favor of RCRA, it formally cited nine cases of damage related to hazardous waste as evidence to support passage of this law.

Now the Chief of your Implementation Branch concludes that six of these cases—or two-thirds of them—would not have been prevented by the regulations that you have now promulgated. Can you comment on that?

Mr. PLEHN. Well, I have been away, and came back and first saw this memorandum yesterday. I think we could do one of two things. I could provide for you a detailed reaction to this memorandum or alternately we could take an initial stab at it. I know Gary Dietrich spent a little time reviewing it.

Mr. GORE. Or alternately, you could come out with some regulations that cover all nine of these cases. We can go through them one by one.

I understand your statement that you have not had sufficient time to review the memo and I am sensitive to the problems that surely poses for you. Mr. Dietrich has some additional familiarity with the memo. So maybe with him I can go through the cases.

The first case involves the spraying of waste oil with dioxin. Dioxin is not classified as hazardous waste, is it, under these regulations?

Mr. DIETRICH. Dioxin itself is not classified because dioxin itself does not exist by itself; it is typically and always an impurity in other wastes.

Mr. GORE. It does exist by itself, Mr. Dietrich, if I may presume to correct you, as a byproduct in the manufacture of 2,4,5-T; is that not correct?

Mr. DIETRICH. It is an impurity in the byproduct, yes. It is usually an impurity in commercial products or an impurity in waste.

Mr. GORE. It can exist in waste oil, correct?

Mr. DIETRICH. It can exist in waste oil if waste oil has been mixed with another waste that looks oily and does include dioxin as an impurity.

Mr. GORE. Why wouldn't dioxin be classified as hazardous waste?

Mr. DIETRICH. We have listed a number of wastes because they have dioxin in them. Some of the wood preservative wastes are, in fact, listed for that reason.

Mr. GORE. But you still haven't answered the question. Why isn't dioxin itself characterized as a hazardous waste?

Mr. DIETRICH. Because it does not exist by itself. You can't go and get——

Mr. GORE. Mr. Sanjour says that this case which involved the spraying of waste oil contaminated with dioxin would not have been taken care of by the RCRA regulations that you have promulgated.

Mr. DIETRICH. In order for that case to be taken care of, we would have to list all waste oils in the regulation.

Mr. GORE. Or alternatively, you would have to list dioxin?

Mr. DIETRICH. Not the way our regulation is set up.

Mr. GORE. Well, your regulations are not set up right, if it doesn't cover this case.

Mr. PLEHN. The point is, no one produces dioxin, nor is dioxin by itself ever produced as a waste. The only time that dioxin is created is as a contaminant in the production of other wastes which are listed.

Mr. GORE. What about kepone, kepone is not listed as a hazardous waste, is it?

Mr. PLEHN. Kepone is no longer manufactured in the United States.

For a period of time many meat processors were using the reduced levels of nitrite on a voluntary basis before the regulation went into effect. The regulation allowed a higher level and we dropped it to that level. Many were using it on a voluntary basis.

Mr. BALDUS. The new regulation was a lower level. But that was on consultation with the industry in a formal manner?

Ms. FOREMAN. Over an extended period of time, all of those things.

Mr. BALDUS. You said that new level was suggested by the industry as both safe from a botulism point of view and also one where they felt it would produce the right color, taste, and so forth?

Ms. FOREMAN. Yes; and, in response to our requests to the industry to show that nitrite could be used in curing bacon without having the formation of nitrosamines. That was the issue.

We asked the industry: Show us that this can be done so that we can take an appropriate action rather than an action that none of us would like to take, that is, not use nitrite at all.

The industry did that research and presented us with data that showed that you could use nitrite—in combination with ascorbic acid—and not have conformable levels of nitrosamines form. It was that regulation that we put into effect. We had a proposed regulation on the books during all this period of time. The industry was complying on a voluntary basis with our proposal. Then we made that final in March 1978.

Mr. BALDUS. There are a large variety of producers and packers. Did you find that this meant any particular burden on large or small, chicken versus pork and beef or whatever?

Ms. FOREMAN. We had a very great concern when we began to try to reduce nitrosamine levels in bacon that we knew some large processors were quite capable of producing nitrosamine-free bacon. We were very concerned that perhaps not all could.

So, we had to make a regulatory decision. Were we going to go out, and every time we found a processor that had nitrosamines, close them down? Or, were we going to try a course of action that would prevent that from happening?

We chose the second.

We had people go out into the bacon plant and do tests. If they found in a preliminary test that there were levels of nitrosamines above 10 parts per billion we said to the processor: "We have consultants that can come help you alter the processing so you can comply with the regulation. Would you like that assistance?"

Many of them, in fact, said they would. They were able, with the assistance of those consultants to alter their processing mechanisms. The program has been successful, both in allowing bacon manufacturers to continue in an ordinary and acceptable fashion and in allowing us to be able to say to the public: "You can buy bacon knowing that there are no detectable levels of nitrosamines in that bacon."

We did not find that it was particularly more difficult for small processors to comply than it was for large processors to comply. As a result, we sent out consultants that would help all these people.

Had it not been for our consultants, then I think, yes, many small processors might have had a real difficult time hiring the expertise necessary to make those adjustments.

We took that on as a public expense.

Mr. BALDUS. I do not recall any plants being shut down in my area. Did you have a very high percentage of plants?

Ms. FOREMAN. I will submit these test results for the record.

We have sampled from September 5—I am sorry. It is the whole series since December 1978; 2,131 samples, 1,908 were in compliance immediately, 209 failed preliminary tests but were able to meet the standard eventually, and six plants no longer process pumped bacon.

We do not have any indication that those plants are not in operation anymore. Some of them were facilities belonging to larger companies and they simply began bringing in bacon and slicing it at the local level.

Mr. BALDUS. Thank you, Mr. Chairman.

The CHAIRMAN. Mr. Fithian?

Mr. FITHIAN. Thank you, Mr. Chairman.

I appreciate the testimony of both our witnesses this morning. It seems to me that one of the problems you have administratively, assuming that all the scientific material goes as you outlined, is the public relation's problem.

What do you do between that time when the research comes up with something which can be sensationalized or demagogued or at least frighten the public and the time that you confirmed it by peer review?

It is that period, it seems to me, that we should try to look about. I am wondering if you both established in your respective agencies the procedure of commenting initially—and I agree with you that the FOI Act will cause you to reveal it anyway—if you would be able to comment on the reports, using such terms as "unconfirmed," "tentative," "preliminary finding,"—all conveying to the public that this is a tentative or interim step in the reporting process and that clearly the peer review would finalize that either way.

It would be rejected or finalized. I am wondering if in your policy mechanism you could not, as a routine matter, refer to the preliminary unconfirmed data, which has had no peer review, in all of those tentative or preliminary terms so that we here on the Hill, and the public out there, and everyone dealing with this—except those who want to sensationalize it.

For those who want to sensationalize it or demagogue it, there is no way of dealing with those people in the food issue because everybody buys food every week. The result of that is that the food issue can always be demagogued.

But, for people other than demagogues, I think you might work out a system of regular terminology that would convey that tentative nature.

I wonder if either or both of you can comment on that.

Dr. GOYAN. I would be delighted to respond.

I think you quite ably described it. We do make a point of trying to make clear to people what basis we think we are speaking of, how important the data is and how tentative it might be, and also to try to point out that there may be other studies that show other results.

that purpose. But clearly in that area the burden is on the agency to characterize those wastes and list them for their genetic activity.

Mr. GORE. So the burden is on the agency?

Mr. DIETRICH. That is right.

Mr. GORE. Now back to the 7,500 injection wells, you said that those are not all wells that inject hazardous wastes directly into drinking water. Some of them inject wastes into areas directly above drinking water, right?

Mr. PLEHN. I am not sure inject is quite the right verb here. As I said, this includes septic tanklike facilities, it includes leaching fields, it includes pits and it includes wells which are deeper than they are wide. It is a catchall category. Injection wells, which the GAO was talking about this morning, are highly engineered, very deep facilities, of which there are approximately 400 in the country which presently manage hazardous wastes.

Mr. GORE. All right. There are 7,500 wells into which hazardous waste is either dumped or injected and of those 7,500, all directly—either directly contaminate drinking water or contaminate areas directly above drinking water, correct?

Mr. PLEHN. The only thing I quarrel with is the last four words. Some of them place waste directly in the earth, which may be isolated—may be isolated from drinking water.

Mr. GORE. How many of the 7,500 wells are directly connected to drinking water supplies.

Mr. PLEHN. I do not believe we know the answer to that question.

Mr. GORE. Now in the regulations—let me just ask you, can you think of any worse way to dispose of hazardous wastes?

Mr. PLEHN. No, it is a bad practice which should be phased out.

Mr. GORE. Why wouldn't you cover that in the RCRA regulations?

Mr. PLEHN. The reason we didn't cover it is because the Agency's intention until not very many months ago was that, pursuant to the act of Congress which specifically established a regulatory framework for the regulation of underground injection, that regulatoin should be handled under the authority of the Safe Drinking Water Act. We so proposed the regulations in April and June of 1979. We asked for public comment on the question—the reason we did that was in part because of the specific congressional directive and in part because we felt——

Mr. GORE. What specific directive?

Mr. PLEHN. The directive of the Safe Drinking Water Act.

Mr. GORE. Back in 1974 the Congress passed the Safe Drinking Water Act.

Mr. PLEHN. As I said, I am not responsible for that program. That date sounds like it is about right. What we wanted to do was to not subject, unless it was imperative that we do so, the operators of those facilities to dual jurisdiction under two pieces of legislation. We asked for public comment on that question when we proposed those regulations in April and June of last year.

The public came back to us and said, for some of the reasons that you are really getting at here, we think that dual jurisdiction is not such a bad idea and, as a result of those comments, we have

both promulgated and proposed regulations with respect to class 4 wells and class 1 wells in this package which we issued on May 19.

Mr. GORE. I am not quite sure I understand that answer. The regulations under the Resource Conservation and Recovery Act do not cover the injection or dumping of hazardous wastes in a well that is directly connected to drinking water supplies.

The answer to that question is yes, isn't it?

Mr. PLEHN. No. This is what has been promulgated under the RCRA regulations. Any facility, whether a class 1 or a class 4 well which receives hazardous wastes, must notify EPA and must participate in all of the interim status standards excepting groundwater monitoring, closure, and postclosure.

Mr. GORE. These are the housekeeping standards?

Mr. PLEHN. That is correct. We have proposed under RCRA in this May 19 package additional housekeeping standards, complementary interim status standards for those wells.

We have also indicated in the preamble that we intend to take action under RCRA authority to eliminate the direct injection of wastes into aquifers under RCRA authority.

This package, under the Safe Drinking Water Act, promulgates a requirement that says within 6 months after a State assumes operation of the underground injection program, under that act, that practice must terminate.

Mr. GORE. You put it in the preamble and this is the same preamble that was designed purposely to be "mushy, so as to give us as much leeway as possible."

Let me rephrase what you said and you tell me if you disagree. Under the Safe Drinking Water Act the practice of dumping hazardous wastes directly into drinking water supplies by way of a well may be banned in 1982, hopefully, if and after States have adopted underground injection control programs, but until that indeterminate point in the future, this practice of dumping hazardous wastes directly into drinking water is covered or could be covered by RCRA, but in implementing RCRA with these regulations you have specifically decided not to cover that practice in the regulations that we have now promulgated.

Mr. PLEHN. I have to amend your statement in two respects.

The first point is, under the Safe Drinking Water Act promulgated, this practice must be ended 6 months after a State assumes responsibility for the underground injection and that could, pursuant to statute, occur within a very few months.

Mr. GORE. What if States show the same kind of delay that EPA has shown in implementing these regulations and they don't get around to adopting a State underground injection control program?

At that point they can ask for additional time, there is no definite point at which your jurisdiction or the Federal jurisdiction kicks in; right?

Mr. PLEHN. No. My knowledge is somewhat secondhand but, the Safe Drinking Water Act says the States must take action to achieve or not achieve delegation within 9 months. It then contains a section that says provided they are making good faith efforts they can have an additional 9 months. If they fail to successfully complete action within 18 months—this is a statutory require-

to give people, such as yourself, more discretion in administering the law.

Ms. FOREMAN. Do you really want to give me more discretion? [Laughter.]

Mr. HAGEDORN. I do not think you could go any further than you already have. On the right side or correct side I do not think you want to go any further in this particular area.

I am somewhat reassured by your statement to Mr. Fithian that maybe we should handle things in a tenuous, early finding, but not definitely factual, or something like that.

I believe that would have been somewhat more assuring to consumers 2 years ago when we brought up the issue that you, in your own mind, were administering the law as it called for, but perhaps had reservations which I do not think you reflected at the time.

Many of the people felt that you were advancing forward a solid case based on the tentative information that you received from the Newberne study.

I noticed in a 1979 Agriculture Yearbook, "What's To Eat," page 102, was a statement about some preservatives are harmless and others may not be:

"Right now, the Government is considering banning the use of sodium nitrite as a preservative. Even though these preservatives are useful in keeping some kinds of meats from spoiling, they also cause cancer in animal tests.

I do not believe that has been conclusively proved. I think all the people who reviewed the Newberne study almost without exception disqualified it and did not reach that conclusion.

Yet, here is an official Agriculture Department publication going out a year before the final report came in citing this as a source of cancer in animal tests.

It would appear to me that some type of correction ought to be made: Send out a disclaimer or a substitution of that particular paragraph to all the Congressmen, all the committee people. At least add that little bit to it to straighten out any incorrect statement that you made.

Would you be amenable to that type of recommendation?

Ms. FOREMAN. Congressman, I must really take exception to your statements that I, especially, was not sufficiently concerned with tentative statements in 1978.

In fact, the quote from the House hearings—and I think you were here that day—on page 49, September 1978, I said:

If it were proved to the satisfaction of the Food and Drug Administration and the Department of Agriculture that this was a specious study, then we would have no desire at all to continue with the course of action toward prohibiting nitrites.

I think we pointed out the various statements we used to qualify those statements at that time.

Dr. Kennedy went on to say in direct response to a question from Congressman Mathis that this study had not yet been subjected to sufficient peer review and was, therefore, still open.

Mr. HAGEDORN. I realize that. I am not contesting you on that. I am just talking about a meeting that a number of us had in Congressman Pressler's office. At the time you may remember that Mr. Butler accompanied you. My legislative aide was there.

We pressed this point that you admittedly were following the Delaney clause and the applicable legislation that affected your

direct jurisdiction. And, even though you were doing this, in your own mind the possibility of getting cancer from nitrites was probably extremely remote. That is what we attempted to get you to stress to the public, to be somewhat reassuring that this was very technical and that in all likelihood, there are many other more threatening situations which might cause someone to come into contact with a carcinogen.

That is the point. We want to provide that margin of assuredness and security to the consumers that you said at that time you were unwilling to do so.

I admit I have not followed every comment you have made on the subject, but I am encouraged today by what you have said after 2 years.

Ms. FOREMAN. I think everyone would acknowledge that I am not a spokesman for the food industry.

Mr. HAGEDORN. I realize that. But nonetheless you are a spokesman for consumers.

I yield to Mr. Wampler.

Mr. WAMPLER. No questions.

The CHAIRMAN. The time of the gentleman has expired unless unanimous consent is requested. Mr. Panetta?

Mr. PANETTA. Thank you, Mr. Chairman.

I think the problem we run into in this area is a problem that has appeared in other areas where we try to deal with concerns that we see by enacting laws and subsequent regulations that try to implement those laws.

What we eventually wind up with is a jungle of regulations and rules and somehow very few comments because we have constricted it so that it is very tough to be flexible.

It has happened in food stamps. It is happening in medicare. It is happening in disability. It is happening in all kinds of areas.

It is unfortunate because in reality the issue needs discretion and flexibility. In the end all the laws we pass will never supplant people who are in positions who have to make those decisions. We cannot, in effect, by laws try to control how every law eventually will be implemented. That is up to the people in the administration.

Recognizing that jungle of regulations and rules, I think there is some confusion on the part of the public right now, I would like to ask either of you, in terms of speaking to the American public, what is the situation with regard to nitrites? What would you say to the American public if they asked if nitrites are dangerous or not dangerous and should we eat nitrites or should we not? What is the best information you have to give the American public on that issue?

Ms. FOREMAN. There is no evidence that nitrites in and of themselves are carcinogens. There is no evidence that nitrites are of themselves unsafe.

There is very clear evidence that nitrites have a role in the formation of nitrosamines and that in some products nitrosamines are formed before they are eaten.

I think we have successfully stopped that in bacon, the one place we found within our jurisdiction that it occurred. So, we think we can say that there is no problem from nitrite.

We do not have a proof of a problem from nitrites per se and do not have any proof of a problem from preformed nitrosamines in meat products.

There is research that is not sufficient for any regulatory action, but which is there that suggests that nitrite combined with amines in the digestive tract can form nitrosamines in vivo in the digestive tract and that may be hazardous to health.

We are not in a position, therefore, to say: "They are safe. Eat all you want." But we can say that there is no basis for believing that they are unsafe at the present time.

Dr. GOYAN. I might just add that there certainly continues to be concerns about nitrites because of nitrosamines. Because of that we have, of course, jointly sponsored some research with the National Academy of Sciences to look at this further.

I have stated on a number of occasions, and will do so again that my belief is that we eventually will phase nitrites out of the food supply because we will find other equally useful additives that meet the needs.

They will be substances that do not quite cause the concerns that nitrites do.

Mr. PANETTA. Are there ongoing studies that are contracted out by either your Agency or the Department of Agriculture relating to nitrites?

Dr. GOYAN. Yes. The National Academy of Sciences, in particular.

Mr. PANETTA. They are proceeding with this?

Dr. GOYAN. Yes.

Ms. FOREMAN. We have about $2 million in ongoing research in the Department on the development of substitutes for nitrites which was started at the urging of the Congress and which we have pursued.

Mr. PANETTA. With regard to the issue of implementing this regulation, you obviously have cross jurisdictions that are involved here.

Would it not make sense to put all the jurisdiction related to safety of foods and the health impact of foods in one agency instead of having it split between Agriculture and FDA?

Ms. FOREMAN. Do you want to say it in unison?

Dr. GOYAN. No.

Ms. FOREMAN. I thought he was going to say we could say in unison: "So long as it is my agency."

Mr. PANETTA. If you would say no I would be interested in why you would say no.

Ms. FOREMAN. I think, in fact, there is a legitimate reason for continuing what appears to be a bifurcated relationship that exists right now. It is less irrational than it appears to be.

One of the problems is not the difference in the way laws are being administered, but the strange way in which the laws cross-hatch.

I think we all have to take a look at trying to resolve these differences between prior sanctions and added substances and naturally occurring substances and unavoidable contaminants because that appears to me to be the thing that is giving us the problem in

administering the laws reasonably, and not the fact it is going on in two different agencies.

Dr. GOYAN. One might argue that there is some advantage to two agencies because it requires us to work together, to consider each proposed action on a scientific basis.

So it is not just the FDA that is concerned about it. It is also the USDA.

Mr. PANETTA. Thank you, Mr. Chairman.

The CHAIRMAN. Perhaps I could interject a question in the time I have remaining.

You mentioned in your statement, Dr. Goyan, that the action taken in 1978 was the least action that the Agency could take under those circumstances. That is at the top of page 13 of your statement.

Assuming that is true—and I have not accepted that it is—what raises a problem for some of us is that that indicates that much more strenuous action would have been possible within the law and the existing regulations, action which might then have led to some immediate regulatory sanctions against nitrites.

I assume, in retrospect, that many people would say that would have been unfortunate if it occurs since we do not have an effective substitute for nitrite as a food preservative.

I think it raises the problem for some of us concerning the need for review of the food safety laws generally.

Combined with the Freedom of Information Act, and the American tradition of ceaseless court interventions by groups of all kinds and persuasions in the activities of not only regulatory bodies but executive actions of the Government in general, is there not a severe problem that the existence of such statutes as the Delaney Clause, very rigorous in its requirements, the existence of the Freedom of Information Act, which you say responsible agencies must observe, and including releasing information of a tentative scientific character not yet confirmed, and the operation of many different interest groups ready to go to court at the drop of a hat to ask a Federal court to intervene and mandate some action, is there not a serious problem in the appropriate judgment and caution that you say your agency wants to observe and be able to carry that out in a climate of judicial intervention, freedom of information, and restless observation by conflicting interest groups of all kinds of very controversial questions?

Is not an agency likely to be forced by the courts or forced by its own lawyers to take an action that they might think better to wait and to confirm because of the existence of the combination of the Freedom of Information Act and court intervention?

Dr. GOYAN. I am glad my chief counsel is here so I can speak freely on this.

I would point out that we again come back to the fact that what happened was the proper thing to happen. In my judgment what we did in 1978 was the least we could do, but it was also the proper thing to do at the time.

I call to your attention that Commissioner Kennedy resisted all those forces that you so rightly have laid out.

The CHAIRMAN. If I could interject, I really am not criticizing the action that was taken by the FDA. That is not the thrust of my question.

For the purpose of the question let me say you did exactly the right thing. Thank Commissioner Kennedy and all the Agency for their wisdom and judgment and caution.

But, if that was the least, then certainly the statement on page 13 indicates that something more could have been done, something more vigorous in the way of sanctions could have been posed.

Is there not a danger that a Commissioner has to resist the possibility of lawsuits, the demands of freedom of information, the preemptive interventions of the court in order to reach, in some cases, what he might think is an appropriate review of scientific information at an early stage before rushing headlong into a regulatory scheme?

Dr. GOYAN. Yes, I agree with you. I think that is exactly the job of the Commissioner of FDA, to be sure he does not do that.

The CHAIRMAN. Is it not also the job of the Congress to review whether the Commissioner and the Secretary are not jointly forced to take an action which they might think inappropriate, but which their counsel will tell them is mandated by the court, even though their scientific administrative judgment is offended by it?

Is that not also true?

Dr. GOYAN. I agree.

The CHAIRMAN. Is it not possible under the existing framework of our food safety laws that a Commissioner of FDA, or a Secretary of the Department of Agriculture might be forced to do—either by the courts or by advise of their own counsel—to take an action that they think was wrong in the public interest, not necessary to protect the public health, and even, in fact, dangerous to the public health because of the automatic and categorical operation of some of our food safety laws?

Dr. GOYAN. Yes, I would agree with that. Indeed, the nitrite case is one point in which our two agencies really wished to phase it out if it were found to be carcinogenic.

The CHAIRMAN. Thank you.

Mr. Glickman?

Mr. GLICKMAN. First of all, I want to thank you both. Ms. Foreman, your statement is an excellent synopsis. I am glad you read it because it did answer some questions that we may have otherwise had.

I also want to compliment Congressman Wampler because I do not think without the congressional oversight over the situation that we would have come out with the same results that we would have come out with today.

I think there might have been a tendency on the part of the agencies to perhaps move more zealously had it not been for the congressional oversight.

I might ask this question of Dr. Goyan. You have read the GAO report. I would like to ask you this.

Do you intend to implement their suggestions with regard to the internal review process? They have made several in there to you.

In answering that question, I would like to indicate my concern about the initial studies. I know that scientists are like everybody

else. There are scientists within your agencies—and I assume that you are one, a physician, or have some sort of expertise——

Dr. GOYAN. I am glad you know the difference between a physician and a scientist.

Mr. GLICKMAN. You tend to have your favorites and have the people that you think are more scholarly than others. You have your prejudices.

What worries me is that you might tend to reject a study that Dan Glickman does on nitrites, but you might have your favorites. But you think: "A-ha. This is a credible study." In fact, it is not.

Do you intend to follow the GAO recommendations?

No. 2. I am a little concerned about your peer review process. If all your peers share your same biases, it is worthless.

I would like to ask if you have ever thought of who you include on this? Outside scientists? Nonscientists who may have some experience with this subject matter but may not necessarily be of the same bias?

What I am really asking you is this. How can you remove the element of bias from, one, the initial contracting of a study, and, two, from the peer review process?

Dr. GOYAN. Your question got more complex as you went along. I will try to answer it in some order.

We certainly are looking at the GAO recommendations. We will be implementing most of them. I cannot go into detail now. I would be glad to for the record, if you wish.

Mr. GLICKMAN. I would like you, in writing, to indicate, if possible, to the committee what you plan to do with the GAO recommendations.

Dr. GOYAN. Yes, we will be glad to do that.

Mr. GLICKMAN. Thank you.

The CHAIRMAN. Without objection, so ordered.

[Material not received at time of printing.]

Dr. GOYAN. With regard to people who happen to believe the same way I do, I would point out that we have an Office of Health Affairs with a scientific group of about a half dozen individuals whose job it is basically is to disagree with what the Bureaus bring forward.

They look at it and say: "We find the following faults. Here are other studies that say the things about this, Mr. Commissioner, before you take this into account."

So, we have that. These people are not in any way hooked up to the Bureau itself. They do not benefit in any way by agreeing with the Bureau. Their job is to advise me.

Mr. GLICKMAN. What about in the initial contracting process, when you contract for studies?

Dr. GOYAN. When the Bureau contracts, the Bureau is the one that is contracting. They describe how it is to be carried out. They monitor it.

Mr. GLICKMAN. Is there not the danger that they will contract in a biased fashion to those people who they may believe to be those that will come out with the conclusion they want?

Or else, they have done the conclusions in the past that they want to be reached?

Dr. GOYAN. I certainly do not believe that anybody in our Bureau contracts on the basis that this person will get the results I want. I simply do not believe any reputable scientist would do that.

Mr. GLICKMAN. Do you have any nonscientists or people outside the agency that may be participating in this process at all?

Dr. GOYAN. Yes, we do. I would like to ask the Director to elaborate on that.

Dr. MILLER. Just let me comment generally about the question of bias.

The Bureau of Foods has about 600 scientists. I can assure you that given 600 scientists there is no general consensus on any given subject. There is always a wide diversity of views from our scientists.

In terms of the contracting process, the selection of the contractor is generally made after an open and competitive bidding situation and is made on the basis of an evaluation.

It very often involves outside review. Generally speaking, our program advisory committees include at least one person outside the Bureau. For this reason, in answer to your question, it would be difficult to predetermine a particular conclusion for a study and then select a laboratory to reach that conclusion. Not only the presence of diverse scientific opinions within the Bureau would assure this objective evaluation, but also the inclusion of an outside scientist would also reinforce this.

There are some contracts for which there is a peculiar expertise in some places. If there is one piece of equipment in only one place, then there is no where else to go. In this case we are restricted in our selections.

Mr. GLICKMAN. Thank you, Mr. Chairman.

Mr. BEDELL [acting chairman]. Mr. Whitley?

Mr. WHITLEY. Thank you, Mr. Chairman.

As I alluded in my earlier comments to my colleague from North Carolina, there are not many Members of the House who are scientists and are really that familiar with the scientific process.

We do know that theoretically the scientist starts off not believing anything and requires that any hypothesis be proven. Many of us are lawyers. We understand proof and we understand evidence. We understand that in law he who alleges has the burden of proof.

In a civil action where nothing is involved but money damages—this sort of thing—the burden of proof is that the proponent must satisfy the jury by the greater weight of the evidence.

In a criminal action where the defendant's life or his personal freedom is at stake, we require a much higher degree of proof, what we call proof beyond a reasonable doubt. That is defined in law as not vague or imaginary, but any real or substantial doubt.

I would just suggest to you two agencies, the FDA and the Department of Agriculture, that, if necessary by amending the law or by regulation or by changing our practices or whatever, we not publicize studies that have been done, reports that have been filed, or anything else until they have been subjected to a test that can satisfy you administratively beyond a reasonable doubt that they at least have a substantial degree of reliability.

As I say, it is very difficult for us to apply scientific tests and say that Dr. Newberne should have been able to differentiate between

different types of lesions as he studied the tissue under the microscope, but at least doubts were raised early by others in the scientific community who did have the ability to raise these questions.

I would suggest to you that it would be very logical and very reasonable for you to require the same burden of proof where there is as much at stake, money, property, and life itself, as there is in a matter in the courts of the land, that you require before we start issuing any public notices and certainly before we take any action that the threat be established beyond any reasonable doubt.

Dr. GOYAN. As you know, the law really does not allow us to sit back and say: "We are not going to tell you what was in the study until we have spent 5 years peer reviewing it and making sure it is absolutely right."

In the food additive law, a food additive is basically guilty until proven innocent. That is perhaps unfortunate, but it is the way the law is written.

On the other hand, a prior-sanctioned substance carries the burden upon us to prove it is dangerous in some fashion, that it may render injurious. That is the language.

Mr. WHITLEY. If you recall the preamble to what I said, in some instances perhaps we need to amend the law. Perhaps in other instances we need to reevaluate your assessment of the factual situation.

I am certain we would be glad to have your recommendations as to which areas might require some congressional action.

Certainly I think that the propensity is there for great harm to be done by a study that later turns out to be unreliable.

Mr. WAMPLER. On that very point, Dr. Goyan, your predecessor, Dr. Kennedy, promised the Congress back in 1977 that he was going to forward his recommendations to Congress for changes in the Delaney clause and other food safety laws. I understand you have indicated you will honor that promise.

Have you prepared those recommendations? If so, where are they now?

Dr. GOYAN. We have been discussing food safety since I arrived at the agency. Indeed, I was somewhat amazed, and even to some degree appalled to discover, when I became Commissioner, that there were nine categories of food, each of which legally is handled in a different fashion.

Certainly we are very concerned about food safety. It has my highest personal priority in terms of legislation in the coming Congress. We are discussing it within the Department and hope to come forward with recommendations early in the new year.

Mr. WAMPLER. I ask the same question of Ms. Foreman. Have you made any formal recommendations? Are you studying that possibility in the Department?

Ms. FOREMAN. We are certainly studying the possibility. Obviously when recommendations come forward they will be from the administration and represent changes in the Meat and Poultry Inspection Acts, if that is necessary, in order to accomplish what we need to do.

Mr. WAMPLER. We urge you, because time is terribly important. I do not want to be partisan, but your tenure might be limited. So I suggest you hurry up. [Laughter.]

Ms. FOREMAN. I was going to say that we will send them to you as soon as the President is sworn in again.

Mr. WAMPLER. That can be disputed. [Laughter.]

Mr. BEDELL. We have just been called for a vote. We have 5 minutes or 6 minutes. There are a series of three votes.

It is up to the committee. It would be my recommendation that since there are three people left we will give them each 2 minutes.

Is that agreed upon? Or, would you rather do something different?

Mr. Martin, you indicated you wanted to speak as well. I am including you.

I will defer to members of the committee.

Is that agreeable with the members here?

Mr. COELHO. Yes.

I have been involved with some of these problems for years. Go back to cranberries, go back to cyclamates and saccharine and now look at nitrites.

I do not want to be partisan, but because of the predominance of agriculture in my congressional district I would prefer the way the Department is handling nitrites to the way the previous Department handled cyclamates. We did have people who were injured. We do have a case before the court right now to settle the damages.

Mr. Foley had some questions about agencies being forced by our own personnel to take actions. In the case of cyclamates we found that absolute panic set in.

As a result of that panic, the Agency in the last administration took some action that unfortunately hurt many innocent people.

Ms. Foreman, I do not totally agree with everything you did on the nitrites issue, but so far as I am concerned, this one individual Member of Congress surely applauds your action as compared to previous actions taken on food additives.

We are moving in the right direction. I would hope that you and the FDA would get together and cooperate more. During the President's next term we can have some legislation that makes more sense, but for the time being we must keep things in the right perspective.

Many of those involved in nitrites see only one side of the story. Go back in the history of the case relating to cranberries. We have no choice but to applaud you and the way you went about it as opposed to the previous experience.

Mr. BEDELL. Thank you, Mr. Coelho.

Mr. Stenholm?

Mr. STENHOLM. I have been led to believe, based on what I have seen and heard, that there was a difference in the manner in which the two announcements were made. I want to make sure I understood your original answer to Mr. Wampler's question regarding the issue of press conferences and sensationalizing the information.

You did say that in your opinion there was no difference between 2 years ago and a couple of weeks ago?

Ms. FOREMAN. There was no press conference 2 years ago in August when the original Newberne study was later released. I will be glad to give you a press release that went out that day. It is a

statement actually by the two departments. I will let you make a judgment for yourself about the language that was used.

Mr. STENHOLM. In your opinion, there was no difference between the agencies concerned in the sensationalizing of the information 2 years ago and a few weeks ago?

Ms. FOREMAN. It was our intention in both cases not to do so.

Mr. STENHOLM. I have a further question in regard to following up on Mr. Whitley's comments.

When I read on page 18 that if you were a rat and were fed nitrites, 7.9 percent of you were going to get cancer whether fed it or not and 12.5 percent if you had it.

Why do we not tell the American people that 92.1 percent of you are not going to get cancer no matter what? Then, 4.6 percent would get it if you had nitrite instead of saying 50 percent greater in controlled groups?

Ms. FOREMAN. I am going to let Dr. Goyan go into any detail you want on the efficacy of that kind of testing.

The one point I would make is that there are now 220 million Americans. If you were to say that 4 percent of them who would not ordinarily get cancer would get it as a result of a substance, that is an awful lot of people.

Mr. STENHOLM. But it is a lot less than 50 percent is what I am saying. In the mind of a farmer from Texas, I would much rather we say it that way that 50 percent because it is more sensational.

Ms. FOREMAN. I think you are absolutely right. I think it is important to know that in making releases that go out to the public, the two agencies, I think, are rather careful to spell things out in a great deal of detail and attempt to make them as easily understood as possible.

I suspect we sometimes fail at that. Sometimes our testimony is substantially more sophisticated than press statements put out knowing there is a difference in the two audiences.

Mr. STENHOLM. Thank you.

Mr. BEDELL. Thank you, Mr. Stenholm.

We thank you, Dr. Goyan, Ms. Foreman, and the rest of your people for being here. I think I speak for the whole committee when I say it has been helpful.

Thank you very much.

Dr. GOYAN. Thank you.

Ms. FOREMAN. Thank you.

Mr. BEDELL. The committee will recess now until 2 o'clock this afternoon.

[Whereupon, at 12:53 p.m. the committee was recessed to reconvene the same day.]

AFTERNOON SESSION

Mr. JONES of Tennessee [acting chairman]. The full Committee on Agriculture will come to order.

Before I call the next witness, I would like to give an explanation here. This afternoon we will have an opportunity to hear from a number of witnesses on this important issue, that has been discussed all morning.

As you can see from the agenda, we have 17 witnesses. The staff has advised each of the witnesses that it will be necessary to limit their oral presentation to no more than 5 minutes.

For the information of our witnesses, you will note that there is a timing device on the witness table. The white light will come on when you have 1 minute remaining. The red light will signify that the expiration of your time has arrived.

The full statement of each witness will be placed in the hearing record. We will appreciate your cooperation in limiting your oral presentation.

In order that the witnesses may be heard expeditiously and in order for members to have an opportunity to question all witnesses, it is the Chair's intention to hear the first nine witnesses on the list without interruption.

I understand that there is one gentleman who may not be able to make his plane. Therefore, I will change the order of appearance of the witnesses, so that he may catch his plane.

After the last of these witnesses is heard, all nine witnesses will return to the table for questioning en block.

After these witnesses have been questioned, they will be excused. Then we will hear the remaining witnesses without interruption. They will also be questioned en block.

We have found that this system works rather well when we have a large number of witnesses to be heard.

We recognize that some witnesses may have some time problems. I am sure that our members will understand if it is necessary for some witnesses to depart at any time during the proceedings.

I am not going to call the first witness at this time. One witness was omitted from the list.

Mr. Wampler would like to question Dr. Endicott, the executive officer of the Bureau.

If Dr. Endicott will come forward at this time, Mr. Wampler will ask you some questions at this time.

## QUESTIONS TO DR. KENNETH M. ENDICOTT, EXECUTIVE OFFICER, UNIVERSITIES ASSOCIATED FOR RESEARCH AND EDUCATION IN PATHOLOGY

Mr. WAMPLER. I appreciate your patience, Dr. Endicott. I do have a few questions to which I would like you to respond.

Will you briefly define UAREP?

Dr. ENDICOTT. UAREP is a consortium of 15 universities which are very active in the field of experimental pathology. The board of directors is made up, by and large, of the chairmen of the departments of pathology of the medical schools of those 15 universities.

Mr. WAMPLER. Were you the director of the slide-by-slide review of the Newberne studies?

Dr. ENDICOTT. Yes, sir. I was.

Mr. WAMPLER. Will you tell the committee of the magnitude of your review and of the general results derived therefrom?

Dr. ENDICOTT. It was an extensive and exhaustive review of approximately 50,000 tissues—that is, an examination of the tissues carried out by pathologists under a code system, so that they did not know to what the animals were exposed or what the MIT diagnoses were.

In any cases of doubt, a tissue would be reviewed by a committee of three to arrive at a consensus.

The entire study was supervised and many slides were examined by a joint committee of experts comprised of six outstanding experts in this area.

Mr. WAMPLER. Dr. Endicott, would you favor a revision of the current system used by regulatory agencies requiring a better scientific review procedure of the studies on which they rely in the regulatory decisionmaking function? If so, what would you propose?

Dr. ENDICOTT. We have done three studies like this one. In two of the three we agreed essentially with the original pathologists' diagnoses.

This is the only one with which there were substantial differences. There would be no way of anticipating this.

If it had been possible for the FDA pathologist to have reviewed a sample of tissues during the course of the study, perhaps this thing might have been laid out more expeditiously.

As it was, they felt that we should review all of the tissues, which made it a massive effort.

Mr. WAMPLER. Do you have any specific recommendations, on the basis of the testimony you heard here this morning, to revise the so-called Delaney clause or any of the laws affecting food quality?

Dr. ENDICOTT. I am inclined to agree with the witnesses this morning, that some greater latitude needs to be provided in weighing risk versus benefit. Of course, that presents problems too.

Mr. WAMPLER. Would it be fair to say that you believe the time has come for us to engage in a meaningful dialog in this country to try to find a better regulatory mechanism than that which is now in place, as it affects human health and food quality? Would that be a fair statement?

Dr. ENDICOTT. Yes, sir. I would agree with that.

Mr. WAMPLER. I thank you very much for your appearance here and for your very direct responses to the questions.

Thank you, Mr. Chairman.

Mr. JONES of Tennessee. Thank you, Mr. Wampler.

Thank you very much, Dr. Endicott.

Now, Mr. Wampler, we will come back to you for an introduction of our first witness, who is from the State of Virginia.

Mr. WAMPLER. Thank you, Mr. Chairman.

The first witness on the published witness list is Hon. Mason Carbaugh, who is commissioner of agriculture of the Commonwealth of Virginia.

Unfortunately, he is not a constituent of mine, but I hold him in very high regard. He is extremely knowledgeable in the field of agriculture.

In addition to serving as our commissioner in Virginia he has been very active in the National Association of State Departments of Agriculture.

I certainly welcome him this afternoon.

Mr. JONES of Tennessee. Thank you, Mr. Wampler.

You are certainly welcome, Commissioner Carbaugh. You may proceed.

**STATEMENT OF S. MASON CARBAUGH, COMMISSIONER OF AGRICULTURE AND CONSUMER SERVICES, COMMONWEALTH OF VIRGINIA**

Mr. CARBAUGH. Thank you, Mr. Chairman.

I particularly want to thank the House Agriculture Committee for affording me this opportunity to appear before you and for the kind remarks made by our distinguished Congressman from the Ninth District in Virginia. I appreciate it very much.

I will not take your time here this afternoon in recounting the matters surrounding the nitrite issue, because I think that territory has already been covered today and will be done by others.

I do have some comments and a prepared statement, which I have submitted for the record.

My purpose in testifying is really twofold. First, I do believe that the course of action that was taken with regard to nitrites, as outlined by USDA and FDA, for release of the UAREP findings is both prudent and proper. We can rightfully ask: Why was the use of our total scientific capability delayed so long?

In light of current scientific knowledge, the use of nitrites in cured meats, poultry, and fish should be continued. Since nitrites are used so extensively, it is worthwhile to thoroughly review the existing scientific data, as USDA and FDA have now done and projected. They have determined whether any further studies are needed.

The American people enjoy the most abundant, wholesome, and safe food supply on Earth, and we must see that it is not jeopardized.

My other reason for testifying today is to share with you my concerns over food additive regulations in a broader perspective. I might add, that in my responsibilities I do have responsibility for the Virginia food law, the Virginia meat and poultry inspection law, the Virginia pesticide law, and a number of other product regulatory responsibilities.

The potential consequences we face in dealing with the nitrite question serve to emphasize and to remind us of the problems we will face in the future, unless the Delaney amendment controversy is resolved.

The Delaney amendment, as you well know, prohibits the use of any substance as a food additive if scientific evaluation finds it produces cancer in man or in animals.

When the Delaney amendment became law more than 20 years ago, no one could foresee the great advances that science and technology would make. These advances have made it possible to isolate, identify, and study compounds and biochemical structures unknown at the time that the Delaney amendment was passed.

These advances have also given scientists and researchers the ability to reliably detect chemical compounds in parts per billion range.

In view of these scientific advances, it is apparent that a comprehensive review of the Delaney amendment should be undertaken. I believe that such a review would lead to a revision of the Delaney amendment that allows for scientific judgments based upon risk-benefit considerations.

A revised Delaney amendment should also allow for scientific judgments as to the validity of the test procedures used to determine carcinogenicity.

Concurrent with a review of the Delaney amendment, I believe that the concept of the scientific panel to decide questions of scientific fact is, in my judgment, a very feasible and needed process, which should be given serious consideration.

If the findings of such a panel were made binding upon the various regulatory agencies involved, a greater measure of uniformity could be expected. Such action would increase the credibility of the Government and give the American people more confidence in their food supply.

I think the basic question is: Can the process that we now have be improved? I think that it can be improved.

This means using our considerable scientific capabilities to bring that about, as well as developing a better system and using it.

Thank you, Mr. Chairman.

Mr. JONES of Tennessee. Thank you very much, Mr. Carbaugh. We appreciate your being here.

Without objection, your prepared statement will be included in the record.

[The prepared statement of Mr. Carbaugh may be found at the conclusion of the hearing.]

Mr. WAMPLER. Will the chairman yield?

Mr. JONES of Tennessee. I would be happy to yield.

Mr. WAMPLER. I want to say to Commissioner Carbaugh and our next witness, the director of the Illinois Department of Agriculture, Mr. John Block, that our distinguished chairman is a former commissioner of agriculture in his State of Tennessee. I think he can perhaps relate to some of your problems better than some others of us can.

Thank you so much for your testimony.

Mr. JONES of Tennessee. Thank you, Mr. Wampler.

Our next witness is Hon. John Block, director, Illinois Department of Agriculture, Springfield.

We are delighted to have you, Mr. Block. You may proceed.

## JOHN BLOCK, DIRECTOR, ILLINOIS DEPARTMENT OF AGRICULTURE

Mr. BLOCK. Thank you very much, Mr. Chairman.

My name is John Block. I am the director of Agriculture for the State of Illinois. In addition to being the State's chief agricultural spokesman, I own and operate a large grain and swine operation in Knox County, Ill.

My home State of Illinois is the Nation's second largest producer of hogs, and Henry County, the county situated just north of my home county, is the largest pork-producing county in the Nation.

Last year Illinois farmers marketed nearly 2.6 billion pounds of pork valued at more than $1 billion. At the beginning of this year there were more than 7 million hogs on Illinois farms.

Needless to say, the pork industry is critical to the total economy of the State of Illinois.

It has now been 2 years since the USDA and FDA stated that nitrites cause cancer and therefore should be phased out of use as a

meat preservative. This announcement sent shock waves throughout American agriculture and the general public.

The consequences of that announcement have been considerable, causing economic hardship to the livestock industry and developing a poor image of cured meat in the eyes of the consumer.

The Illinois Pork Producers Council estimates that the industry has lost $1 billion in bacon sales alone due to the negative image many consumers now have of cured meat products, and this happened in a year when farm income was down 30 percent.

Let us consider the importance of cured meats to the food industry. According to Supermarket News, the 1978 value for provisions such as cured hams, sausages, hot dogs, bacon, baloney, and luncheon meats—not to mention such ethnic favorites as kosher meats, Polish sausage, German knockwurst, Italian salami, and Irish corned beef—totaled $14.5 billion. This is over 7 percent of the total supermarket sales.

In 1978 the Senate Agriculture Committee requested an impact analysis by the USDA of the consequences of the banning of nitrites in curing bacon. The USDA report stated that we could expect long-term reductions in the net farm income for livestock and crop producers and smaller quantities of animal products available per capita, accompanied by a small increase in the consumer price index.

The Council for Agricultural Science and Technology, or CAST, reported in 1978 that 44 percent of all federally inspected edible flesh is cured with nitrites. This includes 60 percent of all pork products.

Consumers spent $2.7 billion for bacon alone in 1977. If cured bacon were unavailable, American consumers would lose an additional $2.25 billion in paying for higher priced bacon substitutes.

According to CAST, the effects on farmers, consumers, and processors would be devastating, being multiplied several times. Each sector of the industry could potentially lose billions of dollars.

The consumer would be the ultimate victim, suffering increased costs for not only food but important byproducts of a smaller pork industry such as medicines, clothing, and cleaning products.

Now, 2 years later, after considerable uproar from the agricultural and scientific communities, the USDA and FDA admit that their judgment was incorrect in assessing the results of Dr. Newberne's study. The USDA's own researchers found that nitrosamines are not formed when bacon and cured meats are cooked. This was revealed before the first scientific review of the MIT study declared it invalid.

It is customary that research is not published until it is reviewed by two unidentified, noncommitted reviewers. Thus, an editor of a scientific journal will not publish anything until the work is independently reviewed by two other scientists to double check findings. The General Accounting Office found that routine review by interagency scientists utilized in the past was brushed aside by the FDA when making this far-reaching statement.

The implications of the nitrite statement by the FDA and USDA have been tremendous, unjustifiably injuring the agricultural industry and misinforming the American consumer.

Political, rather than scientifically, based decisions have caused deep wounds to an important industry that will take many years to heal. Biased and uninformed decisions by Government agencies must be prevented in the future. Regulatory decisions must be reviewed by an independent panel of scientific experts and explored thoroughly to prevent such misjudgments from ever happening again.

I do not think that anyone really appreciates the amount of energy and the numbers of resources that have been expended in the last 2 years to bring some sanity, some judgment, and some reason into this whole situation.

I know many farmers—and some of them will talk to you today—who have come here on many occasions and gone to FDA, USDA, and Members of Congress. I compliment Congress for being receptive in working to solve this problem as they have done. Nevertheless, we hit a stone wall in the administration on this issue.

I want to cite a very brief example that I have been through. Shortly after the original announcement in 1978 by the U.S. Department of Agriculture and the Federal Food and Drug Administration, Congressman Findley, a member of your committee and a Congressman from the State of Illinois, invited Mrs. Foreman to the State of Illinois to discuss the issue with farm leaders in the State.

I was privileged to be on the panel posing questions to her. We had a big turnout.

One of my questions to her exemplifies the runaround that we have had. I presented research to her that had been performed by Southern Illinois University, which clearly showed that vitamin D fed to rats causes cancer. Consequently, vitamin D is a carcinogen.

That being the case, the Federal Food and Drug Administration should ban the use of vitamin D.

Of course, my objective was not to get vitamin D banned. It was merely to point out the inconsistencies in the whole policy, where they arbitrarily attacked the red meat industry in the processing of that red meat without regard to many other instances.

When you feed these tremendous doses of whatever it is to rats, they can become toxic and the rats can develop cancer.

It just so happens that the U.S. Department of Agriculture requires that vitamin D be added to milk. They require the additive vitamin D, which is fine, but vitamin D is a carcinogen.

You would think there would be some action, if you pointed out such an inconsistency, but the action was pretty slow in coming.

I have the letters here. It is all documented. It was 50 days before I got my first response. They said, "We will look into it." In another 60 days—and I also have that response here—I got another response. All it says is that: We think that the research done at Southern Illinois University is inconclusive. It really does not prove the point. We will continue to look into this situation.

The whole point is this. It was never followed up. Nothing has happened since then in this period of time, yet continual effort was made to ban the use of nitrites in curing our red meats. It is just one example of something that we can be up against in the country when we have an administration, or people within an administra-

tion—I do not indict the whole administration—who are unresponsive to the needs of the industry and unwilling to use commonsense, logic, and good judgment in addressing an issue.

It has damaged the red meat industry considerably. It will be years before these wounds are healed.

I appreciate the committee's providing the time for me to make this statement today. I appreciate the committee's taking the time to study the issue, because it is an important one.

We need to develop a procedure, so that it does not happen again. It is just inexcusable. We have to have a solution to restore good judgment and credibility in governmental decisions.

Thank you very much for your time.

Mr. JONES of Tennessee. Thank you very much, Mr. Block, for a very splendid statement.

Our next witness is Mr. C. Manly Molpus, president of the American Meat Institute in Washington, D.C.

Mr. Molpus, welcome. We are glad you are here. You may proceed.

## STATEMENT OF C. MANLY MOLPUS, PRESIDENT, AMERICAN MEAT INSTITUTE

Mr. MOLPUS. Thank you, Mr. Chairman.

I am Manly Molpus, president of the American Meat Institute, the national trade association of the meat packing industry. Our members include over 300 meat packers and processors, doing business within all of the 50 States.

We would like to compliment the committee for holding these hearings on recent Government actions dealing with nitrites and related food safety policy issues. I must acknowledge the continued interest and vigilance which members of this committee have shown in securing a proper resolution of the so-called nitrite problem.

Mr. Chairman, we have submitted a more detailed statement for the hearing record. My remarks will summarize that statement.

I would only like to add to that some concerns we have with respect to some of the testimony this morning dealing with the problem of nitrosamines. I think at one point Mrs. Foreman had the option of indicating her wish, that she could send a message of some clarity with respect to nitrites.

Our message today would be that there is no nitrite issue and there is no longer a nitrosamine issue.

USDA and FDA officials said this morning that there is no evidence that nitrites cause cancer. As for nitrosamines, they have a clean bill of health from Mrs. Foreman in a press release that says bacon is safe, bacon being the only product wherein any nitrosamine formation has been found.

The release gives a clean bill of health to all other cured meat products.

I will be happy to submit those USDA press releases and some other detailed information on that issue for the record.

We are here today to offer constructive analysis of the Government's handling of the nitrite matter. Our underlying belief is that such a constructive review will help in developing improved administrative procedures in dealing with scientific studies.

But, more importantly, these hearings will help all of us to see clearly the need for modernizing the Nation's food safety laws.

Winston Churchill once said, "An optimist is one who sees an opportunity in every calamity. A pessimist sees a calamity in every opportunity." It is our hope that we will move from the near calamity of the regulatory problem with nitrites to seize upon this experience as an opportunity to thoughtfully reassess and revise this Nation's food safety laws.

Such change must be brought about without weakening the protection of this Nation's public health. This must be accomplished with leadership from the Government agencies, the Congress, industry, and consumers alike in a cooperative partnership effort. We need not be adversaries in seeking this goal.

A new food safety policy can benefit everyone by preventing unnecessary scares and fears about food products and food additives. This can be accomplished by bringing scientific judgment to bear on food safety, rather than continuing inflexible, inconsistently implemented policies. Such a new policy would strengthen public confidence in the food industry and in the regulatory agencies, both of which share the common goal of insuring a safe food supply.

This committee is aware of the Government's handling of the nitrite matter and will hear more today of the flaws, conflicts, and problems that arose because of certain ill-advised actions by the regulatory agencies. These actions have been well documented by the Council of Agricultural Science and Technology, the Library of Congress, the General Accounting Office, and members of this committee.

The missteps include the unusual ad hoc procedures FDA followed in considering the study, the lack of appropriate peer review, and the unfortunate nitrite publicity and misinformation spread to the public.

As American Meat Institute pointed out in its congressional testimony of September 1978:

> The fact is that based upon present knowledge there is absolutely no scientific evidence that nitrite as properly used in cured meats is harmful to humans. We are certain that proper peer review of the Newberne study will support this fact once and for all.

Having contracted with the UAREP group for a review and analysis of the diagnosis made by Dr. Newberne and having released those findings with the judgment that there is no evidence that nitrites fed to rats cause cancer, the air is now clear.

In this discussion of nitrites the meat industry's role should not go unnoticed. The industry has set an example of responsible behavior in dealing with this matter of great sensitivity and importance.

It was the industry that brought the nitrite matter to the attention of the Government in connection with nitrosamine formation. It was the industry that voluntarily decreased the amount of nitrite used to cure bacon and increased the use of ascorbate to block nitrosamine formation in bacon. The industry has also conducted research for nitrite substitutes. We will continue this constructive approach.

Where do we go from here?

In response to the UAREP review and recommendations of the Interagency Working Group, the agencies have contracted with the National Academy of Sciences to assist in a review of all data regarding nitrite. This is a logical and orderly way to proceed.

It is our understanding that the Academy also proposed to "examine the institutional means of designing, conducting, monitoring and evaluating research on toxicity of substances in foods." The Academy's proposal in this regard has not been accepted. It should be.

We urge the agencies to reconsider this proposal. We hope this committee will urge the agencies to accept this proposal, so that appropriate administrative agency procedures can be developed and put in place to insure against future problems such as those revealed in the various critiques of the nitrite regulatory mess.

In conclusion, the nitrite situation has demonstrated that the present state of the law concerning food safety can be characterized as confusing, arbitrary, and in need of rethinking.

Chairman Foley stated it quite clearly when he said:

> There is a growing concern that the rigidity of the existing law poses a threat of future regulatory reaction that could do significant harm, without making any real contribution to health protection.

Congressman Wampler identified the problem for Congress when he said:

> The failure on the part of regulators in Government to follow good scientific procedures has evoked such criticism, that the Congress has had to become increasingly involved in implementing regulatory policy with respect to these substances.

Industry, consumers, and the Government are faced with the challenge of changing public policy with respect to food safety laws. There is a growing consensus that our 40-year-old food safety laws are outmoded and do not reflect significant technological advances.

We are pleased to note, that this year both political party platforms contain a provision pledging a review of food safety laws.

There should be no misunderstanding as to why these laws need to be changed. The issue is not pro or con on cancer. The issue is not to relieve the food processor or the regulatory agency of responsibility.

The issue is to provide protection for the consumer and to maintain public confidence in the safety and wholesomeness of our food supply. This should be done in a way which will insure that scientific judgment influences decisions on the safety of food.

The American Meat Institute pledges its cooperative efforts with that of Congress, the agencies, and the consumers toward reaching this necessary goal.

Thank you very much.

Mr. JONES of Tennessee. Thank you very much, Mr. Molpus, for a very good statement.

Without objection, your full statement will be included in the hearing record.

[The prepared statement of Mr. Molpus and an addendum may be found at the conclusion of the hearing.]

Mr. JONES of Tennessee. Our next witness is Mr. John Mohay, chairman of the Nitrite Safety Council, Washington, D.C.

Welcome, Mr. Mohay. We are delighted that you are here. You may proceed.

## STATEMENT OF JOHN G. MOHAY, CHAIRMAN, NITRITE SAFETY COUNCIL

Mr. MOHAY. Thank you very much, Mr. Chairman. I am pleased to be here.

My name is John Mohay, and I am president of the National Meat Association, a nationwide, meat trade association group.

This afternoon, however, I am speaking as chairman of the Nitrite Safety Council, a coalition of some 50 groups which represents all segments of the meat, poultry, and livestock industries and affiliated interests in all sections of the country.

We appreciate the opportunity to appear before this committee to recap briefly the role that the Nitrite Safety Council has played in proving the safety and wholesomeness of nitrite-cured products and combating the adverse impacts that resulted when the Departments of Agriculture and Health and Human Services acted prematurely on Dr. Newberne's findings on nitrites.

I have submitted a statement, which I will merely summarize in the next 2 or 3 minutes, Mr. Chairman.

The Nitrite Safety Council was formed following the Department of Agriculture's October 18, 1977, mandate. Industry was given 90 days to provide information to show whether the use of nitrite in bacon production led to the formation of carcinogenic nitrosamines.

During the ensuing 2 years, we also had to demonstrate whether carcinogenic nitrosamines were formed in other cured products—that is, other than bacon—as the result of ordinary conditions in processing and in the preparation of meat for eating.

I am pleased to report that we met each and every deadline, and I am being conservative when I say that this research and testing cost our industry several hundreds of thousands of dollars.

Our success was documented in the June 27, 1980, Federal Register. The industry verified beyond any doubt that products cured with nitrites do not produce confirmable levels of nitrosamine residues.

In the case of bacon, the Council worked hand in hand with the Department of Agriculture in developing processing procedures that reduced the levels of nitrosamine residues to the point that they are nonconfirmable.

Now, there is just one piece of unfinished business. That is dry-cured bacon.

We urge this committee to request that the Department of Agriculture use part of that $2 million worth of research funds, that they mentioned this morning, to produce an alternative to the USDA proposal that calls for dry-cured bacon to be dried to microbiologically safe maximum water activity levels of 0.92, or be brought to a similarly safe minimum brine concentration of 10 percent in a finished product.

This requirement would make the product too salty for consumer taste. As a result—and this industry is basically a small industry group—many producers would face economic ruin.

In addition, the proposal is contrary to USDA's own advice, that Americans should avoid too much salt to prevent hypertension.

Although we are not here to vent the outrage of the industry itself over the way the USDA and FDA handled the findings of Dr. Newberne, it is safe to say that the premature and erroneous

publicity placed a seed of doubt about cured meat products in consumers' minds, that cost our industry untold millions of dollars in lost sales.

If we are to learn from the past 2 years, Congress must require that USDA and FDA have a well-defined plan that will guarantee an orderly review of any research study which has the potential to create apprehensions in the public's mind about a food product, to damage an industry's economic welfare, or to raise questions about the Government's credibility.

We believe that Government regulatory agencies, the individuals who staff them, and their contracted researchers must be held accountable for their decisions and subsequent actions. One way to achieve this accountability is to require neutral third parties to conduct thorough and complete reviews of sensitive and far-reaching studies prior to any public pronouncement.

Had this been done in the nitrite issue, the economic and mental trauma of the last 2 years would have been avoided.

When a businessman makes a wrong decision, he pays dearly for it, yet there are no consequences facing the researchers or the Government employees who reach incorrect conclusions or who make wrong decisions.

Regardless of the error or the resulting turmoil it creates, they are permitted to shrug it off and proceed to the next issue.

This hearing should also be the first step in securing a careful review of the overall concept we have toward food safety and a thorough reassessment of current laws and regulations that govern it. Since the passage of the Delaney clause and other food safety laws, there has been a cavalcade of technological advancements.

Scientists now analyze foods in parts per trillion. It is conceivable that soon every food will be broken down into such miniscule proportions, that elements of potential danger will be found in everything.

The key, however, is not merely to discover these potentially dangerous elements but to put them in their proper perspective.

Working together, Congress, industry, consumers, and regulatory agencies must find and define a logical, reasonable, and acceptable level of risk. There is no such thing as the perfect zero risk that we are now trying to impose.

In conclusion, I believe it is accurate to say, that there is no way to repair all of the damage that has been done by the nitrite issue, but if it motivates action that will assure thorough peer review studies of research products and leads to improved food safety laws, then the experience will not have been in vain.

Thank you.

Mr. JONES of Tennessee. Thank you very much, Mr. Mohay, for a very good statement. We appreciate your being here.

Without objection, your full statement will be included in the record.

[The prepared statement of Mr. Mohay may be found at the conclusion of the hearing.]

Mr. JONES of Tennessee. I believe we will have to forego the hearing of another witness at this time. We have to vote.

The first member back will chair the hearing for the next witness.

[Recess taken.]

Mr. WAMPLER [acting chairman]. The committee will come to order.

As the chairman explained, there is a vote currently under way on the House of Representatives floor. In an effort to accommodate the witnesses and to expedite our hearing, we are going to proceed. The other members will join us as soon as they have completed their voting on the floor.

Our next witness is Mr. Buller, who is president of the National Pork Producers Council of Des Moines, Iowa. He is accompanied by Mr. Ritchie Jordan.

We will be glad to hear your statement.

## STATEMENT OF WILLIAM C. BULLER, PRESIDENT, NATIONAL PORK PRODUCERS COUNCIL, ACCOMPANIED BY RITCHIE JORDAN, CHAIRMAN, LEGISLATIVE COMMITTEE, NPPC

Mr. BULLER. Mr. Chairman, Mr. Jordan is chairman of our legislative committee.

We have a short statement. I will give you a summary of the statement that we have submitted to the committee.

Mr. Chairman and members of the House Agriculture Committee, Ritchie Jordan and I are farmers. We are also pork producers.

In the capacity of the president of the National Pork Producers Council, I speak today for the Nation's one-half million pork producers and the 100,000-member National Pork Producers Council, which produce $9 billion worth of pork, 70 percent of which is cured.

It is on their behalf that I express the deepest appreciation for your invitation to appear here today to discuss food safety and to tell the nitrite story, as we see it.

I hasten to explain, Mr. Chairman, that pork producers are not antiregulatory. We will be the first to support a ban on any proven carcinogen.

However, that proof must be backed up by research and reliable review procedures.

Pork producers regret that they were forced to take their Government to court twice in the past year because of questionable rulemaking. In both instances the court ruled in favor of pork producers. The rulings in separate courts termed the regulatory agencies "arbitrary and capricious."

In one instance, the term used was "abuse of authority."

We wish to further make it clear that we are not waging a vindictive crusade, nor do we wish to vilify any personality. There is, however, a need to ask penetrating questions and to take whatever measures are necessary to prevent another cranberry catastrophe or nitrite boondoggle.

You see, Mr. Chairman, the farmer has for centuries lived by an unwritten code of ethics. It goes something like this: If my livestock gets out and damages your crops or property, we will assess the damage and I will pay for it. If I use a piece of machinery of yours and break it, I will repair it.

Sir, the regulatory process has done irreparable harm to the pork industry. A conservative analysis estimates the damage to the

value of bacon alone, which represents 10.5 percent of the hog carcass, at over $1 billion.

A recent consumer perception survey, dated September 1, 1980, indicates that almost 50 percent of the people responding believe that bacon contains a cancer-causing substance.

I set these facts before you early, so that you will realize the tremendous damage that has been done, not just to an industry, but to consumer attitudes.

Most recent media probes into consumer perceptions, since the August 19 release by USDA and FDA, indicate that those consumers that have had their faiths restored in nitrite-cured products have had their faiths badly shaken in government and its ability to regulate effectively.

Mr. Chairman, pork producers believe that the time has come for the reform of food safety regulations. The current system is outdated and not sufficiently geared to prevent mishap and abuse.

Congress should make clear that food safety, like transportation, environmental, or any other kind of safety regulation, demands reasonableness.

A discovery of a trace of a suspected carcinogen in test rats, after excessive doses of a substance, should begin rather than end the regulatory inquiry.

It should be permissible to take other relevant considerations into account in making regulatory decisions.

Two years ago, something went wrong. FDA and USDA announced through ranking department officials with optimal press coverage a proposed phaseout of nitrite, based on results of a rat study at MIT.

Mr. Chairman, I say that something went wrong, because a month ago, this time through subordinate Department officials with minimal press coverage, buried in a press release on another subject, FDA and USDA conceded that the MIT study was negative and had not shown nitrite to be a carcinogen.

In other words, the regulators were dead wrong 2 years ago.

One thing that would really help this situation would be if Secretary Bergland and Carol Foreman would be as positive in correcting this as they were helpful to us, the industry, during our hog crisis of last spring.

The predictable effects of this mishap have been many. For one thing, there has been a loss of consumer confidence in regulatory health alarms. Government seems to be teaching us to ignore its health warnings.

The nitrite mishap has also occasioned a kind of backlash to minimize Government participation in food safety regulation. We think that is unfortunate, because, in our view, Government has played and should continue to play a continued role in this area.

A third fallout has been the effective denial of legitimate consumer freedom to choose foods of their preference. When a regulator earnestly calls cranberries a carcinogen and forces them off the Thanksgiving dinner table, we have lost a measure of our precious freedom.

That is what happened with cured foods.

To us, Mr. Chairman, the big question is: What went wrong? If we can get to the bottom of this, we can hopefully protect consum-

ers and producers from future reoccurrences in the area of food safety regulation.

Mr. Chairman and members of the committee, in conclusion, I state the pork producers' case. We are not, at this moment, looking for restitution or reparation. We are more concerned with the future than we are with the past.

With the nitrite-Newberne controversy being put in perspective, it is timely that we deal with food safety procedures.

Such errors as we have just experienced do not only cost industry. They cost the consumer. That is bad Government that none of us can condone.

The National Pork Producers Council has had a special committee studying food safety regulation. We look forward to supporting legislation to insure a return to reason in our food safety regulations.

Nothing would please us more than to be able to go home and tell our half million pork producers and millions of other red meat producers that, as a result of this hearing, we are confident that our regulatory review process will be shaped up and strengthened, that our rulemaking procedures and human judgment, which are so vital to the system, will be enhanced by wisdom and free of capriciousness—and finally, that Government, through wise leadership, will literally bring us together, producers and consumers, and give us a new kind of enlightened leadership. Maybe we could call them "Prosumers".

Mr. Chairman, the pork industry is looking to this committee and to Congress to bring wisdom and commonsense to the development of food safety regulation.

Thank you, Mr. Chairman, for listening patiently to the Pork Producers' summary.

Mr. WAMPLER. Thank you for your very informative statement.

Without objection, your full statement will appear in the hearing record.

[The prepared statement of Mr. Buller may be found at the conclusion of the hearing.]

Mr. WAMPLER. Mr. Jordan, do you have anything you want to add?

Mr. JORDAN. Yes, Mr. Chairman, if I may take a moment. I serve as cochairman of our Food Safety Committee. In the past few months we have been studying what the pork producers' policy should be in this area.

Although this has not been voted upon by our board, there are certain principles that we feel the committee will recommend. The first of those is, that a separate group of scientists should be used to determine scientific fact.

We also believe that the results of this study should be mandatory requirements to the regulators, not an advisory type of counsel. We also feel that there should be a definite procedure or process through which risk is determined.

We feel that the Food Safety Council has done a great deal of research and has found many ideas that could be helpful in developing such a procedure, which would give a uniform set of ideas toward the solution of this problem.

We also feel that benefits should be recognized as well as risks in determining the characteristics of a substance.

We also support the ideas that Congressman Martin set forth this morning concerning the care that should be used in evaluating the credibility of very high dosages. We feel that, where the body's defense mechanisms fail, may be where these high dosages take over.

These are some of the principles that we shall recommend to our producers and that we think should be in any new legislation concerning food safety.

Thank you.

Mr. WAMPLER. Thank you, Mr. Jordan.

I thank both of you for your testimony. If you can stay in the committee room, will you kindly do so, since there may be members of the committee who want to question you, when we question all of the first nine witnesses en bloc.

Thank you both very much.

The next scheduled witness is Ms. Ellen Haas, of the Community Nutrition Institute of Washington, D.C. Ms. Haas, may I suggest to you that you may want to begin your testimony, although when the second bells ring indicating a vote, unless some of my colleagues have returned, I may have to leave. If we do have to interrupt your testimony, I hope you will understand the parliamentary situation that confronts us on the floor of the House of Representatives.

We are delighted to have you here. We would be happy to hear your testimony, if that is agreeable to you.

**STATEMENT OF ELLEN HAAS, COMMUNITY NUTRITION INSTITUTE, ACCOMPANIED BY THOMAS B. SMITH, RESEARCH DIRECTOR**

Ms. HAAS. Thank you very much , Mr. Chairman.

I would like to ask that my complete testimony, that we have submitted to the committee, be put into the record. I will make a summary statement. I am accompanied here today by Thomas B. Smith, our research director at the Community Nutrition Institute.

The Community Nutrition Institute is a nonprofit consumer organization, concentrating on food and nutrition policy issues.

Let me say, that we are also a member of the Consumer Federation of America, the Nation's largest consumer organization, of which I have just been president for the past 2 years.

In 1977 CNI, along with the Consumer Federation of America, the National Consumers League, the Virginia Citizens Consumer Council, and the Americans for Democratic Action, petitioned the Department of Agriculture to ban nitrites as food additives. This action, let me say, was taken before the Newberne study was released, because at that time we felt that there were many indications that nitrite additives caused gravely serious health hazards to consumers.

Thus, it is not unexpected that this continues to be our position today, despite the fact that a cloud has been cast over the Newberne study results.

In short, irrespective of the Newberne study, we strongly believe that steps should begin immediately to have nitrites gradually

eliminated from use as a food additive in meat and other food products.

Our group is not alone. There are other consumer groups, such as Consumer Federation of America, which have also expressed that concern. I have, and would like submitted into the record, a letter from Stephen Brobeck, executive director of Consumer Federation of America, to that effect.

Our concern about the health hazards of nitrite additives relate to their propensity to combine with other, naturally occurring chemical groups to form nitrosamines, which are extremely potent animal carcinogens.

In addition, exposure to nitrite-induced nitrosamines can come either through the ingestion of preformed nitrosamines, such as in bacon, or through a chemical reaction which occurs in the digestive tract.

According to the National Academy of Sciences' 1978 report on nitrates, they stated that the nitrite coming from the ingestion of cured meats "seems to be the most important regular source of exposure to the nitrite critical to the formation of carcinogenic nitrosamines and, equally important, the internal formation of nitrosamines could well be the more important source of exposure in the free-form variety."

From this, we believe that steps are necessary and must be taken to eliminate nitrite additives in the food supply, steps which go beyond those taken by USDA to minimize the preformation of nitrosamines in cooked bacon.

Though the industry may feel that there is not a nitrite issue, consumer organizations feel very much that the issue still exists.

Several other points merit attention. First, the USDA and USDA procedure for making and announcing their decision about the nitrite hazard in March 1979, through the letter of transmittal to the Congress, made it abundantly clear that any action to remove nitrite from foods would be based on a confirmation of the Newberne study.

Then, if such a confirmation were forthcoming, nitrite would be phased out gradually over a multiyear period. No precipitous, unscientific action was contemplated and none would apparently have been taken, had Newberne been confirmed.

Second, some charges have been made that this announcement caused dramatic declines in hog prices. They are both inaccurate and unfair.

According to current USDA information, the decline in hog prices came directly from tremendous increases in hog marketings and sizeable jumps in poultry production, which in turn came because of earlier herd buildups.

In addition, this announcement had a very positive public interest effect, in that it provided an incentive for the development of a suitable alternative to nitrite. Since the April 1979 announcement, a considerable increase has occurred in the search for a nitrite alternative, both on the industry's part and in Government.

To delay the earlier announced phaseout plan now would be to delay the next step in this progression to a nitrite alternative indefinitely.

In conclusion, Mr. Chairman, we feel that an abundance of evidence, as put forth by the National Academy of Sciences and other scientists, suggests that we must continue every effort to eliminate nitrite additives from the food supply.

The earlier plans of the FDA and USDA to phase out nitrite were scientific, logical, and very much in order. Lacking a really clean bill of health for nitrite at this time, we could see no reason to expose consumers to unnecessary risk, and we believe that it is important that these plans no longer be delayed.

I thank you.

Mr. JONES of Tennessee [acting chairman]. Thank you very much for being here. We do appreciate your testimony.

Without objection, your complete statement and the letter you submitted will be included in the hearing record.

[The letter and prepared statement submitted by Ms. Haas may be found at the conclusion of the hearing.]

Mr. JONES of Tennessee. We will move right along to the next witness, who is Mr. Marion Stackhouse, president of the Indiana Farm Bureau. He is representing the American Farm Bureau Federation.

## STATEMENT OF MARION STACKHOUSE, PRESIDENT, INDIANA FARM BUREAU; ON BEHALF OF THE AMERICAN FARM BUREAU FEDERATION

Mr. STACKHOUSE. Thank you, Mr. Chairman.

I am Marion Stackhouse, president of the Indiana Farm Bureau and member of the American Farm Bureau Federation board of directors.

I appreciate the opportunity to appear before this committee on a subject that is very important to livestock and poultry producer members of the Farm Bureau.

The American Farm Bureau Federation is a general farm organization representing more than 3.2 million member families in 49 States and Puerto Rico. FDA and USDA regulations of the red meat and poultry industries are of major interest to Farm Bureau members.

We commend this committee for holding an oversight hearing on the nitrite issue. We will not waste the committee's time reviewing the history of Federal efforts to regulate nitrites. You are familiar with the ill-fated record.

Our principal interest is to suggest modification of the laws and the regulations that result from these laws, that create the climate for the nitrite issue to occur.

The nitrite issue is not unique in Federal regulatory efforts. On November 9, 1979, just 17 days before Thanksgiving Day that year, the Secretary of HEW—Department of Health, Education, and Welfare—announced that some cranberries had been found to be contaminated with the pesticide amitrole, although no regulatory action was proposed. Cranberry sales fell 67 percent and the industry suffered a $15 million loss in 1 year. This announcement was made prior to the development of an approved residue testing method or the establishment of a no-effect level.

On October 18, 1968, the Secretary of HEW labeled cyclamates, a widely used, FDA-approved diet sweetener, as a carcinogenic agent.

All cyclamate-sweetened diet sodas were to be off the market in 2½ months, and a multitude of cyclamate-containing foods were to be off the grocers' shelves a month later.

Several million dollars' worth of canned fruits, already in the pack, were rendered unmarketable. The food industry's losses were estimated to be approximately $31 million. Further studies on cyclamates indicate that FDA was in error in its original charge.

The Government's actions against the use of nitrites follows the pattern already established—a pattern that involves direct costs to producers, processors, and marketers of agricultural products, plus significant additional costs for communications with the agencies, educational programs for farmers and nonfarmers, litigation, time, and travel.

Despite the direct cost of millions of dollars of lost produce and the indirect costs for responses to Government actions, there is an even greater cost involved. That cost is a loss of confidence by the American people in the judgment of the Federal Government.

That confidence must be restored. People should be able to believe Government pronouncements, which declare a chemical harmful or safe. Such pronouncements should be backed by scientifically creditable information.

The Newberne study, upon which the original nitrite action was based, has been largely discredited by peer review. It is inconceivable that such a peer review was not conducted prior to regulatory initiation, but that is what happened.

Now, the public is told by FDA and USDA, that "* * * we have concluded there is no basis for FDA or USDA to initiate any action to remove nitrite from foods at this time." Is it any wonder that people are confused about food safety issues and skeptical of Federal decisions?

Congressman William Wampler has introduced a bill, H.R. 6521, to establish an independent council to decide questions of scientific fact. We heartily endorse this bill.

The bill would create a council of qualified and distinguished members of the scientific community, recommended by their peers as men of professional competence and integrity. The council would review agency-held data prior to initiation of regulatory proceedings and determine what, if any, scientifically valid conclusions could be drawn. Then, the agency of jurisdiction, armed with verified facts, would begin appropriate regulatory steps.

Had such a procedure been available in 1978, the Newberne study could have been reviewed and the entire issue resolved in a timely fashion. Rather than place an additional delaying step in the process, H.R. 6521 would expedite Federal decisions and elevate their quality.

It is not the intention of H.R. 6521 to undercut existing regulatory authorities or to eliminate their ability to perform the important function of assuring the safety of food. Rather, the bill would separate into two distinct steps the scientific and political regulatory functions.

Both scientific validity and regulatory integrity would benefit from this separation. The proposed council, created as an independent body outside the domain of any regulatory agency, would be free of political pressure as it conducted its reviews.

The regulatory bodies would still retain the congressionally authorized authorities of protecting the environment, workers' health, or food safety. The agencies' decisions would, however, take on a new credibility of scientific support—a support the American people could join in.

The nitrite issue has been a source of frustration for farmers, food processors, FDA, USDA, and many others. We urge this committee to use the lessons of the past as building blocks for a better system of assuring safe food in the future.

We thank you for this opportunity to present Farm Bureau's views.

Mr. JONES of Tennessee. Thank you very much, Mr. Stackhouse, for a very fine statement.

Mr. Fithian?

Mr. FITHIAN. I just want to say that I intended to get that last vote cast and to get back here to introduce you, Marion Stackhouse, and to say how carefully and how hard Farm Bureau in Indiana has worked with our pork people to bring about this change. I was going to say all of those fine things in introducing a good farm leader in our State, but I will not say them now, because the time has expired.

[Laughter.]

Mr. JONES of Tennessee. Thank you, Floyd Fithian. The Chair waited for you just as long as it could, but we knew you were hardly speedy enough to get back to be here with the tight schedule that you have.

Now, I yield to Congressman Sebelius for the purpose of an introduction.

Mr. SEBELIUS. Thank you, Mr. Chairman.

It is my privilege to introduce Dr. M. P. Reeve, who is chairman of the Animal Drugs and Feed Additives Subcommittee of the National Cattlemen's Association. He is also a past president of the Kansas Livestock Association.

He is a member of the Kansas Board of Regents, which is the governing body of all of our universities. He is a very able veterinarian, with a good background.

I recommend his words to the attention of the committee.

Welcome, Jack Reeve.

## STATEMENT OF DR. M. P. REEVE, CHAIRMAN, ANIMAL DRUGS AND FEED ADDITIVES SUBCOMMITTEE, NATIONAL CATTLEMEN'S ASSOCIATION

Mr. REEVE. Thank you very much, Congressman. I certainly appreciate all the accolades. I hope that I warrant them.

I am a veterinarian, and I feed cattle in Garden City, Kans. I appreciate the opportunity to appear here to present the National Cattlemen's Association point of view, as it pertains to the handling of the nitrite issue.

Even more importantly, we want to discuss some positive suggestions which will give consumers the assurance they want and deserve, that the food supply is safe and wholesome, and at the same time provide some flexibility, so that we do not find ourselves in this predicament again over another nitrite-type issue.

The National Cattlemen's Association is the national spokesman for the producing segments of the Nation's beef cattle industry—that is, cattle breeders, producers, and feeders.

The National Cattlemen's Association represents approximately 280,000 cattlemen throughout the country. Membership includes individual members as well as 51 affiliated State cattle associations and 15 affiliated national breed organizations.

Our records indicate, that the sphere of activity regarding nitrates and nitrites began nearly 3 years ago, on October 18, 1977, when the U.S. Department of Agriculture gave the meat industry an ultimatum to show in 3 months how bacon could be manufactured using nitrates and nitrites without resulting in the formation of nitrosamines during processing or eating. Interestingly, this action was taken, even though USDA's own expert panel made no such recommendation in its final meeting, which was held just 1 month earlier.

Within 4 weeks, four consumer groups and Congressman Richmond from New York joined to demand that the U.S. Department of Agriculture issue a total ban on the use of nitrates and nitrites in the preparation of bacon, ham, and other meats.

The reason given was that the cancer risk from the chemicals was proven beyond any doubt.

However, within another month, Congressman Richmond exercised considerable wisdom by calling for a 2-year moratorium on USDA's action, instead of an outright ban, while Government and industry worked out a cooperative program to eliminate any problems which might exist from the use of nitrites.

During the next several months, the debate heatedly continued. Extensions were granted. Charges and countercharges of irresponsibility were made. Some no-nitrite products appeared on the market.

USDA proposed that traditional names be allowed on no-nitrite products. Positions were taken, attacked, and defended, and the news media dutifully and gleefully reported every blow. The industry was frustrated. The public was confused.

Then came August 11, 1978. USDA and the Food and Drug Administration announced the results of a recently completed study conducted by the Massachusetts Institute of Technology. That study, said USDA and FDA, ". . . strongly suggests that nitrite (not nitrosamines, but nitrite) produces cancer of the lymphatic system in test amimals."

Within days, United Press International announced it had learned that USDA and FDA considered the evidence so conclusive, that a plan to ban the use of nitrite had already been drawn up.

When the smoke had cleared somewhat from the nitrosamine announcement, this double-barreled blast from two of the Federal Government's most prestigious agencies blew the charge to battle more clearly than ever.

Cast into the center of this new controversy was an eminent MIT scientist, Dr. Paul Newberne. Dr. Newberne was called to Washington for questioning by the Senate Agriculture, Nutrition, and Forestry Subcommittee on Agriculture and General Legislation.

By now, the sounds of battle had grown so loud that it is questionable whether Dr. Newberne was heard, when he told the mem-

bers of the subcommittee that additional information was needed from another strain of rat and another species of animal. Dr. Newberne also said that he personally favored reducing the use of nitrites in food but only when it could be done without affecting public health.

Untold dollars and work hours later, on the parts of Government and industry, and 2 years later almost to the day—that is, on August 19, 1980—USDA and FDA, without fanfare, jointly concluded that there is no reason to initiate actions to remove nitrites from the U.S. food supply.

Industry and consumers alike would be justified in asking searching questions about what has been called a Federal Regulatory Mess. Consumers, in particular, would be justified in expressing concern about the possible health consequences which could have occurred had the use of nitrite been banned, as some demanded 3 years ago.

In the case of nitrite, there was not and still is not an effective alternative food preservative. While there is not one single proven case of cancer caused by the use of nitrite as a food preservative, there are many well documented cases of death from botulism, the primary disease against which nitrites protect us all.

Of concern to everyone is the effect this kind of business has on the credibility of science and scientists. We will let someone else argue whether it was science or the interpretation that was faulty, or if the interpretation and the recommended action was more political than factual.

The point is this. The time may come when the problem is real. Will consumers believe Government scientists? Or, will they ignore them, thinking that they will probably change their minds in a couple of years anyway?

Too often personalities, philosophies, and emotions get in the way, and matters are not handled as well as they might be. The nitrite matter was handled in such a way, that at times it seemed as if the regulatory agencies involved had more interest in seeking vengeance than in resolving the issue to the mutual benefit and satisfaction of everyone involved.

However, to serve crow pie is not why we are here today. What has happened cannot be changed. The challenge now is to look ahead and to think about changes in the basic laws, which will provide consumers assurance that the food supply is wholesome, sanitary, and safe, but which will not lead to near debacles like the one just barely avoided.

This and other similar problems will be best resolved with Government and industry working together cooperatively, instead of viewing each other as adversaries.

Another question of equal importance is the Federal grant system, which may serve to lock scientists into a preconceived point of view.

Food safety law revision should be a high priority for the 97th Congress. Our current food regulation system has been designed around laws which require the assessment of safety but generally do not address risk or hazard. Laws deal in absolutes and leave their interpretation to the regulatory agencies.

The detection of materials present in our food and the environment is an ever-changing science. Not long ago capabilities to detect at parts per million were exceptional. Today methods which measure in parts per million and smaller parts are common and usual.

The ability to find and measure finite levels of the various substances has outrun the ability to assess the significance of these findings.

The chief regulatory concern today of all parties along the food chain is that there is no standard, consistent, commonsense decisionmaking process on which to base food safety decisions. Ideally, such a coherent process should provide the highest possible level of well-being to the public at large. Consumers and industry alike could certainly share this goal.

Several shortcomings are evident in the present procedures involved in determining public policy issues, such as food safety, diet-health relationships, acceptable tolerance levels, et cetera. Some of them are listed below.

One, several different agencies are responsible for regulating food safety.

Two, there is a tendency among the agencies to initiate regulatory action, rather than to consider giving the public full information and promoting consumer choice.

Three, naturally occurring substances, which pose health risks, are treated differently from substances added to food, which pose the same risk.

Four, the Delaney clause, in particular, presumes to treat all carcinogenic materials the same. It is based upon the assumption that a threshold, or no-effect, level cannot be found. Strictly interpreted, the Delaney clause allows determination of whether or not a substance is carcinogenic to be based upon exaggerated dose levels, rather than on dose levels comparable to normal conditions of consumption.

Five, today the assessment of social benefit is generally not considered, whereas, heavy weight is given to social risk. There is no formal method of benefit-risk assessment, nor is there a philosophy present among regulatory agencies that such an assessment should be made.

Six, often consumers and producers are provided little information about why food safety decisions are made on certain food substances.

Seven, the allegation is often heard that regulators make decisions without the full participation of and information from all affected parties impacted by food safety decisions.

Eight, generally there is no range of regulatory options available to the regulator which could allow for a range of consumer and producer choices. Such options could range from doing nothing, to warning labels, to regulations limiting use, to an outright ban.

There are many scientific and philosophical questions to be addressed as positive solutions to such dilemmas. There will be some disagreement between and among interested parties as the process of revising food safety laws begins. However, there is widespread agreement that such action must be initiated as soon as possible.

The National Cattlemen's Association pledges its support and its efforts toward early action. We realize that Congress must ultimately amend several statutes in the process.

We are also aware that the Subcommittee on Health and the Environment, chaired by Mr. Waxman, and the full Committee on Interstate and Foreign Commerce must come squarely face to face with this issue.

Toward this end, we respectfully urge every member of the Committee on Agriculture to become deeply involved.

I thank you.

Mr. ROSE [acting chairman]. Thank you, Mr. Reeve.

Our next witness is Dr. William McCarville, chairman of the Science Committee of the American Industrial Health Council of Washington, D.C.

We are glad to have you, sir.

Mr. MCCARVILLE. Thank you, Mr. Chairman.

Mr. ROSE. If you have a full statement that you would like to put in the record, we will certainly put it all in.

Mr. MCCARVILLE. Yes, I will summarize the statement.

Mr. ROSE. Thank you.

Mr. MCCARVILLE. We would also like to attach to the full statement a list of member companies.

Mr. ROSE. Without objection, it will be a part of the record.

## STATEMENT OF WILLIAM J. McCARVILLE, CHAIRMAN, SCIENTIFIC COMMITTEE, AMERICAN INDUSTRIAL HEALTH COUNCIL

Mr. MCCARVILLE. Mr. Chairman, I am the director of environmental affairs of the Monsanto Co., but I am appearing here today as chairman of the Scientific Committee of the American Industrial Health Council.

Mr. ROSE. Is Monsanto the company that has the ad that says: "If you had to list everything that is in an orange, you would be in trouble"?

Mr. MCCARVILLE. Yes, Mr. Chairman.

The American Industrial Health Council welcomes this opportunity to address the importance of basing Government regulatory and policy decisions on the best science available and to discuss steps to insure that objective.

The American Industrial Health Council commends this committee for its role in creating the Science Advisory Panel under FIFRA and, more recently, the amendment facilitating peer review of Government-generated data.

This hearing makes clear that this committee recognizes these as just first steps toward assuring that the agencies act on the best science.

This is a very important subject. Today, I will confine my remarks to three points: One, the need to improve scientific risk evaluation; two, changes to improve scientific input to regulatory agencies; three, the need for national priorities.

The first step in any scientific evaluation is the validation of the data base. The Government agencies handling of the Newberne study and the Environmental Protection Agency's Love Canal chromosome study, with the resulting public confusion, point up the

need to establish scientific criteria and peer review procedures for the data and studies used by Government agencies.

The Government urgently needs to improve risk evaluation to: One, identify risks using the best science; two, establish the severity of the risk or relative potency; and, three, control the risk where appropriate and not alarm the public when the risk is small.

Scientific risk evaluation now has a cloud over it because of uncertainties in extrapolation methods and differences in the mathematical models used. The numbers generated by mathematical models have their place, but until we can biologically validate a model—and we have not done so—they are only one piece of data.

Given present understanding of biological mechanisms, it is more consistent with the data to establish categories of relative potency, as the National Academy suggested in the saccharine study.

Any change in the manner in which the scientific evaluation is performed should have the following objectives: One, that scientists of the highest qualifications perform the evaluation; two, that objectivity is maintained by separating the scientific evaluation from the regulatory function; and, three, that all agencies have access to all relevant data.

Determining whether or not a material is likely to cause cancer or other adverse chronic health effects involves scientific, rather than regulatory, judgments. AIHC advocates the separation of scientific determination from regulatory consideration.

Such determinations should be made by a panel of scientists, located centrally within the Government or elsewhere, but separate from the regulatory agencies whose actions would be affected. Their determinations would be limited to scientific issues. They would not intrude upon the regulatory responsibilities of the individual agencies.

Mr. Chairman, I have with me a copy of AIHC's proposal for the formation of a science panel, which I would like to submit for the record.

I also understand that, this morning, Ms. Foreman and Dr. Goyan agreed with the recommendation of Senator Eagleton, that they study alternate ways to improve peer review mechanisms used by their agencies. AIHC endorses the need for such studies but believes that they should not be limited to these two agencies.

I would also like to submit for the record an AIHC recommendation which urges that the National Academy of Science be considered as the appropriate group to carry out such studies.

To my last point—the need for national priorities—it is clear that the concept of a risk-free society is a cruel illusion. Chief Justice Burger made that point very clearly in his recent benzene decision.

Regulation must deal with real hazards. We need a system of priorities which handles worst cases first and disregards trivial cases.

Each agency has some system of establishing priorities, but there is no basis for establishing national priorities.

AIHC has made two proposals to facilitate the establishment of sound national priorities. First, we have proposed a comprehensive approach to the issue of cancer, which deals with the whole prob-

lem, not only exposure to chemicals but also cancers due to lifestyle—smoking, diet, and alcohol.

Second, AIHC has made a proposal for a science panel, which would facilitate the establishment of national priorities.

In the integrative process between the agencies and the panel national priorities would emerge.

We do not have endless dollars to spend. Establishment of national priorities is essential to insure that health dollars are wisely spent.

We believe that this matter should, and we hope it will, receive the attention of the Congress.

Thank you.

Mr. ROSE. Thank you very much, Dr. McCarville.

Without objection, your entire statement and other submissions will be included in the record at this point.

[The prepared statement of Mr. McCarville may be found at the conclusion of the hearing.]

Mr. ROSE. I believe that Dr. Nesheim, chairman of the task force on health, safety and quality, of the Grocery Manufacturers Association of America, had an understanding with the previous chairman of the subcommittee that he would be allowed to speak briefly out of turn because of his schedule problems.

Is that correct, sir?

Dr. NESHEIM. That is correct, sir.

Mr. ROSE. If you will summarize as quickly as you can, your written statement will be printed in its entirety.

**STATEMENT OF ROBERT O. NESHEIM, CHAIRMAN, TASK FORCE ON HEALTH, SAFETY, AND QUALITY, GROCERY MANUFACTURERS OF AMERICA, INC.**

Mr. NESHEIM. Thank you, Mr. Chairman. I appreciate your accommodation to my schedule.

My name is Robert O. Nesheim. I am vice president of science and technology of the Quaker Oats Co. I am testifying today on behalf of the Grocery Manufacturers of America.

It has become increasingly apparent that our food safety laws and their implementation are badly out of date. There has been an enormous change in our scientific knowledge.

In 1958 the lower limits of analytic chemistry were capable of detecting substances at parts per million in the food supply. Today substances can be found at orders of magnitude down to parts per trillion or less.

The net result has been a dilemma that has confused and confounded the public, the regulatory agencies, the food industry, and the Congress.

FDA officials have underscored the impossibility of banning all food that contains a carcinogenic substance or even of including a cancer warning in labeling.

FDA stated, in October 1979: "Indeed, a requirement for warnings on all food that may contain an inherent carcinogenic ingredient or a carcinogenic contaminant (in contrast to a deliberately added carcinogenic substance) would apply to many, perhaps most, foods in a supermarket."

A no-risk food policy is thus impossible of achievement. As the Supreme Court stated in its recent decision on regulation of benzene: "But 'safe' is not the equivalent of 'risk-free.'"

We agree with the Supreme Court decision in that case, that only a significant risk can properly be the subject of regulatory action.

This is not the time or place to engage in a detailed analysis of the current food safety provisions of the Federal Food, Drug, and Cosmetic Act. We offer, however, the following five general principles that, if adopted, either through administrative action or through a change in the law, would reflect current scientific knowledge about food safety and assure a continued safe and abundant food supply in the future.

One, the food supply, like all other consumer commodities and indeed all human activity, must be judged on the basis of acceptable risk, not on the basis of no risk. There is no item of commerce and no human activity that is absolutely risk-free. We must not tolerate significant risks from our food supply, but we cannot expect to eliminate insignificant and minor risks.

Two, the Government should properly be restricted to assessing the risk of food and should be precluded from regulatory decisions based upon its perception of the benefits of particular food products. Without doubt, FDA has substantial expertise in assessing the risk that any food may present. It is properly within the province of the Government to determine those risks and to inform consumers about them or, where they are unacceptably high, to ban them from the marketplace totally.

However, the FDA has no expertise whatever in determining the attributes of food that consumers desire. Nor is it the proper function of government to dictate to the public the kinds of food they will be permitted to purchase and consume.

Three, the law must continue to reflect the special status of food components with a long and recognized history as a part of our diet. It would be unreasonable and unworkable to revoke the current provisions of the Federal Food, Drug, and Cosmetic Act, that exclude substances subject to a prior sanction or that are generally recognized as safe, or GRAS, from the requirements for food additives.

Four, it is important to bring to bear on food safety decisions the best scientific expertise that exists in the country. GMA agreed when FDA turned to the Federation of American Societies of Experimental Biology to conduct the initial evaluation of the safety of GRAS food substances.

This outside review has resulted in decisions that have gained widespread acceptance in FDA, in industry, and in the public at large. Continued reliance upon outside experts in food safety decisions is essential if they are to have high scientific validity and public credibility.

Five, more flexible enforcement of the food safety provisions of the law is badly needed. Administration of food safety laws must be undertaken with calm deliberation rather than in a crisis atmosphere.

These five general principles outline a reasonable food safety policy for the future. GMA would be pleased to work with the

committee in developing specific legislation, if administrative action is insufficient to accomplish these goals.

Again, I appreciate the opportunity to present this statement.

Mr. ROSE. Thank you very much, sir.

Without objection, your entire statement will be included in the record.

[The prepared statement of Mr. Nesheim may be found at the conclusion of the hearing.]

Mr. ROSE. Will all of the previous witnesses since 2 o'clock please return to the table now for questioning as a panel.

We will go through our usual procedure of allowing members to question a panel for 5 minutes each. We will then proceed to the next series of witnesses.

Before I yield to Mr. Wampler, I would like to make one observation about this subject, that I think those of you in the meat industry may find interesting.

If you have not read it, you ought to get the September issue of Psychology Today. The cover article talks about cancer being healed through positive thought forms.

The suggestion is that, if cancer can be cured through positive thought forms, it is caused by negative thought forms. Therefore, some of you might consider the announcements from USDA and from the Food and Drug Administration in light of that article. The announcement that nitrites cause cancer could, under that theory, have more carcinogenic effects than nitrites themselves.

Do not laugh at it until you read the article. It is worth a dollar to read it.

In the Intelligence Committee we have looked at the interest the Soviets have in this, and it is certainly not to be taken lightly. We do not know what causes cancer. How you think about it might have a lot more to do with it than we think right now.

Mr. Wampler is getting to be known as the father of the nitrite issue, so I will yield to him.

Mr. WAMPLER. I do not know whether to take that as a compliment or not.

Thank you, Mr. Chairman. First of all, let me make a general observation, that, as least as far as I am concerned, the most significant thing that came out of our session this morning was the acknowledgment by both Dr. Goyan and Mrs. Foreman that the time has indeed arrived to take a more careful look—and Congress should take a more careful look—not only at the Delaney clause but at other of our laws affecting food safety.

I certainly agree with them. I think it has taken us quite a while to get into that posture. I am delighted that they are now taking that position.

I want to compliment all of the witnesses who testified thus far this afternoon. We had a variety of interests represented by the witnesses. You are all individuals who are extremely knowledgeable in the field of food safety.

I guess this question should most appropriately go to Mr. Mohay. Is there a known effective chemical substitute for nitrite as a food preservative, which is available in commercial quantities in the United States today?

Mr. MOHAY. No, sir, not at this time. I cannot relate the number of chemicals and other additives that have been tested. There are something in the neighborhood of 1,200 or 1,400 research projects to try to develop a substitute, but there is none known at this time.

Mr. WAMPLER. Dr. Tannenbaum of MIT testified previously before this committee. As I recall, it was to the effect that you could use ascorbate. I think he was talking about vitamin C, which I think is one and the same thing.

In any event, I think what Dr. Tannenbaum was saying was, that you could use vitamin C and block nitrosamine formation. I think he was referring primarily to bacon.

What is customarily used as a food preservative in other countries in the world, especially the industrialized nations of Western Europe?

Mr. MOHAY. Sodium nitrite and sodium nitrate are the only known cures, and they are used worldwide in manufacturing and processing to cure food products.

Mr. WAMPLER. Is there any new or startling research that has taken place in other consuming countries of the world which are highly industrialized, that you are aware of?

Mr. MOHAY. There is a lot of research going on, but there have been no breakthroughs that I am aware of.

Mr. WAMPLER. Therefore, it would be fair to say that nitrite is still being used universally as a food preservative, even in some societies that we might classify as primitive compared to modern technological countries. Is that correct?

Mr. MOHAY. If they have the right kind of salts, they are using nitrite. That is right.

Mr. WAMPLER. I am sorry that I did not get to hear Ms. Haas' testimony. Is there general agreement that the time indeed has come for us to take a hard look at the rigidity of the Delaney clause and other laws affecting safety? Is that a fair conclusion?

[Several panel members respond in the affirmative.]

Mr. WAMPLER. If I may use this expression, the ball is in our court now, and it is up to Congress to respond. In many ways, this is a highly emotional issue.

As you well know, Mr. Chairman, it is because of the multiplicity of jurisdictions among the committees of the Congress, that it would be very difficult indeed for one committee of the Congress to bring about universal reform in this area. I suppose each committee can deal with its own turf, so to speak.

It occurred to me, as I was walking over to answer one of the rollcalls this afternoon, that the committee might want to give some serious consideration to consultation by the chairman of our committee with other committee chairmen, that have jurisdiction over this subject matter, as well as to consultation with the Speaker of the House of Representatives to see if it would be possible or advisable to consider the feasibility of appointing an ad hoc committee, as we did on energy and other matters.

We could approach this as a unified effort. As I envision it, we are going to have to amend at least four or five basic statutory authorities in order to get an overall, intelligent, and coordinated approach to solve what I perceive to be quite a dilemma.

I just want to say to the witnesses, that we appreciate your coming here and sharing the information with us. Many of you have been kind enough to respond to letters that I have written to you about legislation that I have introduced. Some of you have been very helpful in drafting that legislation by making constructive suggestions.

I offer that as one possibility, Mr. Chairman, because I think it ought to be of the highest priority in the next Congress. Regardless of which administration is in the Congress, I think this issue should be approached in a nonpartisan way. It should not necessarily be an adversarial proceeding but one wherein we can get everyone to cooperate.

I want to thank you for your appearance here this afternoon.

Mr. ROSE. That is an excellent suggestion and is certainly one we should pursue. I would observe that a newspaper in my district said recently, about the school prayer amendment, that the last place we needed to look for help with prayer was to Congress. There are some in the audience who might feel that the last place we need to look for aid in assessing health risks is to Congress.

However, I think it is our responsibility.

I hope the panel and those in the audience will give us some guidance as to how that might be changed.

I recognize Ms. Haas.

Ms. HAAS. I would like to make one comment. Mr. Wampler, in my prepared testimony I made reference to the importance of scientific peer review. Certainly, consumer organizations who work with Congress and who work with the Federal agencies are aware that some fine tuning may need to be done to the food safety laws.

However, in any kind of ad hoc effort, let me underscore the importance of working with consumers and of recognizing that the Consumer Federation, CNI, and CFA in particular, at the last meeting of the 240 organizations representing over 30 million people supported the retention of strong food safety laws, which would not increase consumer risk.

I think, in developing public policy, we have to work with all who are part of the food system in that development. The consumer role, while it may differ from the industry, should be taken into consideration equally.

Mr. WAMPLER. If I may, Mr. Chairman, I would like to say that I could not agree with you more. You are exactly right.

To the extent that I can influence the deliberations, your views will not only be welcome but they will be sought.

The point I want to make is, that it seems as if the legislative process of recent years has become an adversarial kind of proceeding, but that does not necessarily have to be. I think we all seek the same answer. The question is: How do we get there?

Ms. HAAS. I think that is very true. I think one of the important ways to get there is for consumers to be represented by consumer organizations.

We may differ very strongly when it comes to protection of consumers, but I think we are very willing to work with the committee in looking at a very important problem.

Legislation should not remain static forever. I think we all recognize that, but at the same time, we cannot minimize necessary health protection.

Mr. WAMPLER. Again, I could not agree with you more. I think that is a very wise observation.

As I indicated, if this committee proceeds in that direction next year, we will actively seek your counsel. I think, in the past, your organization and others that you have represented and speak for today have been very helpful.

You know, I have been a very strong believer in consumer education, because we are spending a considerable amount of the Federal tax dollar in various forms of nutrition programs, most of which I have supported. However, sometimes just throwing dollars at a problem does not necessarily solve it.

The lack of proper nutritional education thrust is certainly an important matter, and it is not always low income people who are in need of nutritional education. This is why I have been a strong supporter of EFNEP, the one-on-one type of educational program, that is carried on by the Department of Agriculture to help, primarily, low income people—not only in nutritional education but to have better management of their total resources. This is an area in which I am sure we share a great deal.

We must consider that this year we are going to be spending something in excess of $10 billion for food stamps. Let me hasten to add, that I have supported the food stamp program. I have tried to modify and reform it, at least as I perceived that it needed reforming, but I have no quarrel with it. Nevertheless, with a program of that magnitude, I think we probably ought to be spending a little bit more of that total amount in trying to help people through nutritional education, so that we can indeed provide a more adequate diet for all the American people.

In that regard, I am sure you and I could find much common ground on which we could agree.

Mr. ROSE. Without objection, the gentleman will be allowed to revise and extend his remarks. [Laughter.]

Mr. Fithian?

Mr. FITHIAN. Thank you, Mr. Chairman.

I am impressed by the various arguments that are made by industry and the concerns that were expressed by the American Pork Producers and others during this controversy and during the time when sales, revenue, income, and profitability in the industry from top to bottom were seriously impaired.

I was rather impressed by the American Farm Bureau's ticking off of the various examples of this, that have happened with FDA announcements on the possibility of carcinogenicity in this, that, or the other product.

You list here, Mr. Stackhouse, two or three kinds of impact—the cost, the loss of confidence of the American people in the judgment of the Federal Government. Beyond that, there is sort of an embargo. There is a loss of confidence in the source and quality of the supply of food, which could well be added, as you indicated earlier.

I am concerned with the dilemma in which the Government finds itself, when a commissioned test study comes up with something of this nature, and with how you handle it in such a way

that, in the interim between when you first get the information or the suspicion and the time when you have finally removed the product altogether, because it is in fact harmful, or, as in the case of nitrites in cured meat, you declare that the initial study was at fault.

It is the economic impact in the intervening time that causes such havoc, not just economic impact. It is my judgment that people, for some time to come, will be less likely to buy bacon and less likely to buy cured meats, because it is like a political charge against one. You read that, but you do not get the answer as fully later on.

I would be curious to know whether you or any of the panel have any suggestions to make as to how those of us, who are in support of Mr. Wampler's bill, might try to grapple with that—the loss of confidence and loss of income which come between the time of the first blush of the report and the its final disposition.

Mr. STACKHOUSE. I am not sure I can answer your question, other than to say that I think you are exactly right. If everybody had followed the advice, we would have been in an even worse economic condition.

I do not think farmers want to poison anybody. I certainly want to eat. I am a consumer too.

My wife tells me that she goes to the grocery store and sees people avoiding bacon. I had bacon for dinner. I intend to die happy fed on it.

Nevertheless, this is part of our problem. It does cause an economic loss. I am a pork producer. I pay membership to the American Pork Producers. I belong to the Cattlemen to try to promote meat, because I think it is healthy.

However, I then have to take the same money and fight the Government, because today they say: "Eat less meat."

This is really the kind of problem we have today. It is adversarial. I think that has been brought out here.

I heard your comments this morning about public relations. I agree with them. I think we need caution.

I do not think Government people realize that a statement may be made in good faith and have the impact on industry that it has.

This country does not have unlimited resources. I will tell you that we have a lot of young farmers in our State that may sell out this year, because they had $27 hogs this year.

The testimony today said that this did not have any affect, but this effects demand. If anyone in the Department does not recognize that demand is half of this cycle, then they do not recognize the problem. I think that is part of our problem. They are dealing with issues that they really do not understand.

There is nothing wrong with the consuming public getting involved, if they are an educated consumer public. If they are not, they can surely come up with the wrong answer.

We find that in our organization, when we are making policy. If someone comes who is not informed, he can guide you wrongly. We have to avoid that. I think that is what we suffered this time.

Mr. FITHIAN. Does anyone have anything to add?

Mr. MCCARVILLE. I do not want to minimize the import of the economic loss, but I think there is another loss that might be

sustained by the public as the result of the early use of improperly reviewed data. That is the general loss of the confidence in the Government to do proper science.

I think, therein lies the danger which is every bit as real as the economic impact resulting from the misuse of information. That is why we have suggested the prompt and very credible review of scientific information generated by the agencies by a science panel, prior to its being exploited, let us say, in the media.

Mr. FITHIAN. That is, of course, given the likelihood that somewhere along the way, somebody is going to know that tests are being run and given the tendency to run to the media with startling information, there is still a time gap in there where it is very difficult to deal with it, even with the very best of intentions. It is that that bothers me.

There is an old saying, that once the word is out of the mouth, you cannot reach out and bring it back.

Mr. MCCARVILLE. However, in many cases, a good scientific review of the protocol of the study before it even starts could head off a bad study which would generate data that might be harmful.

Mr. BULLER. I have to respectfully disagree with Ms. Haas. Historical data will show, that bellies, of which bacon is made, have been, up until the announcement 2 years ago, 1½ times the weight per 100 of live hogs.

Since that time, bellies have sold for the same price or less than. Therefore, there is, we think, a definite effect.

Pork producers are suffering from this. We are more concerned about consumer attitudes. We want them to know we have a very nutritious product.

By the same token, we as family farmers cannot survive without a product.

Mr. ROSE. Thank you all for your comments. We very much appreciate your response to Mr. Fithian's questions.

I will now turn to Mr. Sebelius for his 5 minutes.

Mr. SEBELIUS. Thank you, Mr. Chairman.

I will be brief, but if you will pardon, I will make a personal reference. A year ago, when I was sitting on this committee, I thought of cranberries, cyclamates, nitrites, and all of that stuff as being basically a relative thing. However, since then I have discovered that I have prostatic cancer.

With that, I have received radiation with cobalt, which is well acknowledged to be cancer-proving or developing.

I think Dr. Reeve mentioned that a lot of the diethylstilbesterol that was used in the battle, so to speak, was supposedly used illegally by people in my district. However, one of the greatest medicines there is for fighting prostatic cancer is diethylstilbesterol.

There it is, an item to assist mankind, especially males over 60.

I am very concerned about cancer. I am very concerned that we do not have anything that would add to the risk of a person developing cancer. I went through the time of saying, "Why me, Lord," as do many of us when we are hit by something like that.

However, I say that the testimony that I have heard here today and a little bit of the defensive presentation by FDA and the Assistant Secretary for Food and Consumer Services, said to us

something that Mr. Wampler confirmed; namely, that the Delaney amendment has to be updated. To deal with cancer, or to deal with the subject, it cannot be black or white in view of the technologies that we had when it was adopted by Congress.

This Congress, for political reasons and otherwise, has not stepped up and faced the problem.

I want to compliment Mr. Wampler for his suggestion that we go at it another way, because many of us are apprehensive about where the jurisdiction lies. I hope that the next session of Congress, of which I will not be a Member, will establish an ad hoc committee and get together with you people and all those who have a vital concern and will take the proper steps to put the Delaney amendment in perspective, so that it can be a working tool that will take into account the shades of gray that we have.

It should not be just black and white. It should not promote the scare things.

I am very apprehensive about anything I eat, more especially if it has been suggested through some test with rats, or otherwise, that it is carcinogenic.

I guess the substance of my remarks are that, I think, Mr. Wampler's suggestion is valid. From my own standpoint, I know that many of you came here at your own expense to testify on this problem—and it is a problem—and to give us the benefit of your expertise. I just want to thank you and hope that you will join with this committee and other Members of the Congress in trying to come forth with the right workable solutions, so that we fight the problem, rather than just sitting in two camps and fighting each other.

I appreciate your attendance.

Thank you, Mr. Chairman.

Mr. ROSE. Thank you, my friend. We will miss you in this committee next year, because you always lent great insight to our deliberations. We appreciate your comments.

Congressman Grassley?

Mr. GRASSLEY. Thank you, Mr. Chairman. I appreciate the panel, as Mr. Sebelius does, coming here on your own time and at your own expense, to help share with us some of these problems we have had.

I think that the nitrite issue proves that our checks and balances system of government can work. We have probably had, in the last few years, in the bowels of the bureaucracy people who have gotten positions, who have really been waiting for a long period of time to take certain directions on the dietary, nutritional involvement of the Government, to use that tool and maybe to accomplish certain goals. Although I am not exactly certain what they are, I am sure that they know.

We have dealt in this committee not only with the nitrite issue but with the dietary guidelines. There has been the full weight of the power of Government brought to bear on some things that have not been entirely scientifically upheld.

The people promoting them probably felt that a social good was being accomplished, even though there might be some harm brought to others. I suppose that they felt they were following the dictates not only of their consciences but of law.

We have gotten ourselves to a place where it is probably believed that we can have a risk-free society. The proponents of the various points of view on changing our diet or restricting certain ingredients in meat products and food products generally believed they could accomplish their goals that way, even if there was some harm done to the producers, and even with the threat to the consumer, for instance, in the case of botulism.

We have reached a point now when, because of the checks of our Government on the administrative process, we have hopefully brought to the bargaining table the various sides, so that a rational approach can evolve from the system, and where there is need for change of public policy that must be made, that they can be made, but made in a responsible manner and, most importantly, based on sound scientific judgment.

I see the process, even though it has been very frustrating to me to wait for a long period of time for some of these problems to be worked out, as one that nevertheless gives me additional faith in our system of government. Out of a lot of battles do come some good.

If we can get some people in the administrative branch of Government, who felt that they could move to almost any length to accomplish their goals, to slow down, and if in the process we can get people on this committee to wake up to the fact that there may be some dangers to which we have not given proper attention, and if in the process we can get science more deeply involved, then obviously out of the whole system, I think, only good can come.

That is what I feel has come out of this controversy over nitrite. I am glad to have been a part of it, not only for the good of helping some of my constituents who felt that they were hurt, not only for the good of protecting my consumers from botulism, but also for getting more scientifically sound judgment into the political process.

I am glad to have participated in it, and I thank you folks for participation in it.

Mr. ROSE. I said that we would miss Mr. Sebelius next year. I will say that I hope you are back in this committee next year.

Mr. GRASSLEY. I will either be back on the farm or over in the Senate.

Mr. ROSE. We want you back over here.

I thank all of you very much. We appreciate your testimony. You are excused.

I will at this time turn the chair over to Congressman Baldus, chairman of the Dairy and Poultry Subcommittee.

Mr. BALDUS. The problem now is how to proceed. I understand that Dr. John Todhunter has a time problem and has asked to be moved ahead on the schedule, so I will ask Dr. John Todhunter as well as the panel of the Council of Agricultural Science and Technology, made up of Dr. Cecil Howes, Dr. Richard V. Lechowich, Dr. Bernard L. Oser, and Dr. Thomas E. Shellenberger, to come to the table at the same time.

Mr. Todhunter, if it is all right with you and with the committee, we will excuse you after your presentation and defer questions. They may be given to you in writing. You may respond in writing.

With that, and while the other members are assembling, Dr. John Todhunter of Catholic University, Washington, D.C., for the American Council on Science and Technology of New York, N.Y. Dr. Todhunter, I am sure that you and all of the other members realize the time constraints here that have been spelled out by the chairman. We would appreciate it if you would summarize your remarks.

We will probably have another problem—that is, a vote. However, you may proceed.

## STATEMENT OF DR. JOHN TODHUNTER, CATHOLIC UNIVERSITY; ON BEHALF OF THE AMERICAN COUNCIL ON SCIENCE AND HEALTH

Dr. TODHUNTER. I thank the chairman of the committee for his indulgence in allowing me to give my statement ahead of time.

I would like to point out that our organization is called the American Council on Science and Health. It was inadvertently written as the American Council on Science and Technology.

I am Dr. John Todhunter, chairman of chemistry at Catholic University here in Washington. I am appearing today on behalf of the American Council on Science and Health, to which I will refer as ACSH.

We are a consumer-oriented educational association, directed by a panel of some 70 scientists from around the country.

The evaluation of food chemical safety is a complex task. It depends not only on the analysis of scientific evidence of hazard, but for those chemicals already in use in foods, it must consider economic and political factors as well.

Today there are about 2,000 chemical additives approved for use in foods. There is also an unknown number of chemicals which occur naturally in foods or are present as the result of accidental contamination.

For the vast majority of these chemicals we have no information about their potential health hazards. Neither do we have the economic and scientific resources to study each of them in depth.

In general, our system of food additive regulation has worked well. The United States has the most abundant, varied, nutritious, and safe food supply in the world. This is largely the result of the use of chemicals to fertilize crops and control pests, and to package and preserve foods for distribution throughout the country.

The controversies over saccharin, nitrite, and now, caffeine are exceptions to the general success of the system, but they are important exceptions, because they raise fundamental questions about the process by which we regulate food safety.

Advances in the scientific capacity to detect minute quantities of chemical in foods and to evaluate the potential health effects of food chemicals have made it clear that food safety is a relative term.

These advances have demonstrated that a food supply that is absolutely safe under all conditions for all consumers is an unattainable goal. The American Council believes that this absolute safety concept, as embodied in the Delaney clause of the Food, Drug, and Cosmetic Act, is no longer an acceptable basis for making food safety decisions.

If the Delaney principle were uniformly applied to all food chemicals, it would result in the banning of an unacceptably large number of foods. The loss of these products would inflict health and economic costs on consumers and food producers far in excess of the benefits gained.

For this reason, the American Council endorses changes in the food safety laws that would require balancing risks against benefits. Health risks should be balanced against health benefits. Economic costs should be balanced against economic benefits. There is at present no way to acceptably balance health benefits and risks against economic benefits and costs.

Under the current system of safety regulations food chemicals are classified in one of several categories. These are naturally occurring food constituents, unavoidable contaminants, pesticides, new animal drugs, color additives, food additives, GRAS substances, and prior sanctioned substances.

For each of these regulatory categories a different set of safety criteria may apply. The nitrate and nitrite present in leafy vegetables, for example, does not require the rigorous testing demanded for nitrite in cured meat.

Thus, in many cases, the safety determination of certain food chemicals is determined by their regulatory definition rather than by their inherent toxicity.

This dichotomy between chemicals naturally present in foods and those deliberately added by man has led many consumers to believe that natural substances are harmless, while identical man-made substances are dangerous. This inconsistent approach to safety evaluation is one of the most serious shortcomings of the current law.

In recent months several proposals have recommended changes in our food safety laws. We believe that the suggestions of the National Academy of Sciences report, "Food Safety Policy: Scientific and Societal Considerations", and the Food Safety Council's system of food safety assessment deserve careful consideration.

Although neither of the reports can be adopted in their entirety, together with the Food and Drug Administration's recommendations and the various bills already pending before the House, Congress has a sufficient base from which to devise a food safety policy that fits our changing needs.

The American Council on Science and Health believes that a thorough congressional review of our food safety laws is needed. In our opinion, the most effective system of food safety evaluation is one which is based on realistic concepts of safety, takes into account both the risks and benefits of use, is internally consistent, and allows equal access for consumers, food producers, and regulators.

We feel that in the absence of complete peer review and the demonstration of reproducibility, no single bioassay in animals is compelling enough by itself to warrant the banning of a food chemical already in widespread use. There are too many statistical and methodological problems inherent in bioassays to warrant such precipitous action.

Thank you.

Mr. BALDUS. I want to thank you, Dr. John Todhunter. With the permission of the committee, we will excuse Dr. Todhunter, so that he may catch his plane. Thank you.

Mr. WAMPLER. Mr. Chairman?

Mr. BALDUS. Mr. Wampler.

Mr. WAMPLER. If I may, I would like to have the privilege and opportunity to introduce two of the panel members, since they are constituents of mine and friends.

If you will note on the witness list, the panel is appearing here on behalf of the Council on Agriculture, Science, and Technology, popularly known as CAST.

I would like to publicly express my appreciation to CAST for the excellent way in which they responded to a request that I made of them, when the nitrite controversy first came to my attention, and the very excellent way in which they called upon the expertise of their membership to give advice and guidance to me and to others in the Congress.

For that, and for their many good deeds in the past, I do want to thank them.

Mr. Chairman, the person who will be introducing the panel is Dr. Cecil Howes, associated with Virginia Polytechnic Institute and State University, which is the land-grant university of Virginia, and of which I happen to be a graduate.

We also have Dr. Richard Lechowich, who is head of the department of food science and technology at Virginia Tech, as it is popularly known.

This does not mean that I do not have equal regard for Dr. Oser and Dr. Shellenberger, but they do not happen to be constituents of mine.

Let me say, Mr. Chairman, that Dr. Lechowich is recognized, I think, as an international authority in the general field with which we are concerned. We appreciate them taking time to come here and to share with us their expertise.

Again, I want to express my appreciation to CAST and to its entire membership for the many fine contributions that you have made in helping, particularly, this committee to have a better understanding of the complexities of many of the problems that we are called upon to legislate upon.

Dr. Howes, I thank you very much.

Dr. HOWES. Thank you for those very fine words.

Mr. BALDUS. Let me just interrupt for a moment. It has been suggested that perhaps the four panel members could hold their testimony to 10 minutes. Is that agreeable?

Dr. HOWES. We will make very effort.

Mr. BALDUS. Thank you very much. I will simply allow you, Dr. Howes, to allocate the time.

Dr. HOWES. Thank you.

## STATEMENT OF DR. CECIL HOWES, VIRGINIA POLYTECHNIC INSTITUTE AND STATE UNIVERSITY, ON BEHALF OF THE COUNCIL ON AGRICULTURAL SCIENCE AND TECHNOLOGY

Dr. HOWES. Thank you very much for your comments, Congressman Wampler. I would like to express my condolences, even in the short time that exists, to Dr. Oser and Dr. Shellenberger for not

having you as their Congressman. They miss a great deal by not being in that category.

I am Cecil Howes. I am the cultural liaison officer for Virginia Polytechnic Institute and State University. Also, on a volunteer basis, I am Washington representative for the Council on Agricultural Science and Technology, as the Congressman stated, better known by our acronym, CAST.

It is in the latter capacity that I am here today.

Just for the record, CAST is a consortium of 25 scientific societies, designed specifically to provide scientific input into food and agricultural matters of national concern. As such a consortium, we believe that we represent the agricultural scientific community quite adequately.

CAST has enjoyed the opportunity of working with this Committee on Agriculture on numerous occasions, including the nitrite evaluation.

Among these activities were the preparation of a scientific task force report, initiated by requests from Congressman Wampler and Congressman Foley, entitled "Nitrite in Meat Curing," which was actually issued in March 1978.

There was also a congressional report and a press conference on nitrites in food processing in October 1978, and upon the request of members of this committee, we were among the first to attempt a scientific analysis of the now well known Newberne report from MIT and to point out certain scientific weaknesses in the structure of that report.

We, therefore, are especially pleased, Mr. Chairman, that Congressman Wampler has invited CAST to assemble a group of distinguished scientists here at this hearing. Each of these scientists has been selected by his peers in recognition of his personal qualifications. Each will speak on an individual basis, not for CAST because CAST as an organization makes no policy recommendations.

As requested, Mr. Chairman, in view of the extreme pressures of time today, each of these scientists will make only a very brief statement relative to his prepared comments. We wish we could say more.

We will request, with your approval, that their full texts be introduced into the proceedings of this hearing.

Mr. BALDUS. Without objection, they will be included in the record.

Dr. HOWES. Thank you, Mr. Chairman. I should like first to introduce Dr. Richard Lechowich. He is head of the department of food science and technology at Virginia Tech. He was chairman of the CAST nitrite force, earlier referred to, and he is a distinguished and world known food microbiologist.

Dr. Lechowich?

## STATEMENT OF DR. RICHARD V. LECHOWICH, HEAD, DEPARTMENT OF FOOD SCIENCE AND TECHNOLOGY, VIRGINIA POLYTECHNIC INSTITUTE AND STATE UNIVERSITY

Dr. LECHOWICH. Thank you, Dr. Howes.

Mr. Chairman and Congressman Wampler, I would like to address my remarks to go beyond the nitrite issue and that of dry-cured products, and summarize my remarks by attempting to place

the risks we have associated with food in perspective, then to mention the development of methodology for toxicological assessment of foods, and finally to list four points dealing with food safety regulations.

Safety is a term that has been previously used in quantifying risk assessment situations. Current knowledge, however, suggests that safety as applied to our food supply is an allusive concept, that cannot be established with certainty.

In light of presently changing concepts, the acceptability of some degree of risk might be compatible with the previously accepted general definition of safety.

However, a more realistic approach is the evaluation of risk itself.

The food-associated risks have been grouped into six major categories and will be discussed, ranging from the condition of offering the most risk or hazard to the least hazardous situation.

The first is microbiological risk. The risks caused by the presence of contaminating microorganisms is accepted to pose the greatest risk to human health. However, the exact risk or prevalence is difficult to quantify, since the illnesses that can result from such food contamination are not always reported by physicians nor recognized by the victims themselves.

Nevertheless, informed estimates have indicated that as many of 22 million Americans may suffer from the effects of bacterially contaminated food each year. Thus, about 1 out of every 10 people could be affected, and only the common cold causes more human discomfort and loss of time.

The second risk is that of nutritional risks. These are due to outright malnutrition. They are, however, relatively uncommon in the United States, but several nutritional surveys have shown that suboptimal intake of several key nutrients and poor dietary patterns are widespread.

Some of these deficiencies are due to poverty, some to ignorance, some to indifference, and some to misinformation.

The third risk is that of environmental risks. These rank next but are perhaps one one-thousandth as important as the first two hazards. It is the implied or potential hazard which is the basic concern in the area of environmental risks.

Examples include the polychlorinated biphenyls, or PCB's, and polybrominated biphenyls, or PBB's.

Risks from natural toxicants is risk No. 4. These substances include any food component that shows unusual or serious toxicity or which we consume with a narrow margin of safety. In addition to the real hazards from food allergies, our food supply contains an enormous variety of naturally occurring toxic substances, that can be quite toxic, even when consumed in very small amounts.

Natural toxicants are less important to the present American food supply, due to an abundant and more varied diet.

Five is that of pesticide residue risks. Pesticide risks are closely associated with the risk of environmental pollutants. However, they justify separate listing because many of them are intentionally applied to food and food crops.

Six are food additive risks, least important as a food hazard. The low risk from pesticide residues and food additives is partly the result of the scientific and regulatory attention they receive.

Moreover, the risks from microbiological and nutritional factors are high, because they are the result of how each of us chooses, uses, and abuses our food. The hazard from food additives, pesticide residues, and environmental pollutants are both remote and small, yet in the press, legislative and consumer groups, they receive the most attention.

Microbiological and nutritional hazards are clearly far greater but are widely and largely ignored, yet these most important and disregarded sources of risk are precisely the ones most within individual consumer's control.

In short, the attention we give these matters is inversely proportional both to their actual importance and our ability to control them.

In order to restructure present food safety policies, an extremely important first step is to establish the mechanisms for choosing appropriate methods for establishing the toxicity of compounds. Second, the subject of prediction of risk is also a very important factor.

The food protection committee report, to be published in 1980—this is by the National Academy of Sciences' National Research Council—covers the subjects of selection of test procedures, species selection, sensitivity to toxic effects, metabolism, methods of predicting risk, the concept of the uncertainty factor, and extrapolation of dose response data from animals to predict human toxicity.

It is recognized by investigators working with food chemicals, that research to refine the validity of extrapolation methods for interpreting animal toxicity data should continue to be conducted.

Mechanisms should be developed to promote consideration of both risk and benefit in the food safety decisionmaking process.

Finally, a uniform regulatory policy should be adopted that would be applicable to all food components, food additives, and food contaminants.

Thank you.

Mr. BALDUS. Without objection, your full statement will be included in the hearing record at this point.

[The prepared statement of Dr. Lechowich may be found at the conclusion of the hearing.]

Dr. HOWES. Thank you, Dr. Lechowich.

May I now introduce Dr. Bernard Oser, an outstanding food toxicologist and, for 48 years, with the Food and Drug Research Laboratories.

## STATEMENT OF BERNARD L. OSER, BERNARD L. OSER ASSOCIATES, INC.

Mr. OSER. Thank you.

Mr. Chairman, I am grateful for the privilege of appearing before the House Agriculture Committee to express, however briefly, my support for the concept embodied in the Wampler bill of an independent national science council to resolve scientific controversies concerning the safety of various types of food chemicals.

Although I was asked to testify as a representative of the Society of Toxicology, it should be understood that the views I express are my own, not those of the society as a whole, which to my knowledge has neither considered nor arrived at a consensus on the issues involved.

In my prepared statement which, in view of time limitations, I submit for the record I discuss what I believe to be the excess of time and resources devoted by the several branches of Government to the safety of food chemicals in proportion to any real rather than public perception of hazard.

No small part of this concern results from regulatory actions taken with respect to substances long used and generally regarded as safe, when such action has been based on incomplete, inconsistent, unconfirmed, or unvalidated tests in animals.

I believe it was in 1956 or 1957 when I wrote to a House committee proposing a provision for an ad hoc advisory committee or committees to resolve controversial scientific questions concerning the safety of food additives. This suggestion was not adopted.

The law now handles referral to advisory committees in different ways depending upon whether the controversies concern pesticide residues, color additives, or food additives.

According to the Miller amendment, a pesticide question may be referred to an advisory committee appointed by the Secretary from a panel selected by the National Academy of Sciences, which reviews the data and submits a report and recommendations to the Secretary.

No provision whatever was adopted for an advisory committee procedure when the food additives amendment was enacted. In the case of the color additives amendments, adopted later, recourse can be had to an advisory committee only when the substance is found by the Secretary to induce cancer. The selection of the committee by the National Academy of Sciences is independent of the Secretary.

These statutory provisions relative to the three types of chemical are inconsistent and should be resolved. I believe the proposal in the Wampler bill to establish a permanent national science council is an acceptable, pragmatic approach toward settling not only questions of potential carcinogenic hazard but any scientific dispute concerning the safety or, for that matter, the utility of food chemicals.

I discuss some of the difficulties encountered by the toxicologist in attempting to conform to the literal language of the law, such as to "prove" to a "reasonable certainty" the safety of a substance under conditions of intended use, or the absence of a residual chemical for which no tolerance is allowed.

The lack of definitions and the changing concepts implicit in such terms as "found" to "induce" "cancer" combined with advances in analytical chemistry, toxicology, and related disciplines, necessitate a degree of scientific judgment concerning toxicological procedures and interpretation which, because of differences among experts, add further complexity to the regulatory process.

Among the examples of precipitate or, in my view, ill-considered decisions to ban various food chemicals, color additives, and pesticides, I refer specifically to the artificial sweeteners, saccharin and

cyclamate, the latter based on work conducted under my direction at food and drug research laboratories.

The latency or induction period between initial exposure to a chemical carcinogen and overt occurrence in man has been variously estimated to range from 15 to 50 years, yet epidemiological studies of these sweeteners have failed to reveal any solid evidence of cancer from many years of use, at dietary levels, it may be added, of many trillions of molecules per target cells.

Finally, in my prepared statement I discuss the manifold benefits of food additives, not solely limited to health, the unfeasibility of assessing them objectively, and the need for regulatory authority to consider perceived as well as observable benefits in relation to acceptable risk.

Thank you.

Mr. BALDUS. Without objection, your full statement will be included in the record.

[The prepared statement of Mr. Oser may be found at the conclusion of the hearing.]

Dr. HOWES. Thank you, Dr. Oser.

In view of the fact that our time has elapsed, may I ask for an extension of 2½ minutes in order to repair to this next scientist for his comments?

Mr. BALDUS. That is unanimously granted.

Dr. HOWES. Thank you, sir.

I would like to introduce the final member of the panel, Dr. Thomas E. Shellenberger, a very outstanding toxicologist and director of the department of pharmacology and toxicology at Midwest Research Institute.

**STATEMENT OF DR. THOMAS E. SHELLENBERGER, DIRECTOR, DEPARTMENT OF PHARMACOLOGY AND TOXICOLOGY, MIDWEST RESEARCH INSTITUTE, KANSAS CITY, MO.**

Dr. SHELLENBERGER. Thank you, Dr. Howes.

Mr. Chairman, it is a pleasure to be here. I think I am here in part because in the past I have worked for the Food and Drug Administration, so I have seen both sides of the picture.

I think, that in my testimony I amply describe some of the issues of science, quality of science, and consistency of methods and protocols that must be established between the various regulatory agencies. I think this is important.

I also touch on the quality of the reviewer in the review process.

I want to spend a short period of time on the basic issue, as it was stated this morning very aptly by Mr. Martin and other speakers today—that is, the basic issue of the Delaney clause as a no-risk, carcinogen-free diet policy espoused in 1958.

Since that time, advances in science—specifically, analytical chemistry—have shown us a vanishing zero as an elusive end point to follow. The conclusion now is inescapable that the diet of everyone in this room every day must contain some level, albeit very low, of some carcinogen.

The question now is: Is the 1960 policy of a totally risk-free diet still in the public interest?

I think that the public policy as it has been espoused is now leading to the inconsistency of regulation, as specifically shown by

the saccharin and alflatoxin issues as well as some of the other chemicals which have been brought up.

FDA moved to ban saccharin, as we are all aware. The public's opinion was expressed as an outcry, and Congress placed a moratorium on the process.

Now, I would have been more upset if the FDA had not moved to ban saccharin, because I must think that they would not have been doing their job. However, this placed Congress in the position of regulating for FDA on a chemical-by-chemical basis. I think FDA should be allowed to do its own job.

The inconsistency ultimately erodes the public's confidence in the regulatory process and in the regulatory officials. Therefore, I think that it is time to examine and draw up a long range food policy. This policy must be set to ensure public protection, and it must include risk estimate as well as health benefit estimate.

I think the public has spoken. They are willing to accept some risk for some chemicals, and this must be recognized.

However, another key issue is the societal decision which is always involved with each chemical on a case-by-case basis. That is: What level of risk, for what chemical, will they accept?

Nevertheless, a long range food policy seems essential.

Thank you, sir.

Mr. BALDUS. Without objection, your entire statement will be included in the record.

[The prepared statement of Dr. Shellenberger may be found at the conclusion of the hearing.]

Dr. HOWES. Mr. Chairman, we appreciate this opportunity to provide some input into your discussions from the agricultural scientific point of view.

Mr. BALDUS. Thank you, Dr. Howes.

Just now we are playing musical chairs. There has been a bell, indicating a vote occurring now.

I will excuse you. You may have written questions from the committee members, when they review your testimony more carefully. Since I have no questions at this time, I will excuse the panel.

At the same time, I will call the remaining witnesses as a panel. That is our established method. I call Dr. Ira I. Somers of the National Food Processors Association of Washington, D.C., first; then, Mr. Taylor L. Grizzard of the Virginia Poultry Federation in Harrisonburg, Va.; Mr. Jack D. Early, who is president of the National Agricultural Chemicals Association of Washington, D.C.; Ms. Joan Dannelley, American Association of Meat Processors of Elizabethtown, Pa.; and Dr. Joseph G. Sebranek, associate professor of animal science and technology, Iowa State University, Ames, Iowa.

You may begin your testimony, Dr. Somers. I will ask each of you to summarize as best you can, and if you can stay within the time limitation of 5 minutes, of course, we would appreciate that.

## STATEMENT OF IRA I. SOMERS, EXECUTIVE VICE PRESIDENT, NATIONAL FOOD PROCESSORS ASSOCIATION

Mr. SOMERS. Thank you, Mr. Chairman. I would like to have our full statement submitted for the record.

Mr. BALDUS. Without objection, each of you will have your full statements included in the record.

Mr. SOMERS. We appreciate this opportunity to testify on the subject of food safety.

It is no coincidence that the National Food Processors Association should have a strong interest in this subject. It has been one of our major concerns for over 70 years.

I think that, in the discussion of this subject, one should not lose sight of the fact that the food safety problems which have been of the greatest concern have already been eliminated.

The problems we are dealing with today are not absolute but theoretical or speculative. They have to be proven.

For instance, take the case against nitrite. I can easily cite an example from our history to prove what I am saying.

The National Canners Association, our predecessor organization, was organized in 1907, just 1 year after the enactment of the Pure Food and Drug Act. Food safety was a prime factor in the creation of the association. For example, the bylaws of National Canners Association contained the following statement:

> Any person, firm, partnership, association or corporation engaged in the manufacture or preparation of foods packed in hermetically sealed containers and sterilized by the use of heat alone, free from chemicals for preservative purposes, may become an active member of the association . . . if and so long as such person, etc., shall maintain a sanitary canning plant, conduct the same in a sanitary manner and use only wholesome raw products.

The reference to the exclusion of chemical preservatives was a recognition that, prior to the enactment of the Pure Food and Drug Act, unfresh substances, such as formaldehyde, copper salts, and so forth, were added to foods by unscrupulous packers. The canning industry wanted them to know that they did not condone such practices. We do not condone them today.

However, we do recognize the use of safe, frugal, Government-approved preservatives.

With this as a background, I would now like to comment just briefly on the subject of food safety legislation. First, we believe that major revisions in the food safety provisions of the Federal Food, Drug, and Cosmetic Act are undesirable and impracticable. Now, I said "major revisions."

The act clearly provides for somewhat different safety standards for naturally occurring contaminants or food additives and for added substances that are not food additives but that are required in the production of food or that cannot be avoided by good manufacturing practices.

In 1958 an amendment to the act imposed stringent safety standards, including the Delaney clause, or approval of new food additives but exempted from food additive control those substances which were approved for use in food by FDA and USDA prior to September 6, 1958, or which were generally recognized as safe.

It is our view that these different food safety categories constitute sound public policy and should be retained.

The exemption from food additive control of prior sanctioned and GRAS substances is based on what would be an otherwise impossible administrative burden.

Mr. BALDUS. Dr. Somers, either Mr. Wampler, the ranking minority member, or Mr. Bedell, will be back within a very brief

time, and will reconvene the committee. I will recess temporarily, so that I may get my vote in.

[Recess taken.]

Mr. BEDELL [acting chairman]. The committee will come to order.

I understand that you were in the middle of your testimony, Dr. Somers.

Dr. SOMERS. I will try to pick up at a point that will be meaningful to you, Mr. Chairman.

As this committee is aware, there have been several proposals to overhaul the food safety provisions of the Food, Drug, and Cosmetic Act. These include proposals to abolish the different statutory provisions for various categories of food substances and create a single safety standard applicable to all food ingredients and provide for unqualified risk assessment.

National Food Processors Association opposes these proposals. They would impose enormous costs and administrative burdens on FDA and the regulated industry and would create a prolonged transitional period of substantial uncertainty.

Second, we also strongly oppose a recent proposal for risk-benefit review of new food additives. As the Congress recognized in 1958, the benefits of new food additives should be determined in the marketplace by the companies that process and distribute them and by the consumers who buy them.

Within the framework of the existing food safety provisions, we would recommend two changes.

The first is that we support explicit authority for FDA to phase out the use of valuable food or food-packaging ingredients discovered not to be safe, for which there are no suitable alternatives.

Second, we support some refinement and clarification in the review of food additives under the Delaney clause. The recent advances in analytical methodology with greater sensitivity, coupled with the continued controversy over the interpretation of animal feeding studies, make it essential that FDA act only on an informed scientific basis in restricting the use of food additives.

Accordingly, we suggest that the Delaney clause be expanded to assure sound scientific decisions. First, FDA should be required in each instance to consult with qualified experts in cancer causation. Second, with the assistance of those experts, the FDA should be required to prepare a full factual analysis of the scientific data upon which FDA and those experts have reached their conclusions.

They should then be required to provide a detailed explanation of the basis upon which it and those experts have scientifically concluded, from a fair evaluation of all of the available data, that a food additive is not safe.

These supplementary requirements for the application of the Delaney clause would contribute to scientifically sound decisions, would avoid controversy and possible litigation, and would reduce both unwarranted consumer apprehensions and loss of public confidence in our food supply.

Certainly, had the procedures been followed in dealing with the nitrite issue consistent with the principles we have here outlined, the confusion associated with that episode could have been avoided.

Thank you, Mr. Chairman.

Mr. BEDELL. Thank you, Dr. Somers.

Without objection, your entire statement will be included in the hearing record.

[The prepared statement of Dr. Somers may be found at the conclusion of the hearing.]

Mr. BEDELL. Mr. Grizzard, we will hear from you next.

Mr. GRIZZARD. Thank you, Mr. Chairman. I am Taylor L. Grizzard, of Richmond, Va.——

Mr. BEDELL. Excuse me. Mr. Wampler wanted to have an opportunity to introduce you. I want to give him that chance.

Mr. WAMPLER. Thank you, Mr. Chairman.

This really was not designed to be Virginia's day, but it seems as if we have had a number of distinguished Virginians here, for which we are most grateful.

Mr. Chairman, our witness is from Harrisonburg, Va., and he is here representing the Virginia Poultry Federation, but he wears many hats and wears them all well, I might add. He is the chief executive officer of Wampler Foods.

Now, I hasten to add that I have no financial interest in that enterprise. I wish I did.

He is extremely knowledgeable and very active in the National Turkey Federation. He has been closely identified with many agriculture movements in Virginia and in associations. He is an extremely knowledgeable man, and we appreciate his coming here.

He is not my constituent. I wish he were.

Thank you.

Mr. BEDELL. What is Wampler Foods?

Mr. WAMPLER. I think he can probably tell you better.

Mr. GRIZZARD. It is an integrated turkey-producing company. We produce and process turkeys and turkey products.

Mr. WAMPLER. Mr. Charles Wampler, who, I guess, was the father of the principal owners of the business, was the first president of the National Turkey Federation and was one of the pioneers in turkey feeding in the great valley of Virginia, the Shenandoah. I am not privileged to represent that area, but it is a great agricultural section of our Commonwealth.

Mr. BEDELL. Thank you, Congressman Wampler.

Mr. GRIZZARD. Thank you, Congressman Wampler. We are sorry that you do not represent the Shenandoah Valley. We would like to have more Congressmen like you.

## STATEMENT OF TAYLOR L. GRIZZARD, VIRGINIA POULTRY FEDERATION

Mr. GRIZZARD. I am delighted to be here speaking on behalf of the Virginia Poultry Federation. Our federation includes more than 1,200 members from every facet of the poultry industry, the men and women who give America's consumers the cleanest and best quality protein foods ever known.

Many of our members have for several years now been increasingly concerned with the regulatory burden imposed on us by Government. We are concerned with the growing number of regulations; the amount of time and money spent in filling out forms, responding to proposals, defending against unfair and aribtrary rulings by regulators, and similar problems; the loss of productivity with no offsetting benefits to industry or consumers; and with

regulations that seem to be proposed for political purposes rather than being based on sound, scientific background data.

As president of the National Turkey Federation last year, I was in a position to observe an example of the latter kind of problem at its worst in the joint proposal of the U.S. Department of Agriculture and the Food and Drug Administration to ban the use of nitrites as food additives.

I commend both of these agencies for their recent withdrawal of the ill-conceived proposal, but the fact remains that irreparable damage was done by the push for such a regulation and by bureaucratic indifference to scientific fact, positive proof of prior sanction, or to reason itself.

Look at the direct costs incurred by just our turkey industry alone. There were approximately $170,000 in legal fees, some $50,000 worth of tests run by Swift's laboratories, and an estimated $200,000 to $250,000 in additional laboratory and related work by others in our industry.

That may not sound like much when you are used to talking in billions, but to some of our turkey growers it is a big, unnecessary expense. In fact, it is enough to pay seven or eight Congressmen's salaries for a year.

Then, there were the indirect costs, many of them inestimable. What did it cost our industry in needless loss of consumer confidence because of publicity that attended the proposed nitrite ban? What did it cost in the diversion of employee time from productive pursuits to such endeavors as developing incontrovertible proof of prior sanction, searching for potential alternative preservatives that met all of the necessary criteria, and other such defensive maneuvers? What did it cost members of the consuming public, who out of fear removed a superior protein product from their diets, possibly replacing it with a higher priced product in the store?

Mr. Chairman, it appears to us that the original nitrite ban proposal, with all of its tremendously negative effects, was a political decision—designed to discharge perceived obligations to certain groups of consumerists—rather than one based on solid scientific judgment. In fact, certain appointed officials seemed to have their minds made up and did not want to be bothered with the facts.

Because of the proliferating problems, like the proposal to ban nitrites, it seems to us that the time has come for Congress to mandate a review process in which adequate peer review would have to precede any acceptance of supposedly scientific research as a basis for regulatory propositions.

As Sir Winston Churchill said, "Only as light is shined upon an object from all sides can full illumination be secured."

We believe that a panel of eminent scientists, selected from among recommendations from the National Academy of Sciences, the Council for Agricultural Science and Technology, or some similarly prestigious, unbiased body, would be a refreshing assurance of protection for the public and industry from arbitrary and capricious actions by regulators.

In addition, we would propose that the Delaney clause and any sections of the Federal Food, Drug, and Cosmetic Act that mandate zero tolerances be reviewed in the realistic light of today's technol-

ogy. Modern methodology permits detection of infinitesimal amounts of certain substances, which in high concentration may be harmful to human health in any manner, even far below the amounts normally found in the bodies of healthy human beings.

Mr. Chairman, I believe that a realistic review of the record will show that the Virginia poultry industry has been a leader in efforts to provide the public with nutritious, wholesome food. Both voluntary and mandatory Federal inspection of poultry plants began in Virginia. I could enumerate many more moves.

The time has come to take a hard look at what is really necessary for consumer protection, what is really in the consumers' best interest. That is what we request of you today.

Thank you, Congressmen.

Mr. BEDELL. Thank you very much, Mr. Grizzard.

Our next witness is Mr. Jack Early, who is president of the National Agricultural Chemicals Association.

## STATEMENT OF JACK D. EARLY, PRESIDENT, NATIONAL AGRICULTURAL CHEMICALS ASSOCIATION

Mr. EARLY. Thank you, Mr. Chairman.

I am Jack D. Early, president of the National Agricultural Chemicals Association (NACA). The members of NACA produce a substantial portion of all the pesiticides used in the United States for agricultural purposes—both the basic pest control chemicals and the end-use pesticides formulated from these basic chemicals.

This oversight hearing, as it addresses the vindication of the use of nitrites in food preservation, is a most appropriate situation in which to call for the examination of policies and procedures by which regulatory agencies evaluate and act on the matter of safety associated with agricultural chemicals too.

The handling of the nitrite situation is not entirely unique but reflects to some extent the general attitude and practices of regulatory agencies responsible for regulating agricultural chemicals, such as preservatives, food additives, and pesticides.

The matter of safety in the use of agricultural chemicals is an important one. It deserves both judicious and competent scientific assessment, as well as responsible handling in relation to public announcements.

Currently, public announcements of presumed hazards are couched in language that encourages emotional rather than factual reactions to the situation and tend to lead the public to believe that there is a crisis, when in in fact a crisis does not exist.

All of this is too often done before the scientific facts are fully assessed and a responsible decision made as to whether or not regulatory action is in order.

Unfortunately, even the reversal of regulatory decision or the vindication of a product leaves many questions in the public's mind as to its safety. The net effect, Mr. Chairman, is a reluctance on the part of the public to accept the continued use of the product.

What is so very disturbing in this issue is the unscientific handling of scientific information by regulatory officials responsible for making societal decisions. Biological science, especially toxicology, is a relatively dynamic science.

Based on the objective, design and merits of a toxicological study, ethical scientists will report results accordingly, ranging from highly guarded presumptions, to fairly assured conclusions. The nonscientific public official tends not to distinguish among such information and will therefore consider both extremes as equally creditable for regulatory purposes. Presumptive evidence when it is arbitrarily assigned a level of credibility that was not intended nor can be scientifically justified without further investigation, is used as a makeshift trigger for regulatory action.

This most often seems to be the case when agencies deal with the carcinogenic potential of a chemical. The handling of nitrites is an example wherein the public pronouncements of hazards and contemplated regulatory action preceded a comprehensive review of the data at hand. We understand there was no peer review requested. It also preceded the completion and analysis of toxicological investigatons under way to help resolve the earlier presumptions. The subsequent vindication of nitrites and the need to publicly reverse prior contentions of carcinogenic hazard seriously impairs the credibility of the agencies in the handling of such serious matters.

We do recognize that, while such actions are agency initiatives and can be corrected, the agencies are constrained, when they have to implement some legislation wherein no assessment of risk is permitted as is the case with the Delaney clause.

The Delaney clause in effect writes into effect two scientific hypotheses: one, the hypothesis that any compound that induces cancer in animals is a human carcinogen, and, two, that there is no threshold or societally acceptable level for exposure to such a compound.

The Delaney approach to the regulation of suspect chemical carcinogens heavily influenced the Environmental Protection Agency's first 5 years in the regulation of pesticides. DDT, for example, was said to impose a remote and unquantifiable risk of cancer on the basis of mouse studies and was banned in the United States.

Experience has forced EPA into a recognition, expressed in its current cancer policy, that the Delaney approach is often impracticable and unacceptable because "* * * in many areas risks cannot be eliminated completely without unacceptable social and economic consequences."

Despite this pronouncement of EPA's interim cancer policy, however, the ghost of Delaney continues to haunt the regulatory thinking and has produced such unfortunate regulatory constructions as the "cancer principles" created by EPA staff attorneys and advocated in the proceedings on mirex and heptachlor/chlordane, as well as more recently in the announced OSHA cancer policy now on appeal before the United States Court of Appeals for the Fifth Circuit.

These approaches to the regulations of suspect carcinogens are heavily influenced by the Delaney clause, because they attempt to write into regulation scientific hypotheses about cancer which are unproven and often highly controversial. Writing scientific hypotheses into law has a long and unfortunate history and should not be perpetuated even for an important national concern such as cancer.

Our national policy should encourage the use by regulators of the best scientific evidence and judgment in the regulation of suspect chemical carcinogens. It should not attempt to freeze science, discourage the use of informed judgment, and accept inadvisable, "no-risk," "absolute-safety" methods of regulation as are those embodied in the Delaney clause.

On several occasions during the past few years I have testified before this committee and asked for a reevaluation of the Delaney clause. I was also very pleased to see that the chairman of this committee, Mr. Foley, back in January 1979, introduced legislation to call for a reevaluation of the Delaney clause.

NCA recognizes the established essentiality of chemicals in the agricultural process of food production and its members are committed to the reduction of all risks to the health of the public.

The determination of carcinogenic potential includes the extrapolation and assessment of risk to humans. It is a complex process that NACA believes must be done by a properly constituted scientific group devoid of any regulatory responsibility.

Mr. Wampler has introduced legislation, H.R. 6521, that would establish such a scientific group. H.R. 6521 calls for the establishment of the National Science Council that will decide questions of scientific fact which arise in the agencies.

Risk determinations should be the basis for benefit/risk evaluations and priority setting by appropriate regulatory agencies consistent with their legislative mandates.

NACA has also addressed these issues in the release of its cancer assessment and regulatory policy in June 1979. A copy is attached for the committee's review and consideration.

I would also like to commend this committee for attaining and maintaining the principal jurisdiction over matters related, not only to food production, but also to food safety. Food production and the essential chemical aids that assure food production and its wholesomeness are intertwined throughout this process, which is continuous from the seed to the table.

For this reason, this committee, which is best qualified to understand and appreciate this fact, must be the principal purviewer of all agricultural chemicals—their availability, their use, and their safety.

Thank you, Mr. Chairman.

Mr. BALDUS [acting chairman]. Thank you, Mr. Early.

Without objection, the attachment to your statement will be included in the hearing record at this point.

NATIONAL AGRICULTURAL CHEMICALS ASSOCIATION

Cancer Assessment & Regulatory Policy

1. Statement of the Problem

The development of a consistent "National Cancer Policy" must address two related but distinct matters - first, the assessment of carcinogenic potential, a scientific matter, and second the regulation of presumed carcinogens. General confusion has existed between these two matters and over an assumed legislative requirement to ban any substance because of the presumption of human carcinogenicity arising from any kind of animal test. The Delaney Clause of the Food, Drug, and Cosmetic Act is the only law that mandates banning of such a substance, and then only in case of food additives, animal drugs, and food colorants. To add to the general confusion, contradictory short-term legislation was enacted to forestall such regulatory action being taken against saccharin, and probably will be enacted again.

The matters of assessment and regulation have been emphasized in the case of pesticides because of the public concern over hazards going back to the publication of Silent Spring. The associated benefits of the use of pesticides in improving both the quantity and quality of food and fiber production is information with which the public is generally unfamiliar. The extraordinary benefits of pesticides must be weighed against any presumed or actual risk to man arising from their use as mandated by the FIFRA, as amended. Regulatory action should be based on the results of scientific evaluation of available animal data and human experience combined with the assessment of benefit.

The following NACA Cancer Assessment and Regulatory Policy addresses these issues:

2. Applicable Laws and Regulations

The sections of applicable law are as follows:

FIFRA, as amended, September 30, 1978

Section 2(bb) - Unreasonable Adverse Effects on the Environment
Section 3(c)(2) - Data in Support of Registration

Title 40 CFR Part 162

Section 162.8 - Data in Support of Registration
Section 162.11 - Criteria for Determination of Unreasonable Adverse Effects

3. Development of the Problem

As pointed out previously, the need for a formal NACA policy has developed over the past 15 years as the public became increasingly concerned over the potential for chronic toxicity long-term effects. The Mrak Commission Report of 1969 formalized Federal concern for risks of presumed carcinogenicity with little attention given at that time to presumed benefits of pesticides.

In May 1976 EPA published a cancer assessment procedure which placed emphasis on balancing valid risks and benefits, as mandated by the amended FIFRA. The form of a reasonable cancer regulatory process began to emerge with the creation of the intensive risk/benefit analysis program of the Office of Pesticide Programs RPAR process.

In addition, the acrylonitrile, diethylstilbestrol, saccharin, and nitrite regulatory proposals of FDA and USDA have served to focus public attention on the difficulty of product bans in the face of widely recognized benefits.

4. Policy Statement on Cancer Assessment and Regulation

A. Perspective

The member companies of NACA are committed to a reduction of all risks to the health of the public. It is the NACA view that there is not a national cancer epidemic. If lung cancer is excluded, the overall cancer rate is not increasing. There is no evidence that human cancer in the United States including lung cancer is associated with pesticide chemicals.

B. Cancer Assessment

The determination of carcinogenic potential includes the extrapolation and assessment of risk to humans. It is a complex process and must be done by a properly constituted scientific group devoid of any regulatory responsibility. Such a risk determination should be the basis for benefit/risk evaluations and priority setting by appropriate regulatory agencies consistent with their legislative mandates.

Presently, the only universally accepted means of evaluating carcinogenic potential are human epidemiology studies and animal bioassays. While there are practical limits to these studies, they do serve as the scientific basis for human cancer assessment. Evaluation of the data from animal studies should include, but not be limited to, the animal species, identification of the nature of the response, appropriate routes of administration, dosage levels, and comparative metabolic studies.

NACA encourages and supports the improvement of these methods of evaluation and the development of new methodology. NACA further believes that the assessment of carcinogenicity must be continuously reevaluated as new scientific data and techniques become available.

C. Cancer Regulation

NACA believes that the use of a pesticide should be subjected to thorough risk/benefit analysis when valid animal studies indicate carcinogenic potential and may be presumed to be a human carcinogen.

The components of the risk/benefit analysis include the scientific conclusions reached on: 1) the carcinogenic response in animals; 2) dosage level of pesticide; 3) potency of pesticide; 4) route of exposure; 5) comparative metabolism if available; 6) quantification of exposure; 7) risk assessment of use; 8) quantification of benefits of use; and 9) comparison of risks with benefits. Human experience must be given precedence over animal data.

Following a complete evaluation of the preceding components, a regulatory decision can be made as to which pesticide uses should be continued.

NACA supports the concept of assigning a finite value to human cancer risk arising from exposure to a presumed carcinogen. In this manner, judgments concerning different carcinogenic risks can be made.

NACA believes that any cancer regulatory policy should be dynamic and based on the best science available. The policy should also reflect the reality that there are important hazard that must be addressed reasonably and rationally rather than emotionally.

Mr. BALDUS. The next witness is Ms. Joan Dannelley. She represents the American Association of Meat Processors, Elizabethtown, Pa.

**STATEMENT OF JOAN DANNELLEY, PROJECT COORDINATOR, AMERICAN ASSOCIATION OF MEAT PROCESSORS, ACCOMPANIED BY FRANK PARRISH, VIRGINIA ASSOCIATION OF MEAT PROCESSORS**

Ms. DANNELLEY. Mr. Chairman, we appreciate the opportunity to be here.

I am accompanied today by one of our members, Mr. Frank Parrish of Manassas, Va. Mr. Parrish is owner and operator of a small plant in Manassas, and is typical of the very small business that our association represents.

Contrary to the statement that I heard Ms. Foreman make this morning, we feel that our members have been hurt by all of the controversy surrounding pump bacon.

We did have some very small operators who suffered economic losses because of their program.

In addition to the statement which we filed with you, we want to echo our support for the National Meat Association's Nitrite Safety Council's statement in calling for revisions to the Delaney amendment. We think that, in view of the massive technological advancements that have been made, it is long overdue.

We also hope that Mr. Wampler's statement to Ms. Foreman this morning about having learned something from the past sank in.

We see a parallel situation developing with dry-cured bacon. The gist of what we got today is that Ms. Foreman took the Newberne study unverified and used it to develop standards for pump bacon.

In a parallel situation, there has been one study done by the Department of Agriculture on dry-cured bacon. There has been controversy surrounding that, in that meat scientists do not agree with the conclusions that she has drawn from that study. In spite of that fact, and in spite of the fact that that study has yet to be duplicated, it is being used to draw up new standards for dry-cured bacon.

We are willing to work with the Department in trying to work out a solution to this problem. Dry-cured bacon is predominantly produced by very small operators, and we are hoping that we can work something out before these producers are hurt to the point that they are driven out of this portion of their businesses.

We will end herewith our statement, the balance of which was presented earlier. We do appreciate the opportunity to be here.

Mr. BALDUS. Without objection, your statement will be included in the record at this point.

Thank you.

[The prepared statement of Ms. Dannelley may be found at the conclusion of the hearing.]

Mr. BALDUS. Dr. Sebranek is associate professor of animal science and technology at Iowa State University, Ames, Iowa.

Before you proceed, if you look in the Ames phone book, you will find some of my relatives there. My mother and father both came from Story County, Iowa.

**STATEMENT OF DR. JOSEPH G. SEBRANEK, ASSOCIATE PROFESSOR OF ANIMAL SCIENCE AND TECHNOLOGY, IOWA STATE UNIVERSITY**

Dr. SEBRANEK. Thank you, Mr. Chairman.

I think, in light of the expert testimony that you have already been hearing this afternoon, I will make my comments very brief. I will be submitting a more extensive written report to the committee in the next couple of days.

Mr. BALDUS. Dr. Sebranek, would you like to make that more extensive report a part of the record?

Dr. SEBRANEK. Yes, I would.

Mr. BALDUS. Without objection, so ordered.

Dr. SEBRANEK. My involvement in this hearing has come about for a number of reasons. I have been directly involved in nitrite research for almost 10 years. Second, I chaired a special Iowa State committee, that provided initial evaluation and comment on the Newberne study when it was first released.

Our report was released in early September 1978 and was one of the first scientific evaluations made of the Newberne project and released for the public. Our review raised many of the same questions that have been pointed out by subsequent groups.

However, our greatest concern following the review was the regulatory proposal based on what we felt was at best faulty, and at worst perhaps even erroneous research.

In light of the testimony here today, I am encouraged that all of the input and the effort that has gone into this nitrite controversy may indeed result in, what someone else said, namely, movement in the right direction.

This nitrite issue has pointed out the need for a broader concern for food safety laws in general and for the ability to inject an element of scientific judgment into these laws. To accomplish this, let me emphasize two points.

There is no substitute for thorough scientific review of research by qualified scientists, especially when the research may contribute to regulatory decisions. The professional credentials of a scientist in research live or die by scientific review.

Certainly, food safety decisions that may be based on research warrant at least an equivalent evaluation.

Therefore, it seems to me that clear-cut procedures should be established for both internal and external review by the regulatory agencies of any research that has bearing on potential regulatory decisions.

Second, it seems that the current food laws need to be rewritten to allow a greater involvement of scientific judgment.

Much of the justification for what transpired in the nitrite situation has been based on what is described as a rigid, inflexible regulatory situation, which could well be corrected by proper revision.

However, even in the present situation food laws are certainly intended for application to actual situations and adequate scientific review to confirm potential facts is again a necessary prerequisite.

Therefore, revision of food laws is certainly desirable, but establishment of adequate, perhaps automatic, review procedure is most critical and would make even the present food laws more workable.

Thank you.

Mr. BALDUS. Thank you, Dr. Sebranek. Without objection, when we receive your written statement, it will be made a part of the record.

[The prepared statement of Mr. Sebranek may be found at the conclusion of the hearing.]

Mr. BALDUS. Mr. Wampler, do you have questions of any of the panelists?

Mr. WAMPLER. Yes, Mr. Chairman.

Let me express my appreciation to this group of witnesses for your excellent testimony. I apologize on behalf of myself and the committee for the legislative situation that exists today. We are voting on a Department of Defense appropriation bill, hence all of the interruptions. It is not a lack of interest or concern for your testimony. It is just the way we have to operate here from time to time.

Dr. Sebranek, I want to say this to you. Your reputation preceded you here. We are well aware of the work that the team at Iowa State did on this. I think it made a major contribution in helping to clear the air on this very controversial subject affecting the banning of nitrites.

I hope you will thank the other members of the team for us for the excellent work that you did.

Ms. Dannelley, I have asked a member of the staff to try to find a copy of the letter that I sent to Secretary Bergland on July 2, regarding research on dry-cured bacon. I have been concerned about this. You raised this question, and quite properly so.

It is my understanding that the Department of Agriculture has spent a substantial amount of money on research, testing the potential application of sorbate in pump bacon production.

These studies, as I understand it, were conducted by the Department of Agriculture to test the effectiveness of sorbate in preventing botulism or the growth of botulism in bacon. I have been concerned that the Department, at least until now, has been unwilling to cooperate in research to help hundreds of small processors with their problems with dry-cured bacon processing.

Now, as far as I am aware, we have not yet heard from the Secretary in that regard. I meant to ask Ms. Foreman if she would be kind enough to check with the Secretary and see what the problem is.

If I may very briefly, Mr. Chairman, I would like to read this. It was written to the Secretary on July 2. It says:

> I appreciate the meeting your Administrator, Dr. Donald L. Houston, of the Food Safety and Quality Service, and Mr. Snyder Butler, the Deputy Assistant Secretary of the Food and Consumer Services, had with the minority staff of the House Committee on Agriculture on my behalf on June 30, to discuss the FSQS proposal for the regulation of dry-cured bacon.
>
> As you well know, this regulation will have a significant impact on many small and medium sized processors in Virginia and many other States.
>
> I believe that the time which the proposed regulation provides for comments and research for alternatives is grossly inadequate. I hope you will expand the time frame significantly, and that your staff will work closely with the affected industry, as represented by the Nitrite Safety Council, to develop and perform research on alternatives which would not result in products containing excessive salt levels.
>
> I further urge that the Department help to support this research, such as you did in your sorbate studies. I do not believe that this is an urgent matter. I think it can

be handled in a more realistic time framework than the draft proposal specifies, since, after all, the Department has known about this problem since June 16, 1978.

I look forward to hearing from you.

I simply wanted to read that into the record to let you know that we are concerned about it. I think here again is a good example of the saying: There's got to be a better way to run a railroad.

Ms. DANNELLEY. Congressman Wampler, we appreciate your help and the help we have received from other Congressmen in this area.

We saw a copy of your letter before. We have not seen any answer to it.

The answer to our same question to her was an absolute "No," that any testing that is to be done would have to be done at the expense of the industry.

I believe, as we have pointed out several times in the past, part of our problem is that dry-cured bacon is produced by very small operators. I am talking about people who cure perhaps 5 to 15 bellies a week. That is nothing. That is not even a drop in the bucket of our total industry's production.

To a small industry that has developed its trade around that product and that has sold it to its customers, and who is now faced with its customers having no confidence in that product, the problem is that they just do not have the thousands of dollars to spend to get that product researched.

There was a mass of information on pump bacon because we went into testing and laundering that product.

All we are asking is for cooperation in entering into a similar testing program for dry-cured bacon. This is a request that was made to the American Meat Institute on behalf of the Nitrite Safety Council almost 3 years ago, and we just did not get an answer. All we want now is an answer and some help.

Mr. WAMPLER. I will do everything I can to get an answer to my letter.

Let me, Mr. Chairman, also commend our friend, Jack Early, who has been before the committee on many occasions. The National Agricultural Chemicals Association has always been very helpful in providing us with technical information that we have needed in trying to formulate public policy in the areas in which they have a direct concern.

I thank all of you again for coming. You have made a valuable contribution, and I hope that this is the beginning of what will be a meaningful effort to bring some degree of reasonableness and commonsense into the total regulatory scheme as it affects food safety.

This is not going to be an easy job, but I think your contribution and your testimony here today will be significant. We appreciate your presence here.

Mr. BALDUS. I want to thank you, Mr. Wampler, for your interest and your dedication to this issue. Certainly, both have shown today.

I want to thank each of the panelists who have come. I apologize to you for our situation here. Your full texts will be made a part of the record.

I will adjourn the hearing momentarily with the provision that certain material may be entered into the record of this meeting.

Are there any further comments?

Mr. WAMPLER. Mr. Chairman, I wonder if I may ask unanimous consent that the hearing record be kept open for 5 days. I am advised that perhaps there are others who might want to submit statements.

I will amend that to ask unanimous consent that the hearing record be kept open for 2 weeks for any additional statements that might be made.

Mr. BALDUS. I hear no objection. So ordered.

Are there any further questions or comments?

If not, this hearing is adjourned.

[Whereupon, at 5 p.m., the committee was adjourned.]

[The prepared statements submitted by witnesses and other material submitted to the committee follow:]

Testimony of Dr. Norman E. Borlaug

before the

House Committee on Agriculture

September 16, 1980

Congressman Tom Foley, Chairman, The House Agricultural Committee and other Distinguished Members of the Committee.

I am Dr. Norman E. Borlaug, an agricultural scientist, who was born and reared on a small Iowa farm. I have spent the past 36 years working in food deficit developing nations--based in Mexico but working in many different Latin American, African and Asian countries. Although I have been concerned about and worked in many disciplines that affect crop production including agronomy, soil science, plant protection and economic policy; however, the greatest part of my time and effort has been devoted to genetics and plant breeding. This involves primarily developing heterogenous populations and thereafter selecting the individuals that possess the unique combination of characteristics that make them valuable for use as superior varieties to increase food production.

In the process of developing new varieties one must classify each generation and select the best several hundred individual plants--among several million.

During the past decade I have watched with dismay the confusion, emotionalism and lawsuits that have evolved, on issues covering food, agriculture, water and air pollutions and environmental issues in the broadest sense.

It is my personal opinion that much of this confusion could have been avoided had there been a better understanding of the great genetic variation that exists in the human species and the fact that there is no such thing as zero risk in the real biologic world--be it plant, animal or human species. We are all different genetically. No two of us are alike with the exception of identical twins.

The average life expectancy at time of birth, in the developed nations, has increased dramatically during this century and especially during the past five decades. Currently in the U.S.A. it has reached approximately 73 years. Nonetheless, despite this achievement there has been surprisingly little increase, if any, in longevity. During biblical and early historical times references are found of individuals living to the ripe old age of four score and ten years, with an occasional individual passing the century mark.

The dramatic increase in average life expectancy has been achieved, in a large part, by the spectacular reduction in infant and childhood mortality. This has been achieved through the composite effect of improvements in nutrition, better public sanitation and personal hygiene and especially from the dramatic improvements in control of infectious diseases resulting from the discovery and widespread use of sulfadrugs, antibiotics and improved vaccines.

Today there are those who apparently believe that we are on the verge of being poisoned out of existence. They visualize an endless, array of carcinogens in the air we breathe, in the water we drink and in every bite of food we eat. Despite such emotional pessimism, in fact, we live a longer and more pleasant life than our parents or grandparents. Since the conquest of infectious diseases that formerly took the lives of many in infancy, childhood, youth and early adulthood have been brought under control during the past 40 years, more people die at a later age from other diseases such as heart and circulatory diseases and cancer. Many that a generation ago might have died at an early age because of genetic susceptibility to one or another of the infectious diseases, survive to die at a later age from the still bewildering and poorly understood group of cancer diseases, giving the laymen the feeling, in part caused by sensationalism in the press--perhaps often designed primarily to sell newspapers and magazines--that there is a startling increase in the incidence of cancer. Nevertheless, with two exceptions on the incidence of cancer an examination of the data currently available adjusted for age in the U.S.A. over the past 30 years does not

bear this out. The exceptions are the increase of lung cancer associated with cigarette smoking and an unexplainable reduction in incidence of stomach cancer over the same period.

Much of the confusion, fear and emotionalism surrounding the incidence of cancer is worsened by the inflexibility of the Delaney Clause--the "47 little words" appended to the 1958 Food Additive Amendment of the Food, Drug and Cosmetic Act of 1938--which denies the Administrator of the Food and Drug Administration the needed flexibility to consider and weigh the mass of all evidence in the process of deciding to ban or not to ban the use of a food additive or contaminant. The clause states specifically "that no additive shall be deemed safe (and must be banned from use) if it is found to induce cancer when ingested by man or animal, or if it is found, after tests which are appropriate for the evaluation of the safety of food additives to induce cancer in man or animals...."

The clause fails to take into consideration dosage effects--and seems to convey the impression that we can achieve complete elimination of carcinogens in our food chain by strict imposition of this law. It implies that we can greatly reduce or reduce to zero the risk of cancer by eliminating completely all compounds from our food supply, water and air that have been shown to be carcinogenic under a wide variety of tests. It fails to recognize: (1) that there is no such thing as zero risk in the real biologic world, (2) it fails to recognize the tremendous genetic variation in the biologic system--including the many shades of tolerance and susceptibility in the human species to infections, allergies and cancer, (3) it ignores the fact that many of the "natural foods" that have sustained mankind from the beginning of Civilization have within them infinitesimally small amounts of compounds which in animal tests have been shown to be carcinogenic, and (4) it does not take into consideration that great recent advances in modern analytical methods and technology which today can measure infinitesimally small quantities of compounds--both natural and synthetic which went unidentified when the Delaney Clause was enacted.

Finally, it ignores the growing body of evidence that indicates that there is an increase in the number of chromosome abberations in human tissue cell cultures, with aging, even when grown in the laboratory presumably in the absence of any known carcinogens. This seems to imply that there probably exists at cellular (or chromosomal) levels some biologic clock or timing mechanism that controls aging and longevity of life. This seems to imply that we will never discover the ephemeral Fountain of Perpetual Youth as some people seem to think is possible. Perhaps it's better it is so, for imagine the chaos on the population and food production front and on the social, economic and political scenes were this impossible dream to come true.

As I reflect on the confusion that has developed in the saccharin and nitrite issues in recent years it seems evident that the Delaney Clause needs to be amended to provide the Administrator of the Food and Drug Act the flexibility to weigh all of the available experimental evidence, and epidemiological evidence and arrive at a reasonable judgment based on benefit versus risk.

It is obvious that we have used such judgments in arriving at using X-ray properly as a valuable diagnostic tool in identifying and setting bone fractures in early diagnosis of internal tumors and infections and also as one of the treatments for cancerous tumors, even though X-rays are known to induce cancer if improperly used. It is a well known fact that the discoverer of X-ray, which has become a valuable scientific tool in many fields of science, Madame Currie, died from cancer which she contracted from her work with radioactive substances, when knowledge of its harmful effects were largely unknown. Yet today it can be and is used effectively and safely as a tool and treatment in modern medicine. Such judgments certainly are not based on zero biological risk but rather on a balanced judgment weighing benefit versus risk.

STATEMENT PRESENTED BY
S. MASON CARBAUGH
COMMISSIONER
VIRGINIA DEPARTMENT OF AGRICULTURE
AND CONSUMER SERVICES

My name is S. Mason Carbaugh, Commissioner of Agriculture and Consumer Services for the Commonwealth of Virginia, with offices located at 203 North Governor Street, Richmond, Virginia 23219. In my position, I have responsibility for administering the Virginia Food Law, the Virginia Meat and Poultry Inspection Act, the Virginia Pesticide Law, and a number of other laws regulating products and services offered the citizens of Virginia.

I appreciate the opportunity afforded me by the House Agriculture Committee to appear before you today, and particularly appreciate the efforts of my good friend, Congressman Bill Wampler, in making it possible for me to present this statement.

For two years a cloud of uncertainty has hung over the continued use of nitrite as a preservative in cured meat products. The questions raised by Dr. Newberne's nitrite feeding study created anxiety not only within the nation's meat processing industry, but also among the nation's farmers and consumers. The possible banning of nitrite and the nearly catastrophic consequences of such a ban have, perhaps, been overshadowed by some of the journalistic sensationalism that accompanied the release of Dr. Newberne's findings.

A ban on nitrite would have had an unprecedented economic impact on this country's food industry. Conservative estimates of this economic loss run into the billions of dollars. Both farmers and processors would have shared in this loss. There also would have been an unprecedented impact on consumers, if nitrites had been banned. In the past, the banning of certain food additives has created only temporary problems. In most of those cases, substitute additives were already

AVAILABLE AND A SMOOTH TRANSITION FROM THE BANNED SUBSTANCE TO THE PERMISSIBLE SUBSTANCE WAS MADE. THE BANNING OF NITRITE, THOUGH, WOULD HAVE BEEN AN ENTIRELY DIFFERENT SITUATION, SINCE THERE IS NO SUITABLE SUBSTITUTE FOR IT. A WHOLE CLASS OF PRODUCTS INCLUDING HOT DOGS, BOLOGNA, HAM, AND MANY COLD CUTS WOULD HAVE ABRUPTLY DISAPPEARED FROM THE NATION'S SUPERMARKETS AND DINNER TABLES. THE AMERICAN CONSUMER WOULD HAVE FELT THE EFFECTS OF SUCH A BAN FIRSTHAND. A BAN ON NITRITE ALSO WOULD HAVE COMPROMISED THE SAFETY OF SOME REMAINING PRODUCTS, SINCE NITRITE IS USED TO PREVENT BOTULISM IN PROCESSED MEATS, POULTRY, FISH, AND OTHER PRODUCTS.

I WAS THEREFORE GRATIFIED TO LEARN THAT THE REVIEW OF DR. NEWBERNE'S STUDY BY THE UNIVERSITIES ASSOCIATED FOR RESEARCH AND EDUCATION PATHOLOGY (UAREP) CONSORTIUM HAD FOUND, "INSUFFICIENT EVIDENCE...TO SUPPORT THE CONCLUSION THAT SODIUM NITRITE...CAUSES CANCER."

MY PURPOSE FOR TESTIFYING TODAY, THEN, IS TWOFOLD. FIRST, I BELIEVE THAT THE COURSE OF ACTION, IN REGARD TO NITRITES, AS OUTLINED BY USDA AND FDA FOLLOWING RELEASE OF THE UAREP FINDINGS IS BOTH PRUDENT AND PROPER. WE CAN RIGHTFULLY ASK WHY WAS THE USE OF OUR TOTAL SCIENTIFIC CAPABILITY APPARENTLY DELAYED SO LONG? IN LIGHT OF CURRENT SCIENTIFIC KNOWLEDGE, THE USE OF NITRITES IN CURED MEATS, POULTRY AND FISH SHOULD BE CONTINUED. SINCE NITRITES ARE USED SO EXTENSIVELY, IT IS WORTHWHILE TO THOROUGHLY REVIEW THE EXISTING SCIENTIFIC DATA ON THEM, AS USDA AND FDA HAVE PROJECTED, AND DETERMINE IF ANY FURTHER STUDIES ARE NEEDED. THE AMERICAN PEOPLE ENJOY THE MOST ABUNDANT, WHOLESOME AND SAFE FOOD SUPPLY ON EARTH AND WE MUST SEE THAT IT IS NOT JEOPARDIZED.

MY OTHER REASON FOR TESTIFYING TODAY IS TO SHARE WITH YOU MY CONCERNS OVER FOOD ADDITIVE REGULATION IN A BROADER PERSPECTIVE. THE POTENTIAL CONSEQUENCES WE FACED IN DEALING WITH THE NITRITE QUESTION, SERVE TO REMIND US OF THE PROBLEMS WE WILL FACE IN THE FUTURE UNLESS THE DELANEY AMENDMENT CONTROVERSY IS RESOLVED.

THE DELANEY AMENDMENT, AS YOU WELL KNOW, PROHIBITS THE USE OF ANY SUBSTANCE AS A FOOD ADDITIVE IF SCIENTIFIC EVALUATION FINDS IT INDUCES CANCER IN MAN OR ANIMAL. WHEN THE DELANEY AMENDMENT BECAME LAW MORE THAN 20 YEARS AGO, NO ONE COULD FORESEE THE GREAT ADVANCES THAT SCIENCE AND TECHNOLOGY WOULD MAKE. THESE ADVANCES HAVE HADE IT POSSIBLE TO ISOLATE, IDENTIFY, AND STUDY COMPOUNDS AND BIO-CHEMICAL STRUCTURES UNKNOWN AT THE TIME THE DELANEY AMENDMENT WAS PASSED. THESE ADVANCES HAVE ALSO GIVEN SCIENTISTS AND RESEARCHERS THE ABILITY TO RELIABLY DETECT CHEMICAL COMPOUNDS IN THE PARTS PER BILLION RANGE. IN VIEW OF THESE SCIENTIFIC ADVANCES, IT IS APPARENT THAT A COMPREHENSIVE REVIEW OF THE DELANEY AMENDMENT SHOULD BE UNDERTAKEN. I BELIEVE THAT SUCH A REVIEW WILL LEAD TO A REVISION OF THE DELANEY AMENDMENT THAT ALLOWS FOR SCIENTIFIC JUDGMENTS BASED UPON RISK/BENEFIT CONSIDERATIONS. A REVISED DELANEY AMENDMENT SHOULD ALSO ALLOW FOR SCIENTIFIC JUDGMENTS AS TO THE VALIDITY OF THE TEST PROCEDURES USED TO DETERMINE CARCINOGENICITY.

CONCURRENTLY, WITH A REVIEW OF THE DELANEY AMENDMENT, I BELIEVE THAT THE CONCEPT OF A SCIENTIFIC PANEL TO DECIDE QUESTIONS OF SCIENTIFIC FACT IS IN MY JUDGMENT A VERY FEASIBLE AND NEEDED PROCESS WHICH SHOULD BE GIVEN SERIOUS CONSIDERATION. IF THE FINDINGS OF SUCH A PANEL WERE MADE BINDING ON THE VARIOUS REGULATORY AGENCIES INVOLVED, A GREATER MEASURE OF UNIFORMITY COULD BE EXPECTED. SUCH ACTION WOULD INCREASE THE CREDIBILITY OF THE GOVERNMENT AND GIVE THE AMERICAN PEOPLE MORE CONFIDENCE IN THEIR FOOD SUPPLY.

IT HAS BEEN A PLEASURE TO TESTIFY BEFORE YOU TODAY, AND I WOULD BE MOST HAPPY TO RESPOND TO ANY QUESTIONS YOU MIGHT HAVE. THANK YOU.

STATEMENT OF THE AMERICAN MEAT INSTITUTE

TO THE

PLATFORM COMMITTEES OF THE DEMOCRATIC & REPUBLICAN PARTIES

The American Meat Institute is the principal trade association representing packers and processors of meat and meat food products. Situated midway between the farmer and the consumer, the meat packer is essential to both. The growth of Federal laws and regulations during the past decade, however, has needlessly stifled the packer in efficiently conducting his business. The government must contain this growth and reverse this trend so that packers can better serve both farmers and consumers.

Meat packing and processing is the largest segment of America's food industry. Close to 40 billion pounds of meat are packed and processed every year by companies large and small. While the product volume is substantial, packer net earnings are small -- less than 1% of total sales -- and regulatory burdens heavy. In addition to the requirements of the Department of Agriculture and the Food and Drug Administration which directly regulate food processing and marketing, meat packers and processors must comply with the disparate regulatory requirements of other Federal agencies and state and local governments. This statement focuses on the food safety regulatory activities of the Department of Agriculture and the Food and Drug Administration and makes recommendations which the Democratic and Republican Party Platforms should adopt to promote better organized and less burdensome regulatory policies with respect to food safety that allow the public health to be protected and insure public confidence in the food system.

Although the United States indisputably has the world's safest, most wholesome and most abundant food supply, there is a misguided fear among some well meaning Americans that much of our food and food ingredients are dangerous to the public health.

This misapprehension stems from a virtually constant barrage of episodes over the past two decades in which various foods and food ingredients have been implicated. These highly publicized

episodes and others that certainly will occur unless our food safety laws are modernized will cause an erosion of public confidence in the food industry and in the regulatory agencies -- both of which share the common goal of insuring a safe food supply. The food industry is perceived collectively as a group of "profiteers" who would poison the public to reap greater financial rewards. The regulatory agencies are viewed as either not fulfilling their mission or being overzealous in their efforts to do so. Against this background, a widespread consensus has developed among academia, industry, regulatory agencies, and in some instances, consumer organizations that the present body of food safety laws are scientifically outmoded, inconsistently implemented, and unnecessarily inflexible. These problems have resulted in unduly restrictive regulatory decisions.

Former Food and Drug Administration Commissioner Donald Kennedy, now Provost of Stanford University, has stated that changes is food safety laws are necessary to recognize that "some level of risk is acceptable if there are significant benefits from the use of the substance, as long as the benefits accrue to the people experiencing the risk."

We believe, therefore, that now is the appropriate time for developing a rational approach to the food safety laws which would benefit the industry, the regulatory agencies, and the consuming public. Impediments in the current food safety laws harm the farmer-producer by fostering an unstable marketplace for his products.

The present state of the law concerning food safety can be characterized as complex, confusing, irrational, arbitrary, and in dire need of rethinking and rewriting. There exists a host of legally distinct categories of food substances. Placement of a food or food ingredient into one or another of these distinct categories can result in radically different regulatory treatment with dramatically different ultimate effects.

Food safety is an area that is ripe for regulatory revamping. The basic laws and concepts which regulate the safety of

food are over 20 years old. The Food, Drug and Cosmetic Act was enacted in 1938 after that agency was split off from the Department of Agriculture. The Food and Color Additives Amendments, each containing the Delaney Clause, were adopted in 1958 and 1960 respectively. However, the greatest real change over recent years has been the scientist's ability to detect low level traces of substances or discern low levels of potential risk. Technological advances in recent years have led to greater inferences and sensationalism regarding the possible risks which may result from the use of foods, food packages, and food additives. Included within this group are aflotoxins, acrylonitrile, saccharin, and nitrities. For example, meat packers have had to defend the use of the preservative sodium nitrite against allegations drawn from fundamentally faulty research. Packaging materials have been suspect where a single molecule of a suspected contaminant migrated from package to product. This process has needlessly eroded consumer confidence in the food supply.

As Congressman Thomas S. Foley (D-Wa.), Chairman of the House Agriculture Committee, has stated in a recent letter to the current FDA Commissioner:

> "(T)here is a growing concern that the rigidity of existing law poses a threat of future regulatory action which could do significant harm -- by increasing food costs or reducing food production -- without making any real contribution to health protection.
>
> "(E)xisting law could force the banning of useful products when new scientific equipment finds previously undectable traces of materials which may not have any real health significance."

In addition, Congressman William Wampler (R.-Va.), ranking Minority Member on the House Agriculture Committee, has stated:

> "Despite recent administrative efforts with the executive branch to establish a consistent approach to identify and regulate (hazardous) substances, regulatory agencies have failed to adopt uniform standards for testing, identifying, and classifying chemical substances which may be carcinogenic or may create other risks to human health; evaluating and characterizing the extent of risks to the health of particular populations created by specific chemicals; and determining the levels of such risks which are acceptable to the general public, members of the scientific community, and representatives of agriculture and industry.

> "The failure of Federal agencies to adopt such a consistent approach to identifying and regulating these substances has imposed an increasing number of stringent and desperate restrictions on the uses of chemicals, without a sound scientific basis for many of these actions, thereby limiting the quantity, quality, and varity of food, fiber, and forest products available to consumers. The failure on the part of the regulators in Government to follow good scientific procedures have evoked such severe criticism by consumers and by scientists in Government, academic institutions, and industry, that the Congress has become increasingly involved in implementing regulatory policy with respect to these substances."

Regulation of hazardous or toxic materials is handled by several different Government agencies, each within a different regulatory framework.

For example, safety legislation administered by the Consumer Product Safety Commission does not adopt the no-risk standard which FDA seems to accept for food safety legislation. Instead, each of the consumer product safety acts under CPSC jurisdiction specifies a lesser standard than absolute elimination of risk and lists balancing criteria which the Commission must consider in promulgating product safety rules.

Another example, as fundamental as food, is the Safe Drinking Water Act which seeks to ensure that public water supplies meet minimum national standards for the protection of public health.

While EPA's position is that carcinogen contamination should theoretically be reduced to zero, it has promulgated regulations which do not meet this goal. Specifically, EPA has promulgated a regulation setting a maximum contaminant level for trihalomethanes, a known carcinogen, in drinking water. The agency established this regulation after balancing the adverse health effects resulting from a ban on TTHM and the technological infeasibility of such a standard against the potential health hazard of setting standard greater than zero.

It is time for a revision of food safety policy -- one that will benefit consumers by increasing consumer health and

safety, while at the same time, provide clearer guidelines for approving or disapproving the use of ingredients in foods. Such a policy should be consistent with other health and safety Government policies and should take into consideration questions of risk assessment, benefit assessment, and regulatory flexibility which prevents precipitous Government action that fosters instability in our food system. Such action on the part of the Party will help by providing stability to the processor, help producers by insuring that precipitous Government action against their product could not occur, but most importantly, this change is needed to insure the continued confidence of the American consumer in the food system.

A new food safety policy is needed to protect the public against unwarranted scares and fears and to insure that the public is not deprived of a sound and healthful food supply due to outmoded and inflexible regulatory policies.

We therefore recommend that the Democratic and Republican Party planks contain legislative recommendations to revise and modernize our food safety laws providing guidelines for risk assessment, benefit assessment, peer review, and regulatory flexibility which are consistent with other health and safety Government policies.

ADDENDUM TO STATEMENT OF C. MANLY MOLPUS

Comments were made at the hearing on Tuesday, September 16, 1980 regarding concerns about nitrosamine formation as a result of use or consumption of nitrite in cured meats. The following information is submitted to provide complete and accurate data for the record with respect to nitrosamine formation.

A. Preformed nitrosamines.

Attached are pp. 43447 - 452 of the Federal Register dated June 27, 1980. This notice describes the results of testing of hundreds of samples to determine if nitrosamines are present or not in cured meats. With the exception of pumped bacon, which is under control, and dry cured and immersion cured bacon, which are undergoing further study, nitrosamines were not detected, no matter how the products were cooked. This information supercedes that presented in the 1978 NAS report entitled "Nitrates: An Environmental Assessment." Detailed reports are available from the AMI.

B. Nitrosamine formation in vivo.

We do not believe that nitrite, as consumed, in cured meats can contribute to the formation of nitrosamines in the stomach, or elsewhere, for the following reasons:

1. The quantity of nitrite available to react with a nitrosatable amine is extremely small at any one time (10 ppm in cured meats, 0.75 mg. in a 75 gram serving). See attached "Residual Nitrite in Cured Meat Products."

2. This nitrite is accompanied by ascorbate or isoascorbate which are known to block such nitrosation reactions (ca. 200 ppm in cured meats, 15 mg. in a 75 gram serving).

3. The possibility of sufficient secondary amine being simultaneously present is remote because of their rare occurrence in foods at low levels. See attached publication by Singer and Lijinsky. This is also true for the few nitrosatable drugs being taken by some individuals.

4. Nitrite can preferentially react with other constituents of the stomach contents or more likely be converted to harmless gas under the acidic conditions in the stomach.

5. Gastric cancer in the U.S. has been declining while cured meat consumption has increased.

6. Over 95% of human exposure to nitrite arises from production of nitrite in the intestinal tract as a result of protein breakdown. The biological significance of this source of nitrite needs more study. See attached article from Chemical and Engineering News, March 31, 1980.

(The attachments referred to are held in the committee file.)

STATEMENT

OF

JOHN G. MOHAY, CHAIRMAN

NITRITE SAFETY COUNCIL

My name is John Mohay, president of the National Meat Association, a major Washington-based trade association whose nationwide membership includes about 300 packers and/or processors. This afternoon, however, I am speaking as chairman of the Nitrite Safety Council, a coalition of some 50 groups which represents all segments of the meat, poultry and livestock industries and affiliated interests in all sections of the country. In November 1977 these groups banded together to prove to both the public and the government that nitrite is a safe and beneficial additive and that meat products cured with nitrite did not present a carcinogenic danger to the American public.

At the onset, let me say it is gratifying that the faith we as an industry had in nitrite and our cured products has been proven correct. It is unfortunate, however, that before being exonerated, the public was exposed to needless apprehensions and the meat industry was pushed toward an economic crisis.

The Nitrite Safety Council welcomes this opportunity to recap briefly the dominate role it played in proving the safety and wholesomeness of nitrite-cured products and in combating the adverse effects that resulted when the Departments of Agriculture and Health and Human Services acted prematurely after receiving the findings of Dr. Paul Newberne's study on nitrites.

The Nitrite Safety Council was formed following the Department of Agriculture's October 18, 1977 mandate. Industry was given 90 days to provide information to show whether the use of nitrite in bacon production led to the formation of carcinogenic nitrosamines. In addition, during the ensuing two years, industry was also to demonstrate if carcinogenic nitrosamines were formed in cured products other than bacon as the result of ordinary conditions of processing and/or preparation or eating.

I'm pleased to report that we met each and every deadline. Vast sums of money were raised, intricate protocols were designed and exacting tests were conducted. I believe I'm being conservative when I say this research and

testing cost our industry several hundred thousand dollars. Our success was documented in the June 27, 1980 Federal Register. The industry verified beyond any doubt that products cured with nitrite do not produce unsafe levels of nitrosamine residues.

In the case of bacon, the Nitrite Safety Council worked hand-in-hand with the USDA to develop processing procedures that reduced the levels of nitrosamine residues to the point that they are nonconfirmable. The standard is 10 parts per billion.

Less than a year after this initial bombshell, the USDA and Food and Drug Administration--with considerable fanfare--revealed the shocking results of the Newberne study. Then without certifying the findings with a thorough scientific review, these agencies announced a game plan that would either ban or phase-out nitrite.

Cancer is a very frightening word to the American public. It has a psychological impact of major proportions.

The inference that our products, because they contained nitrite, could cause cancer make them a pariah in the eyes of many consumers and more specifically gave numerous self-appointed consumer activist groups a cause to rally behind.

It is safe to say that the seed of doubt about cured meat products that was placed in consumers' minds cost the industry untold millions of dollars in lost sales. Even though the Universities Associated for Research and Education in Pathology (UAREP) review has proven that Dr. Newberne's findings were incorrect, we may never be able to remove all the concern that was implanted in consumer thinking.

In some cases eating habits were changed, we don't know if those who changed can ever be fully reconverted. Not only will these changes affect today's parents, it will also be ingrained in their children and passed onto future generations. There really is no way to measure the actual dollars and cents damage that our industry suffered because of the premature and erroneous publicity about nitrite.

I am gratified that this industry did not quitely fold up its tent and steal away. Instead, we launched an all-out effort to counteract the unfavorable and unsubstantiated charges against nitrite. As you know, the UAREP review has proven we were not only correct, but also completely justified in raising questions originally about Newberne's conclusions and in doing what we could to alleviate the public fears that were aroused by the involved regulatory agencies.

But, let me assure you, it is not our purpose today to use this forum to vent any outrage we may have felt, nor to gloat with a series of "we told you so's."

Rather than shouting recriminations, which would only aggrevate old wounds and serve no useful purpose, the Nitrite Safety Council believes there are lessons to be learned from this experience and, if properly applied, will prevent any similar occurences in the future.

However, before discussing the need for changes in the review procedures used by the regulatory agencies to ascertain the validity of scientific studies or research and the need for revising current food safety laws, I would like to take a minute to address a nitrite-related issue that has yet to be resolved.

In the June 27, 1980 Federal Register, the USDA proposed to include dry-cured bacon in its nitrosamine monitoring program and "further require that the salt be applied thoroughly to each surface of each belly to protect it during processing and that each belly either be dried to a microbiologically safe maximum water activity level of 0.92 or be brought to a similarly safe minimum brine concentration of 10 percent in the finished product."[1] The USDA said these precautions are necessary to assure protection against botulism and other food poisoning organisms. The Department anticipates that the extension of the monitoring program to this product will induce manufacturers to "reduce, perhaps drastically, the amount of nitrite and/or nitrate used in the cure to avoid the possibility of producing samples with confirmable nitrosamine levels."[2]

Although the dry-cured share of the bacon market is relatively small, this regulation would have an extreme economic impact on those processors who produce it.

The USDA is cognizant of the effect this proposal, if finalized, would have on sales of dry-cured bacon. It states:

> "The Department realizes that some in industry would anticipate possible loss of some portion of their share of the market if they were required to market a bacon either this salty or this dry."[3]

I can assure you this is fact. Bacon produced under the conditions specified in this proposal would be too salty for consumers' palates and therefore sales would suffer drastically.

It is also ironic that the USDA is proposing a process that would add salt to the public's diet at a time when it is strongly recommending in "Dietary Guidelines" that Americans "avoid too much sodium."
In recognition of the economic hardship its proposal would create, the Department has dangled the proverbial carrot in front of industry. Again quoting the Federal Register:

> "For this reason, they (industry) may wish to perform research to show that a microbiologically safe bacon can be produced using other techniques and with other finished product characteristics. Data resulting from any such research will be considered in formulating any final rule for bacon made with dry curing materials."[4]

Research is needed to find an acceptable alternative if dry-cured bacon is to remain a viable product. We believe, however, it is wrong for the USDA to shunt the responsibility for this research off on industry.

It also demonstrates an inconsistency by the USDA. As, you will recall, the Department showed no such reluctance to fund a study to determine if potassium ascorbate could replace most of the nitrite being used to cure bacon. It would seem logical that the Department would be jsut as interested in

funding research to find ways to produce a safe and wholesome dry-cured bacon product that is acceptable to the consuming public.

We request that this committee urge the USDA to provide the necessary funding and see that such a study is undertaken as soon as possible. It is vital to this segment of the bacon industry that an alternative be found which will reduce the amount of salt required in the June 27 USDA proposal. The successful conclusion of such a project would: 1) provide consumers wiht a safe, wholesome and edible product; 2) preserve the dry-cured bacon producers' market; and 3) be in line with the government's recommendation that consumers reduce their intake of salt to prevent hypertension.

Now I would like to refocus my attention on what can be salvaged from the experience we have had with the entire nitrite issue during the past two years.

First, Congress must mandate that USDA and FDA have a well-defined plan that will guarantee an orderly review of any research study which has the potential to create apprehensions in the public's mind about a food product, to damage an industry's economic welfare, or to raise questions about the government's credibility.

It is vital that procedures be implemented that will force government regulatory agencies, the individuals who staff them and the researchers they contract to be accountable for their decisions and subsequent actions.

One way to achieve this accountability is to require neutral third parties to conduct thorough and complete reviews of sensitive and far reaching studies prior to any public pronouncements. Had this been done in this instance, the economic and mental trauma of the past two years would have been avoided.

When a businessman makes the wrong decision, he pays dearly for it. His reputation may suffer, his product may go unsold, or in extreme cases, he may go bankrupt. Yet, no such consequences face researchers or U.S. government employees who reach incorrect conclusions or make the wrong decisions regardless of the severity of their error or the resulting turmoil

it creates. Instead, they are permitted to shrug it off and proceed to the next issue.

This is wrong. And until this appalling situation is corrected, industry and the public will remain vulnerable with no recourse at their disposal. It is time that a system of checks and balances be devised, implemented and enforced. Industry and the public have every right to adequate government protection against unproven scientific theories and the rash government actions they can provoke.

Nitrite is not the first example of the regulatory agencies taking a helter-skelter approach. Cranberries went over the same treadmill. Again, in this instance, after pointing an accusatory finger, the government was forced to retreat. But not before the public's perception of the product has been altered.

This hearing should be the first step in securing a careful review of the overall concept we have toward food safety and a thorough reassessment of the current laws and regulations that govern it. Any weak links in the process must be remedied.

Let me emphasize that no member of the Nitrite Safety Council, nor anyone in the meat industry, is advocating that the government shirk nor lessen its responsiblity to assure the safety and wholesomeness of any food products that would in any way endanger the public's health.

We are, however, realists. Since the passage of the Delaney Clause and other food safety and law requirements, there has been a cavalcade of technological advancements. Scientists now analyze foods in parts per trillion--a plateau that was thought impossible not long ago. It is conceivable that at these levels, not to mention what the future might bring, that every food can be broken down to such minuscule proportions that elements of potential danger can be found.

The key, however, is not just discovering these potentially dangerous elements, but to put them in their proper perspective. Food Safety laws and regulations must realistically assess what risk they actually pose.

We think that research studies should not be conducted in such a manner that the substance administered to the test animals is done so in quantities that when equated to human consumption it is completely abnormal or impossible for humans to duplicate.

There must also be a very careful weighing of the benefits derived from a food or additive in comparison with the risks posed. To ignore this basic concept is opening the door to the indiscriminate banning of various foods and additives without any consideration being given to their positive aspects.

Regretably, I do not have any magic formula that is the perfect answer to what is or isn't an acceptable risk. Even within our own coalition, there is a considerable variety of opinion. But, there is one area of unanimity.

We all agree that a new approach must be found. There is no such thing as a perfect zero.

Working together, industry, Congress, consumers and regulatory agencies must find and define a logical or reasonable base line. The one certainity in this equation is that we can't remove all the imperfections in food--natural or processed. We must instead take into consideration the significance of these imperfections.

Trying to impose the current zero-risk policy on products containing a possible carcinogens might best be summed up as being a penny wise and a pound foolish.

Nitrite is a perfect example. Even before UAREP removed the onus that Newberne had given it, there was considerable question about whether the benefit--the only known additive that afforded total protection against the deadly food poison botulism--didn't far outweight the carcinogenic risk assigned to it by Newberne.

Two valuable lessons can be learned from the nitrite experience. First, the present food safety laws invite government and regulatory agencies to act

implusively and without scound scientific basis which can result in abuses; secondly, the rigidity of those laws and regulations can very easily deprive the American public of a food or food additive that is beneficial to their health and safety. At the same time this rigidity removes valuable tools from government officials who are charged with the responsibility to protect the food system in the best possible way.

Now, while the memory of this entire episode is fresh in our minds, we urge the numbers of Congress and the regulatory agencies to commit themselves to rectifying the wrongs in our food safety policy.

The development of mandatory regulatory review procedures and an updating food safety laws and regulations antiquated by scientific advancements are a must if the American public is to continue to enjoy the wide variety of foods it has come to expect.

I can assure you that the members of the Nitrite Safety Council, including the National Meat Association, are anxious and willing to work with the Congress in accomplishing these objectives.

There is no way to repair all the harm that was done in this instance, but if it motivates action to improve food safety policy, the experience will not have been in vain.

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1. Federal Register / Vol. 45, No. 126 / Friday, June 27, 1980, p. 43427.
2. Ibid. Federal Register, p. 43427
3. Ibid. Federal Register, p. 43428
4. Ibid. Federal Register, p. 43428.

NATIONAL PORK PRODUCERS COUNCIL

STATEMENT AT HEARING ON

NITRITES AND REVIEW OF NEWBERNE STUDY

TO

HOUSE AGRICULTURE COMMITTEE

Mr. Chairman and members of the House Agriculture Committee.

I speak today for the nation's half-million pork producers and the one hundred thousand member National Pork Producers Council.

It is on their behalf that I express deepest appreciation for your invitation to appear here to discuss food safety and tell the nitrite story as we see it.

The history is a long one, as you well know, dating into the 1950's. Pork producers have felt the gradual encirclement and increased pressure on their product at the market place for ten years.

It was only after the Newberne Study and the subsequent announcement in 1978 of a threat of a ban on the use of nitrites as a preservative for red meat that the economic impact became acute.

I hasten to explain, Mr. Chairman, that pork producers are not anti-regulatory. We will be the first to support a ban on any proven carcinogen. That proof, however, must be backed up by research and reliable review procedures.

Pork producers regret that they were forced to take our government to court twice in the past year because of questionable rule making. In both instances, the court ruled in favor of pork producers. The rulings, in separate courts, termed the regulatory agents as arbitrary and capricious. In one instance, the term used was "abuse of authority".

We wish to further make it clear we are not waging a vindictive crusade nor do we wish to vilify any personality.

There is, however, a need to ask penetrating questions and take whatever measures necessary to prevent another cranberry catastrophe or pork debacle.

You see, Mr. Chairman, the farmer for centuries has lived by an unwritten code of ethics. It goes something like this: If my livestock damages your crop we will have it assessed and I will pay you for the harm done. If I wreck your pick-up truck I will repair it.

Sir, the regulatory process has done irreparable harm to the pork industry. A conservative analysis estimates the damage to the value of bacon alone, which represents 10 ½% of the hog carcass, at over one billion dollars.

Our more recent consumer perception survey completed on September 1, 1980. indicates that almost 50% of the people responding believe that bacon contains a cancer causing substance.

I set these facts before you early so you will realize that damage has been done not just to an industry but to a consumer attitude.

More recent media probes into consumer perceptions since the August 18 release by USDA and FDA indicates that those consumers that have had their faith restored in the product treated with nitrite preservatives have had their faith badly shaken in government and its ability to regulate effectively.

Mr. Chairman, pork producers believe the time has come for reform of food safety regulations. The current system is outdated and not sufficiently geared to prevent mishap and abuse.

The nitrite debacle illustrates our concern.

The Delaney Clause is correct in its purpose of promoting food safety but outmoded in its inflexibility. Congress should make clear that food safety, like transportation, environmental or any other kind of safety, is a matter of reasonableness. The discovery of an infinitesimal trace of a suspected carcinogen in test rats after excessive overdoses of a substance should begin rather than end the regulatory inquiry. And it should be permissible to take other relevant considerations into account in making regulatory decisions.

For centuries, nitrites have contributed to the protection and pleasure of consumers. They inhibit the development of food poisoning. And, because animal feedings and other experimentation testing its toxicity have consistently been negative, government, industry and the consumer have been assured of nitrites safety.

As a result, nitrite has assumed a central place in the American food supply, satisfying consumer preference for hot dogs, bologna, bacon and similar favored items and representing for our industry 70% of domestic pork consumption with a retail value of $13 billion.

Two years ago something went wrong. On August 11, 1978, FDA and USDA announced through ranking department officials with optimal press coverage a proposed phase-out of nitrite based on results of a rat study at MIT. Illustrative of government's approach was Assistant Secretary Carol Foreman's statement several days later on national TV: "Sodium nitrite is a carcinogen." (CBS Morning News, August 21, 1978. 7:00 A.M., E.D.T.)

Mr. Chairman, I say something went wrong because one month ago, this time through subordinate department officials with minimal press coverage, buried in a press release on another subject, FDA and USDA conceded that the MIT study was negative and had not shown nitrite to be a carcinogen. In other words, the regulators were dead wrong two years ago.

The devastating but completely predictable effects of this mishap have been many.

For one thing there's been a loss of consumer confidence in regulatory health alarms. Government seems to be teaching us to ignore its health warnings.

The nitrite mishap has also occasioned a kind of backlash to minimize government participation in food safety regulation. We think that's unfortunate because in our view government has played and should continue to play an important role in this area.

A third fallout has been the effective denial of legitimate consumer freedom to choose foods of their preference. When a regulator erroneously calls cranberries carcinogens and forces them off the Thanksgiving Dinner table, we've lost a measure of our precious freedoms. That's what happened with cured foods.

To us, Mr. Chairman, the big question is what went wrong. If we can get to the bottom of this, we can hopefully protect consumers and producers from future recurrence in any aspect of food safety regulation.

Many explanations have been offered. Some suggest the regulatory process itself was deficient. Some touch the intentions of the regulators. Still others say outmoded food safety laws contributed. We're not here to deliver the verdict. But several observations may help.

First, outside government, and on the farm specifically, law and practice require that you look before you shoot, that you check your facts before you make your charges. The rules in government shouldn't be different. The January 31, 1980 GAO report on the government's handling of the MIT study raises more questions on the obligation of investigation than it answers. At a minimum it strongly suggests to us that there was inadequate monitoring of the study during its performance and inadequate review of the study results before release to the public. Seemingly, those inadequacies were fully avoidable and the question remains why they weren't avoided.

In any event, Congress and/or the agencies should adopt requirements that mandate and assure proper performance monitoring and adequate review of results before an investigator's tentative conclusions are publicized or used as the basis for regulatory initiative.

The ultimate loser in this controversy is the consumer. Discouraging the producer limits production and reduces supply availability to the consumer.

In April of 1979 in a conference phone call, the Assistant Secretary of Agriculture, Carol Foreman, asked the Executive Committee of the National Pork Producers Council to support legislation which would provide for a moratorium on a ban of the use of nitrites. Our position was that we would support a moratorium on a ban provided nitrites were found to be carcinogenic. We felt then that the Newberne Study needed careful review and recommended it be reviewed by the National Academy of Science.

Now a year and a half has gone by with the cloud of suspicion hanging over the red meat industry. The atmosphere has been saturated with anti-nitrite propaganda. The consumer confidence has been shaken in this long standing traditional source of healthful nutrition. This nation's diet-conscious consumers and much of the world's population were taken to the brink of condemning pork, the world's number one source of animal protein. A half-hearted, low-key retraction is presented to compensate for a high-level flag waving of a suspected problem that never materialized.

The cloud of suspicion has not yet been removed. The low-level release and explanation was only a slight shift of position and not adequate to clear the atmosphere.

It will require a great deal more than has been done to date to rebuild the confidence of the consumer in a government that has cried wolf far too often about carcinogens.

It will require obvious corrective measures to regain the support of farmers and food producers in a regulatory system that has been declared "capricious" by succeeding court actions in the past few weeks.

I share with you a telegram sent to Secretaries Harris and Bergland after the low-key joint announcement by their departments on August 18, and a letter written to President Carter prior to the joint USDA-FDA release.

TELEGRAM

The pork industry has endured a catastrophe. Preliminary estimates indicate more than a billion dollars in economic damage to bacon alone since the highly publicized announcement of a threatened ban on use of nitrite as a preservative. Many consumers now perceive nitrites as a cancer causing substance resulting from the rash assumption by FDA and USDA. The threatened ban in 1978 was given cabinet-level play with full press coverage. The retraction on August 18 was given obscure treatment and appeared to be intentionally low-keyed with both cabinet Secretaries and Assistant Secretaries absent and noncommitted. 450,000 pork producers are concerned that the irreparable damage is being ignored with cold disdain. Are there department plans to further repair damage done and rebuild consumer confidence? (At the time of this writing we have had no response from either Department.)

President Jimmy Carter
The White House
Washington, D.C. 20500

Dear Mr. President:
On behalf of 450,000 pork producers in America and the leadership of the National Pork Producers Council, I thank you for your recognition of and sincere interest in the pork industry.

The few minutes you took from your busy schedule Monday afternoon, July 28, to meet with agriculture leaders was indicative to us that you consider agriculture high on your list of priorities.

Mr. President, I mentioned in my brief moments with you that the pork industry had been under severe regulatory pressure for nearly three years. It makes it even less palatable to us when those regulations are predicated upon flimsy scientific evidence which has since failed to stand the test of scientific review.

What's more, Mr. President, the regulatory agencies have exploited the later-proven invalid "Newberne Study" to further promote preconceived ideas and concepts which have forced pork producers to take their own government into court two times in the past nine months to bring about accountability on the part of these same regulatory agencies. In both cases, judges have ruled the government "arbitrary and capricious."

We know that the Labor Department helps labor...that Education helps teachers. We who produce food think that we should have our department to help us.

We think this department should help us continue to put the world's safest foods on the nation's tables.

Mr. President, I hasten to add on a positive note that Secretary Bergland has been most helpful to us in establishing a turning point in the recent hog crisis.

We feel a model example of government and producer cooperative relationship turned the hog crisis around in less than two months. This is a record response which could well establish a pattern for future programming to cope with crisis.

As we struggle under the yoke of the oppressive regulatory agencies, our alternatives are few. We can continue to seek relief in the courts...an expensive procedure since we must pay both batteries of lawyers and expert witnesses.

> We can ask our President to talk to his cabinet head who could talk to his departmental heads about government in the interests of all the people...not just an activist's clique. This, we decided, is the appropriate first step.

I write you because in our meeting Monday you indicated you wanted to help. You can, Mr. President, by simply asking your department head and appropriate agencies to compensate to a degree for the irreparable harm already done. It would require only a candid statement removing the cloud of suspicion

from our traditionally safe and wholesome product. It could be done with the following statement:

> Based on evidence known today, there is no reason to be concerned about the safety of the use of products prepared with nitrites.

Of the many regulatory decisions that have crippled industry and confused consumers, three stand out as classic examples. There was the cranberry boondoggle, The more recent saccharin syndrome and now the most costly pork-nitrite debacle. These all were the result of inept or over zealous regulatory activity.

In our free enterprise system, those responsible for such costly decisions should be held accountable.

We respectfully appeal to you, Mr. President, to help us remove this cloud of suspicion from our product which provides consumers with an economical source of high quality protein and 450,000 farm families with their source of livelihood.

Sincerely,

NATIONAL PORK PRODUCERS COUNCIL
William C. Buller
President

Mr. Chairman and members of the committee: In conclusion, I state the pork producers' case. We are not at this moment looking for restitution or reparation. We are more concerned with the future than the past.

With the Nitrite-Newberne controversy being put in perspective it is timely that we deal with food safety procedures. Such costly errors as we have just experienced do not only cost industry, it costs consumers. That's bad government that none of us can condone.

The National Pork Producers Council has had a special committee studying food safety regulations. We feel there should be an outside agency peer review before regulatory action is taken. We will look forward to supporting legislation to ensure this happening.

Nothing would please us more than to be able to go home and tell our half-million pork producers and millions of other red meat producers that as a result of this hearing we are confident our regulatory review process will be shaped up and strengthened; that our rule making procedures and the human judgment which is so vital to the system will be enhanced by wisdom and free of capriciousness. Finally that government, through wise leadership, will literally bring us together, producers and consumers, and give us a new kind of enlightened leadership. Maybe we could call them prosumers?

Community Nutrition Institute
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STATEMENT OF ELLEN HAAS
COMMUNITY NUTRITION INSTITUTE
ACCOMPANIED BY THOMAS B. SMITH

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Mr. Chairman, members of the House Agriculture Committee, good afternoon. I am Ellen Haas, Director of the Consumer Division at the Community Nutrition Institute, a non-profit public-interest organization concentrating on food and nutrition policy issues. CNI is a member of the Consumer Federation of America, the nation's largest consumer group. We publish a weekly newsletter (The CNI Weekly Report) for over 6,000 subscribers, and we provide training and technical assistance as well as conduct workshops and national conferences on public policy issues relating to food and nutrition.

Over the years, Mr. Chairman, one of the principal concerns of CNI has been the safety of foods consumers purchase for their families. We have provided this committee and others with our thoughts on these matters many times in the past and have participated in hearings specifically concerning nitrite--the last being a September, 1978, hearing conducted by the Dairy and Poultry subcommittee of this Committee. In addition, CNI, along with the Consumer Federation of America, the National Consumers League, the Virginia Citizens Consumer Council and the Americans for Democratic Action, in 1977 petitioned USDA to ban all uses of nitrite in meat processing--a petition which was denied in 1979 when USDA announced its plan to minimize the concentration of nitrosamines in bacon products. Before 1977, two other petitions had been filed by consumer organizations to ban nitrite, both of which were denied as well.

The undercurrent which has run beneath all of these efforts is that the use of nitrite in meat processing poses very serious health hazards to consumers which the government has a responsibility to reduce and eliminate as quickly as possible. More importantly for our purposes today, however, is the fact that this developed as our position long before the Newberne study on nitrite carcinogenicity had been released and continues today despite the fact that a cloud has been cast over the results of that study. In short, despite the Newberne study, we feel there is more than enough evidence to have nitrite banned as a food additive.

Essentially, the health hazards of nitrite are both many and well known. For many years, nitrite has been known to be toxic

to humans when ingested at higher doses, and several fatalities have occurred from nitrite poisoning. In addition, heavy nitrite intake can cause methemoglobinemia in infants--which basically causes blood to lose part or all of its ability to transport oxygen to the muscles. In addition, the National Academy of Sciences reports that nitrite has been shown to produce reduced motor activity that apparently is unrelated to methemoglobinemia.

The greatest and most throughly documented hazard stemming from the use of nitrite as a food additive, however, arises from the linkages between that chemical and cancer.

As early as 1967, scientists had shown that nitrite compounds interact with secondary and tertiary amine groups to form various nitrosamines which, for at least ten years before that had been known to be extremely potent carcinogens.

According to a definitive review on nitrite by the National Research Council of the National Academy of Sciences in 1978*, nitrite-induced nitrosamines have been detected in a wide variety of food products, including bacon, ham, frankfurters, salami, dry sausage, luncheon meat, fried fish, anchovies and cheese, (p. 442).

Thus, these preformed nitrosamines present the first level of nitrite-related cancer hazard to consumers.

Currently, the Department of Agriculture has taken steps to reduce the concentration of preformed nitrosamines in cooked bacon and other meat products. While the Department is to be commended for taking even this small step after many long years of delay and avoidance under previous Administrations, it is undeniable that these steps have been and will be effective only in reducing the exposure level of nitrosamines somewhat and not eliminating the serious nitrite-induced cancer threat altogether.

In addition, it should also be recognized that the Department has still focused no attention on the important problem of nitrosamine formation in fried-out bacon fat--which many consumers are likely using as a vegetable seasoning or a medium in which other foods are fried. The average concentration of nitrosamines in fried-out fat is over twice that of fried bacon lean.

As another vital concern, the NAS reported that, "The human stomach provides conditions favorable for the generation of

nitrosamines: the gastric juice is low in pH, and nitrite and amines from ingested foods, drugs, and water mix readily with it....Sander and Seif demonstrated the nitrosation of diphenylamine to diphenylnitrosamine, which is not a known carcinogen, by nitrite in the stomachs of human volunteers; nitrosation of a secondary amine also has been measured in the stomachs of rodents and dogs." (p. 441) Thus it seems that "in vivo" or bodily formation of nitrosamines from nitrite presents the second level of cancer hazard to consumers.

The NAS notes that "saliva is frequently cited as the major source of ingested nitrite. According to White's calculations, saliva accounts for three fourths of the average daily ingestion" (p. 436). However, the Academy also notes that while "this amount is large compared to other sources, ingestion from saliva is spread over 24 hours and the amount entering the stomach at any one time is quite small, especially in comparison to the amount of nitrite ingested in meals containing cured meats or certain vegetables. The timing of ingestion of doses of nitrite is especially important because....the nitrosation of amines in the stomach is a function of the concentration of nitrite" (p. 436).

This fact leads the NAS to conclude that "on a daily basis, the major source of nitrite is saliva. However, this dose is presented to the body as a continuous, low-level input, and the relatively high concentrations over short periods resulting from ingestion of cured meats are probably more important in terms of potential hazards to health....Insufficient data exist to quantify the importance of in vivo nitrosation....but the greatest potential for the formation of N-nitroso compounds appears to be in food. In vivo formation of nitrosamines could be the largest contribution to body burden in the general population"(emphasis supplied),(p. 443).

Thus it appears that according to the NAS, the in vivo formation of nitrosamines is likely the more significant source of exposure and, equally important, this exposure source is most prominently related to the nitrite ingested from cured meats.

Considering the gravity of the cancer hazard stemming from nitrosamines, this information should not be taken lightly. Specifically, the NAS reports that:

(1) every vital tissue is suseptible to the carcinogenic action of this class of compounds;

(2) in several instances, a single exposure to infant animals has induced tumors as the animals reached adulthood;

(3) N-nitroso compounds can induce cancers transplacentally;
(4) many N-nitroso compounds are mutagenic if assayed by the appropriate system; and
(5) the toxicity profile of N-nitroso compounds also includes teratogenesis or birth defects (pp. 454-456).

Furthermore, Dr. William Lijinsky, of the Frederick Cancer Research Center reports that nitrosamines are carcinogenic in every animal species tested, and the NAS concludes that "sufficient toxicological data are available to indicate that humans are likely to be suseptible to the carcinogenicity of N-nitroso compounds" (p. 466).

Mr. Chairman, it is this information that has driven CNI and other consumer groups to have nitrite banned from use as a food additive. As you can see, it bears no relation nor imposes any dependence on the finding that nitrite, by itself, causes cancer. Clearly, the links between nitrite, nitrosamines and a human cancer threat are great enough to warrant affirmative regulatory action to remove nitrite additives from the food supply despite the Newberne study or its problems.

Mr. Chairman, we are fully aware that members of this committee are concerned about the effect that such an action would have on the industry, as well as on the safety of cured meats from the botulism hazard. But because of this concern, as well as the need to take action to reduce and then eliminate the nitrite-nitrosamine cancer threat, we think, in retrospect, that there was considerable wisdom in the plan developed by the USDA and FDA in March, 1979, to phase out nitrite from use as a food additive, even though the agencies had waited (we feel unnecessarily) until the Newberne study was released.

At this point it is essential to point out that the FDA/USDA plan was contingent on a confirmation of the Newberne study. In fact, the letter transmitting the proposed legislation (entitled the "Nitrite Moratorium and Food Safety Act") to the Congress specifically states that, "A study completed last spring by a researcher at the Massachusetts Institute of Technology... suggested that (nitrite) causes cancer in laboratory animals. The results of the study are now undergoing comprehensive review by scientists from outside the government. If the review should confirm that nitrites and nitrates are animal carcinogins, and therefore would result in products containing them found adulterated under current law," the Secretaries of Agriculture and HEW would be compelled to ban their addition to food. The letter proceeds to suggest the option of a moratorium

on such a prohibition for one year during which the USDA and FDA "would collect and evaluate information about (nitrites') health risks and health benefits and the availability of alternates to their use. The period assures that any future regulatory action against these additives, if needed, would be based on sound science and careful evaluation of available evidence." The letter continues by saying that, "At the end of the moratorium, if the MIT study has been confirmed, each Secretary, through the rulemaking process, must weigh the botulism danger posed by a nitrite ban against the risks presented by their continued use" (emphasis all supplied).

Clearly this announced plan could, in no way, be seen as precipitous, hurried or unsubstantiated regulatory action. It was reasonable, logical, and above all predicated on a sound scientific base. And, I must admit, we have opposed the plan because it did involve so much further study and time delays--despite what we have known about nitrite and nitrosamines. For this reason, moreover, we feel very strongly that steps to eliminate nitrite additives from the food supply must begin immediately.

It is equally clear, Mr. Chairman, that the USDA/FDA plan correctly anticipated that a phased ban on nitrite, should it become necessary, would cause much less industry disruption than an immediate ban. In fact, a June, 1979, study by the USDA Economics, Statistics and Cooperatives Service* concludes that the magnitude of the economic adjustments on pork producers and the industry in general from a ban on nitrite "would depend almost entirely on when the ban was announced and how it was put into effect." The report states that "an immediate ban on the use of nitrite would be more disruptive to the food and agriculture sector than a scheduled phaseout which explicitly took into account the relative health risk and the economic importance of each products....A scheduled phaseout would allow farmers and meat processors the time needed to make production adjustments without severe financial losses at a point in time... An announced phaseout would provide more time for the development and testing of new products and the purchase of equipment" (p. 7-8).

Despite this USDA/FDA consideration for the industry in announcing a possible nitrite phaseout, there are some who maintain that the mere announcement in 1979 of this plan caused an enormous decline in hog prices for producers. But we feel that marketplace economics indicate otherwise. According to a USDA pork expert, the dramatic declines in hog prices beginning in March, 1979, and continuing through April of this year, were the

result of record increases in hog marketings during that period. In fact, a check of the marketing statistics shows that hog marketings rose fourteen percent in the second quarter of 1979 over the second quarter of 1978, nineteen percent during the third quarter of 1979 over the third quarter of 1978, and a stunning twenty-four percent fourth quarter rise over the fourth quarter of 1978. These dramatic surges in marketings, especially when coupled with the already growing availability of poultry (up sixteen percent in April, 1979 over April, 1978) provide every explanation for the twenty-six percent decline in hog prices between January and December of 1979.

These marketing facts, Mr. Chairman, coupled with the cautious manner in which the USDA and FDA made their announcement lead us to believe that the agencies commendable concern for the public safety is being made into a scapegoat for unavoidable and completely natural changes in hog market supplies and prices.

Rather that having any adverse impact on hog markets, CNI feels that the structure and tone of the agency announcement has had a very positive impact on one aspect of this persistent problem--that of finding an alternative to nitrite or part of the nitrite in processed meat curing formulas. Specifically, since USDA and FDA made their announcement, there has been a significant increase in the amount of energy spent to develop both nitrite scavengers and nitrite alternatives. Aside from Monsanto's petition for the substitution of potassium sorbate for nitrite, overtures have been made by at least one proprietary firm to apply, through special procedures, bacterial cultures to bacon to reduce residual nitrite (and thus reduce the hazard of preformed nitrosamines). Another firm, which earlier had proposed the use of alpha tocopherol to scavenge nitrite, is currently pursuing food additive approval for the compound from the FDA. In addition, at least one preliminary proposal has been made by a consortium of private firms that would allow a reduction in the amount of nitrite used initially in bacon. This approach involves the use of substitute curing compounds.

Government and quasi-government bodies have also become involved in the search for alternatives. USDA's Science and Education Administration is currently exploring methods of bacon processing that can eliminate the need for some or all of the nitrite in that meat and is also searching for substitute compounds. Thus far, at least one safe compound has demonstrated significant anti-clostridial properties in test tube environments. The next stage of research will involve testing in meat. The Food Research Institute in Madison, Wisconsin has also developed what may turn out to be a new cure formula that substitutes for all or part of the nitrite added to bacon.

Finally, Kodak Company had earlier developed what it feels is a viable alternative to nitrite in comminuted meats--but which is not usable in a product that is pump-cured, such as bacon. Apparently Kodak is waiting until the general nitrite phaseout is announced before it spends additional funds to have the alternative cure formula approved.

Combined, these pursuits represent the necessary first step toward the elimination of nitrite from processed meats. This step has come directly from government actions to limit the consumer hazard from nitrite--both in its bacon monitoring program and through the USDA/FDA announcement on a potential nitrite phaseout. Without a doubt, this first step would have otherwise been years away. If the agencies now end their plans to phase out nitrite, the second step could well be delayed indefinitely.

Mr. Chairman, as I said before, CNI feels that on the basis of the strong evidence against nitrite via its conversion to nitrosamines in foods and in the stomach, the USDA and FDA should begin immediately the process of phasing out nitrite. But I think there may be a lesson here for future action on other matters relating to food additives and health hazards, a lesson which may lead to improved processes through which these problems can be handled.

The lesson, we believe, lies in the thorough scientific review of studies on which important regulatory decisions are based. The review of the nitrite study by the Universities Associated for Research and Education in Pathology is a model which should be followed for all decisions of this magnitude. What is more, it would not be unwise to incorporate into food safety law the requirement that the scientific basis for all regulatory actions pertaining to food safety which are deemed significant must either be substantiated by two other credible scientific experiments on the same subject or reviewed by scientist-peers from outside the agency.

In this regard, we feel that the proposal made by Mr. Wampler to establish a National Science Council for the specific purpose of reviewing the science on which key regulatory decisions are founded has merit and deserves further attention. Clearly, this proposal would streamline the process through which peer review could take place.

*Nitrates, An Environmental Assessment. Environmental Studies Board, National Research Council, National Academy of Sciences, 1978.

"Economic Effects of a Ban on Nitrite Use," Staff Report, National Economics Division, Economics, Statistics and Cooperatives Service, USDA, June, 1979.

consumer federation of america
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September 16, 1980

Honorable Thomas S. Foley
Chairman
House Agriculture Committee
U. S. House of Representatives

Honorable Chairman Foley:

Consumer Federation of America is a federation of over 220 national, state and local non-profit organizations that have joined together to advocate the consumer viewpoint. CFA and its member organizations represent over 30 million consumers throughout the United States. (Our members include 60 state and local consumer organizations, 83 consumer cooperatives, 16 national labor organizations and 27 national and regional organizations.)

We at the Consumer Federation of America think that time and energy spent to examine and reexamine the Newberne Study has been misspent since it does not address the central issue regarding nitrites. The most important concern for consumers stemming from the use of nitrite is the propensity of the chemical to combine with amines informing nitrosamines both in the product as it is prepared for consumption and probably in the digestive tract. Nitrosamines are the most potent of the cancer-causing agents.

According to the available scope of scientific evidence, nitrites are the essential ingredients in the formation of nitrosamines. CFA believes every effort should be made to eliminate nitrites from the consumer's diet because of this link to mitrosamines. Regardless of the Newberne Study, there is ample evidence to warrant such action. CFA urges the U. S. Department of Agriculture and the Food and Drug Administration to move quickly to remove nitrites from our food supply.

Sincerely,

Stephen Brobeck
Executive Director

Statement of William J. McCarville, Ph. D., Chairman, Scientific Committee, American Industrial Health Council

My name is William J. McCarville. I am Director, Environmental Affairs for the Monsanto Company. I am appearing today as the Chairman of the Scientific Committee of the American Industrial Health Council (AIHC).

AIHC welcomes the opportunity to appear to discuss the relationship of science to the regulatory process. AIHC is familiar with the specifics of the issue which has served as a basis for this hearing. However, I do not intend to discuss nitrites, but to address more generically the importance of assuring that government regulatory and policy decisions are based on the best science and to discuss what steps can be taken to assure that objective.

## The American Industrial Health Council

The American Industrial Health Council (AIHC) is a broadly based diversified industry organization with some 140 member companies and about 60 cooperating trade associations.

The purpose of AIHC is to coordinate the scientific and administrative resources of its members to assist government agencies that are considering regulation or policies for control of substances which may present a carcinogenic or other chronic health risk to man.

AIHC's members include producers of chemicals, steel, aluminum, textiles, pharmaceutical products, petroleum products and consumer goods. I have with me a list of members which I would be glad to give to the Committee.

AIHC's charter is simple. AIHC recognizes the need for improved and efficient regulation of substances presenting a carcinogenic risk or other chronic health risk. To achieve that objective, the regulatory process and policy decisions associated with that process must proceed on a sound scientific and cost effective basis.

## The Compelling Need for the Best Science

This Committee has addressed this subject in the past and AIHC commends the Committee for its role in the creation of

the Science Advisory Panel under FIFRA and more recently the amendment to the FIFRA authorization act requiring the development of criteria for the peer review of government generated data. These are important steps in the direction of assuring that decisions by regulatory agencies are based on the best science.

This hearing makes clear that this Committee recognizes that these were just first steps and much more needs to be done to assure that the agencies have available and act on the best science. In our complex society, this compelling need for sound science as a basis for meaningful regulation makes the work of this Committee essential.

This is a very large and important subject and today I am going to confine my remarks to three points:

1. The need to improve scientific risk evaluation.
2. Changes to improve the scientific input to regulatory agencies.
3. The need for national priorities.

The Need to Improve Scientific Risk Evaluation

It is obvious that the first step in any scientific evaluation is validation of the data base. The way in which the government agencies handled the Newberne study and the resulting public confusion point up the need to establish scientific criteria and peer review procedures of data and studies used by government agencies.

The public has been attuned to react strongly to any identification of risk, particularly risk of cancer, by any government agency. The strong reaction to the discredited chromosome study of Love Canal residents is another illustration of the failure of the government to provide the public with reliable information; rather it inflamed the public with poor data and worse science.

AIHC is pleased that EPA has recognized the problem and that procedures are being established to prevent repetition of such unfortunate episodes.

This is a subject of such importance that AIHC believes there should be a general requirement for agencies to establish

procedures to validate data before they are used or released to the public. This problem which is bad enough is bound to get worse in the future.

We suggest that the government is in urgent need of improving risk evaluation to

(a) identify risks using the best science,

(b) establish the severity of the risk or relative potency,

(c) control the risk where appropriate and not alarm the public when the risk is small or trivial.

Scientific risk estimation now has a cloud over it because of the uncertainties associated with extrapolation methods and because of differences in the mathematical models being used. Unfortunately, the public and, in many cases, the regulators believe the numbers derived by the models are hard numbers - real forecasts of what will happen.

Mathematical models have their place, but until we can biologically validate a model - and we have not done so - the numbers generated by the model are only one piece of data which science must use in assessing potency and risk.

Until we understand the biological mechanism by which these substances produce chronic illness, I suggest that it is more consistent with the data to establish categories of relative potency, as the NAS suggested in its Saccharin Study, rather than publish and rely on numbers generated by a mathematical model whose biological validity is subject to much uncertainty and doubt.

Changes to Improve the Science Relied on by Regulatory Agencies

Unfortunately, many of the scientific issues are considered now by governmental agencies in an adversarial proceeding. AIHC's position regarding the development of sound regulatory policies in the chronic health area is that there be a better separation between matters requiring scientific determination from those involving societal or regulatory policy judgment.

Any change in the manner in which the scientific evaluation is performed should have the following objectives:

(a) that scientists of the highest qualifications perform the evaluation;

(b) that objectivity is maintained by separating the scientific evaluation from the regulatory function;

(c) that all agencies have access to all relevant data.

A number of proposals to accomplish these objectives have been made. Two bills are pending in the House - one introduced by Congressman Wampler and the second by Congressman Ritter - which would create a central science panel for all government agencies. The President's Office of Science and Technology Policy proposed that a panel of government scientists be created in the NIEHS National Toxicology Program. The Government Accounting Office has proposed a science court.

Based on its experience AIHC has proposed that an independent science panel be established somewhere in government but not in a regulatory agency whose actions would be affected by the panel's determinations (or within the National Academy of Sciences or its equivalent).

The essence of AIHC's proposal for achieving a more cohesive approach to the development of federal carcinogen and other chronic health control policies is to recognize that the determination of whether a material is likely to cause cancer, or to induce other adverse chronic health effects involves scientific rather than regulatory judgments. AIHC advocates that in the development of carcinogen and other federal chronic health control policies scientific determinations should be made separate from regulatory considerations and that such determinations, assessing the most probable human risk, should be made by the best scientists available following a review of all relevant data. These determinations should be made by a Panel of eminent scientists located centrally somewhere within government or elsewhere as appropriate but separate from the regulatory agencies whose actions would be affected by the determinations. These determinations would be limited to scientific issues and would not intrude upon the regu-

latory responsibilities of the individual agencies involved. AIHC recognizes that these regulatory responsiibilities, quite properly, do differ from one agency to another.

Panelists would be selected on the basis of their eminence and would convene periodically to assess materials submitted for their consideration by agencies on a case-by-case basis. The Panel would have its own staff.

The strength of the Panel's determinations would depend upon the eminence of the scientists, the soundness of their judgments, and the objectivity of their review process. I would like to submit for the record a more complete statement concerning the make up and operation of the panel proposed by AIHC.

The panel would in no way replace scientific staffs at the agencies. Indeed the quality of the panel would lead to pressure to upgrade the scientific capabilities of the agencies. The panel will apply sound scientific criteria in validating the data and by its review assure that the best science will be utilized in the risk evaluation. Government agencies will therefore be pressed to generate or rely on data which meet these rigorous scientific standards.

The Need for National Priorities

The decisions by the regulatory agencies have enormous economic impact on our nation. This is not the time to discuss the cost of regulation. The Committee is clearly aware of the cost if nitrites had been banned. OSHA acknowledged that the benzene standard which the Supreme Court set aside because OSHA failed to show that there was a significant risk at present levels of exposure would have cost $500 million.

AIHC's objective is the control of carcinogens or other chronic health hazards. But controls must be based on sound science and be designed to deal with real risks on a sound basis reflecting national priorities.

It is, I believe now, axiomatic that the concept of a risk free society is a cruel illusion. Chief Justice Burger stated this point very well in his concurring opinion in the benzene case.

> "When the administrative record reveals only scant or minimal risk of material health impairment, responsible administration calls for avoidance of extravagant, comprehensive regulation. Perfect safety is a chimera; regulation must not strangle human activity in the search for the impossible."

Sound regulation must therefore be based on sound science, a point I have already covered - but equally important regulation must be aimed at real hazards. To accomplish that objective there must be some sound system of priorities to assure that the regulators deal with the worst cases first and disregard trivial cases.

Each agency has some system of establishing priorities but there is no basis for establishing national priorities. There are various estimates of the cost of regulation, some running as high as $100 billion a year. Whatever the true figure, the amount is surely high enough to compel the matter to be addressed on the national level.

The establishment of the Interagency Regulatory Liaison Group is a step in the right direction. But this loose coalition of the regulatory agencies provides minimal guidance on national priorities. The Regulatory Analysis Review Group established in the Office of the President by Executive Order 12044 is also a step in the right direction. RARG, however, does not make comments on the basis of national priorities but within the regulatory scheme of each agency.

AIHC has made two proposals which we believe would facilitate the establishment of sound national priorities:

First, AIHC has repeatedly called for a more cohesive approach to the whole problem of cancer and other chronic health concerns. We need a national policy which deals with the whole problem: not only exposure to chemicals but also cancer due to lifestyle, smoking, diet and alcohol. A national policy must be based on a careful analysis of the cancer problem. A chart prepared by the National Cancer Institute reproduced on the next page shows that under the age of 60 cancer mortality is flat or actually declining. It is only in the older group over 60 where cancer mortality is increasing.

Not only do we lack a national cancer policy, even in the narrow aspects in which the regulatory agencies address this problem, the agencies act on different scientific principles and criteria.

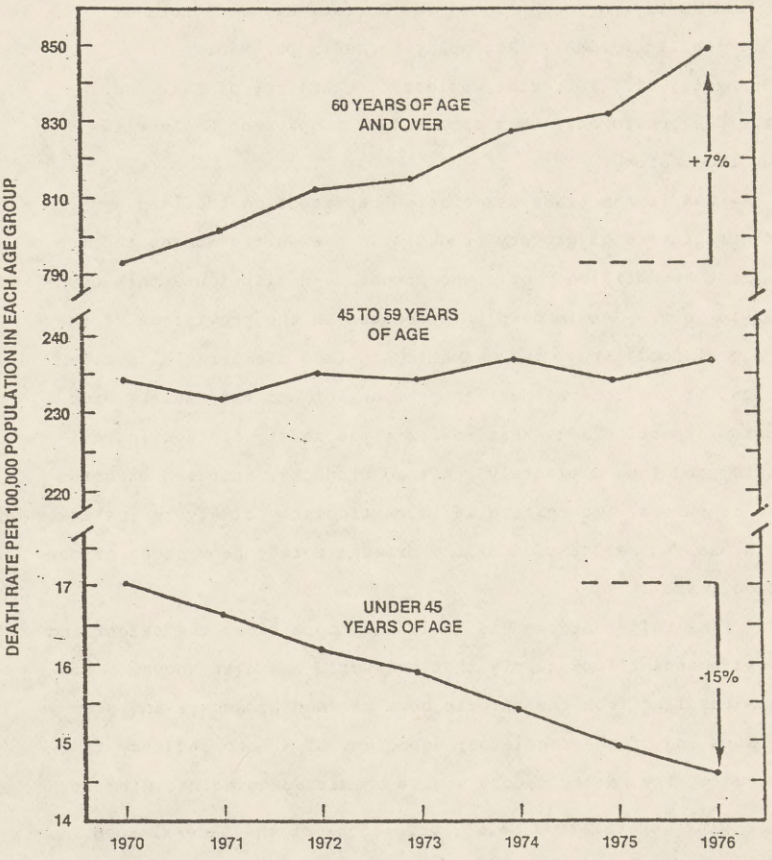
Second, AIHC's proposal for a science panel would facilitate the establishment of national priorities. In the iterative process between the agencies and the panel, the agencies would get the best scientific evaluation of the relative potency of substances. This will assist the agencies in establishing their own priorities. Those data together with exposure information from the agencies would provide a basis for establishing national priorities.

We do not have endless dollars to spend. It is wise both economically and from a health point of view that the huge amount of funds be spent wisely and not on trivial risks.

No agency exists at present which is charged with evaluating national priorities. We believe this matter should - and we hope will - receive attention of the Congress. Establishment of national priorities are essential to assure that health dollars are wisely spend.

(Additional material submitted by Mr. McCarville is held in the committee file.)

Figure I-2. U.S. Cancer Deaths, 1970-1976




Source: DHEW National Cancer Program, *1978 Annual Plan*

Statement of Robert O. Nesheim, Representing Grocery Manufacturers of America

Mr. Chairman, I am Robert O. Nesheim, Ph.D., Vice President, Science and Technology, of The Quaker Oats Company. I am testifying on behalf of the Grocery Manufacturers of America, Inc. (GMA). Accompanying me is Dr. Mahlon A. Burnette, III, Director, Scientific Affairs, of GMA. We are pleased to have this opportunity to present GMA's views on food safety.

GMA is the trade association representing the leading manufacturers of grocery products in the United States and the almost two million people who process and distribute this country's food. GMA is deeply interested in the provisions of the Federal Food, Drug, and Cosmetic Act (and the parallel provisions of the Federal Meat Inspection Act and the Poultry Products Inspection Act) that regulate the safety of food ingredients, and thus ultimately the food products, that are marketed to consumers. We believe it is particularly timely to institute a broad reconsideration of the present safety provisions of our food laws.

The United States has available to it today the safest and most abundant food supply that the world has ever known. This has resulted from the efforts both of food producers and processors and of the regulatory agencies. The food industry is proud of its safety record and is committed to maintaining it.

The general food safety provisions of the Federal Food, Drug, and Cosmetic Act have remained virtually unchanged since 1906. The provisions relating specifically to food additives have not been amended since they were enacted in 1958. FDA is attempting to enforce these provisions in the same way that it did years ago.

During this time, however, there has been an enormous change in our scientific knowledge. As more substances have been subjected to chronic animal testing, more have been found to be carcinogenic -- often only in certain species, or strains, or sex of test animals, and under highly abnormal test condi-

tions. Fully half of the chemicals tested in the National Cancer Institute bioassay program have been found to be carcinogenic in test animals.

In 1958, the lower limits of analytical chemistry were capable of detecting substances at parts per million in the food supply. Today, substances can be found at orders of magnitude lower, down to parts per trillion. It is not surprising that, at these low levels, trace amounts of a large number of substances can be found -- many of which have been determined to be carcinogenic in test animals.

The net result has been a dilemma that has confused and confounded the public, the regulatory agencies, the food industry, and the Congress.

In speech after speech, FDA officials have underscored the impossibility of banning all food that contains a carcinogenic substance or even to include a cancer warning in labeling. Nowhere has this been more eloquently stated than in a Federal Register notice issued by FDA in October 1979: 1/

> "Indeed, a requirement for warnings on all food that may contain an inherent carcinogenic ingredient or a carcinogenic contaminant (in contrast to a deliberately added carcinogenic substance) would apply to many, perhaps most, foods in a supermarket."

A "no-risk" food policy is thus impossible of achievement. As the Supreme Court stated in its recent decision on regulation of benzene: 2/

> "But 'safe' is not the equivalent of 'risk-free.' There are many activities that we engage in every day -- such as driving a car or even breathing city air -- that entail some risk of accident or material health impairment; nevertheless, a few people would consider these activities 'unsafe.'"

We agree with the Supreme Court decision in that case that risks that are demonstrated to be "significant" can properly be the subject of regulatory action.

This is not the time or place to engage in a detailed analysis of the current food safety provisions of the Federal

Food, Drug, and Cosmetic Act, or to suggest specific new language for consideration. We offer, however, the following five general principles that, if adopted either through administrative action or through a change in the law, would reflect current scientific knowledge about food safety and assure a continued safe and abundant food supply in the future.

First, the food supply -- like all other consumer commodities and indeed all human activity -- must be judged on the basis of acceptable risk, not on the basis of no risk. There is no item of commerce and no human activity that is absolutely risk-free. We must not tolerate significant risks from our food supply, but we cannot expect to eliminate insignificant and minor risks.

It is the responsibility of industry and government to reduce risks associated with food to the lowest level that can be reached consistent with the availability of an abundant, palatable inexpensive, and diverse source of food for our country. But all risks are not created equal. Some are less important by reason of their consequences. The risk of a mild allergic reaction is not as serious as the risk of poisoning or cancer. Others are less important because of the degree of risk involved. A highly potent carcinogen is more dangerous, and should be treated quite differently, than a very weak carcinogen. Emerging principles of risk assessment and relative risk are available to guide decisions on these matters.

As the National Academy of Sciences pointed out in its 1979 Report on Food Safety, a reasonable food safety policy must provide a variety of regulatory responses that will accommodate differing types and degrees of risk. Some risks are so small that they can properly be ignored. Others are so substantial that the public should not be subject to them. In between, there are risks that justify public information and education but do not warrant an outright ban. Only by distinguishing among types and levels of risk in its regula-

tory decisions will FDA succeed in educating the public about the relative importance of the risks it faces and thus re-establish its damaged credibility in this field.

Second, the government should properly be restricted to assessing the risk of food, and should be precluded from regulatory decisions based upon its perception of the benefits of particular food products. Without doubt, FDA has substantial expertise in assessin the risk that any food may present. It is properly within the province of the government to determine those risks and to inform consumers about them or, where they are unacceptably high, to ban them from the marketplace totally.

But the Federal government has no expertise whatever in determining the attributes of food that consumers desire. Nor is it the proper function of government to dictate to the public the kinds of food they will be permitted to purchase and consume. A consumer should be free to make his or her own determination of the benefits of any particular food, in light of all information material to that product.

FDA has argued that the only benefits that properly should be considered in the regulation of food relate directly to human health. But any of an enormous variety of diets will provide adequate nutrition. Most food choices are therefore made for reasons of personal preference and pleasure, rather than for health considerations. It is apparent that the consuming public views food characteristics such as flavor and color, to mention only two, as highly important and beneficial.

GMA is therefore opposed to any legislation that would permit regulatory consideration of the benefits of food. Congress should assure that food safety regulation is based upon assessment of significant risk, not upon benefit.

Third, the law must continue to reflect the special status of food components with a long and recognized history as a part of our diet. It would be unreasonable and unworkable to revoke the current provisions of the Federal Food, Drug, and Cosmetic

Act that exclude substances subject to a prior sanction or that are generally recognized as safe (GRAS) from the requirements for food additives. All of our raw agricultural commodities may presently be used in processed food products only because of these provisions. If they were revoked, every one of those raw agricultural commodities would be required to undergo the same toxicological testing as a new chemical additive. This would be an extraordinary waste of our testing resources and a remarkable misallocation of our national priorities.

The general safety provisions of the food law provide adequate regulatory authority for those food substances that are excluded from the definition of a food additive. FDA has in fact used the general safety provisions of the Act in the past under these circumstances.

It is therefore unnecessary and unwise to change the prior sanction and GRAS provisions of the law.

Fourth, it is important to bring to bear on food safety decisions the best scientific expertise that exists in the country. GMA agreed when FDA turned to the Federation of American Societies of Experimental Biology (FASEB) to conduct the initial evaluation of the safety of GRAS food substances. This outside review has resulted in decisions that have gained widespread acceptance in FDA, in industry, and in the public at large. Outside scientific review has also been employed by FDA for OTC and prescription drugs and for biological drugs, and has been mandated by statute for medical devices. Continued reliance upon outside experts in food safety decisions is essential if they are to have high scientific validity and public credibility.

Fifth, more flexible enforcement of the food safety provisions of the law is badly needed. It is unnecessary and unrealistic to waste millions of dollars by overnight bans of commonly-used food substances. Preciptious action based only upon theoretical risk needlessly wastes food and raises

food costs to the consumer. Hurried regulatory action of this nature is often counter-productive, resulting in consumer stockpiling of banned products for lack of an adequate substitute and even the need for Congressional enactment of a moratorium.

Where important food items are involved and there is no imminent hazard, a reasonable phase-out is sufficient to protect the public health. Where suitable alternatives are not yet available, a longer period to permit technological adjustments may well be required. Administration of food safety laws must be undertaken with calm deliberation rather than in a crisis atmosphere.

These five general principles outline a reasonable food safety policy for the future. GMA would be pleased to work with this Committee and others in developing specific legislation if administrative actin is insufficient to accomplish these goals.

1/ 44 Fed. Reg. 59509, 59513 (October 16, 1979).

2/ Industrial Union Department, AFL-CIO v. American Petroleum Institute, 48 U.S. L. Week 5022, 5031 (July 2, 1980).

Statement prepared by
Dr. R.V. Lechowich, Head and Professor
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Safety is a term that has been previously used in quantifying risk assessment situations. Current knowledge, however, suggests that safety as applied to our food supply is an elusive concept that cannot be established with certainty. In light of presently changing concepts, the acceptability of some degree of risk might be compatible with the previously accepted general definition of safety. However, a more realistic approach is the evaluation of risk itself.

The risks associated with food were defined more than seven years ago by Dr. Virgil Modicka, former Director of the Bureau of Foods of the U.S. Food and Drug Administration (1). The evidence to support his assessment of these risks is substantial and this assessment has been widely accepted. These food-associated risks have been grouped into six major categories and will be discussed ranging from the condition offering the most risk or hazard to the least hazardous situation.

1. Microbiological risks. The risk caused by the presence of contaminating microorganisms is accepted to pose the greatest risk to human health. However, the exact risk or prevalence is difficult to quantify since the illnesses that can result from such food contamination are not always reported by physicians nor recognized by the victims themselves. Nevertheless, informed estimates indicate that as many as twenty-two million Americans may suffer from the effects of bacterial contaminated food each year. Thus, one out of every ten people could be affected and only the common cold causes more human discomfort and loss of time.

The most recent annual report of foodborne disease is reported by the Center for Disease Control: Foodborne Disease Outbreaks, Annual Summary 1978, issued November 1979 (2). The data indicate that, as has been true in each of the five preceding years, bacterial agents were the most common cause (70.1%) of the foodborne outbreaks of confirmed cause. The overwhelming majority (91.3%) of confirmed cases were caused by bacteria, and this figure is almost identical to the five year average of 91%. Salmonellae accounted for one-third of confirmed outbreaks and

nearly 40% of the cases, figures consistent with results from 1973 to 1977. The second commonest agent was Staphylococcus aureus which was implicated in 15.9% of the outbreaks and 29.3% of the total cases.

For the first year since the beginning of foodborne disease reporting in the U.S., an outbreak of Vibrio cholerae (serotype 01) induced disease was detected in the U.S. (2). In addition to one cluster involving four persons, seven additional cases were discovered, all in Louisiana, with boiled crabs identified as the vehicle.

Of the 110 bacterial outbreaks, 31 or 28.1% were attributed to food eaten in the house and 41 or 37.2% in restaurants.

Mishandling of food in food service establishments accounted for 92.8% of the outbreaks while mishandling at home was implicated in only 5.4%.

The causative agent has not been identified in from 30 to 60% of the foodborne outbreaks that have been reported to the Center for Disease Control in any of the last five years. This lack of identification could be due to late or incomplete laboratory investigation or to the fact that the suspected food was no longer available for analysis. Alternatively, the pathogen responsible was not implicated because either it is not now recognized as a food poisoning microorganism or it cannot yet be identified by current laboratory techniques.

2. Nutritional risks. Nutritional risks due to outright malnutrition are relatively uncommon in the United States, but several nutritional surveys have shown that suboptimal intake of several key nutrients and poor dietary patterns are widespread. Some of these deficiencies are due to poverty, some to ignorance, some to indifference, and some to misinformation.

3. Environmental risks. These risks rank next but are perhaps one-thousandth as important as the first two hazards. It is the implied or potential hazard which is the basic concern in the area of environmental risks. Examples include the polychlorinated biphenyls (PCB's) and polybrominated biphenyls (PBB's). Because of more stringent controls and

greater public awareness these risks tend to be the result of rare and usually accidental incidents rather than pervasive multisource problems. Environmental conditions aside, the risk to man through his food supply is very small, but we cannot be absolutely sure that our present methods are sufficiently sensitive to exclude a low probability of harm. We can presume that as new methods of toxicological investigation are developed, they will detect hazards where none have previously been found.

4. Risks from natural toxicants. These substances include any food components that show unusual or serious toxicity or which we consume with a narrow margin of safety. In addition to the rare hazards from food allergies, our food supply contains an enormous variety of naturally occurring toxic substances that can be quite toxic even when consumed in very small amounts. In some cases, the amount in our food supply approaches the toxic level with only a narrow margin of safety. These substances are found in almost every food, and some even are essential nutrients such as Vitamin D. Natural toxicants are less important to the present American food supply due to an abundant and more varied diet.

5. Pesticide residue risks. Pesticide risks are closely associated with the risk of environmental pollutants. However, they justify separate listing because many of them are intentionally applied to food and food crops. We owe much of the productivity and availability of our food to the effective use of these agents. There is no evidence that connects pesticide residues at the presently accepted tolerance levels in food with any known cases of human injury or death.

6. Food additive risks. Last and least important as a food hazard are food additives. The low risk from pesticide residues and food additives is partly a result of the scientific and regulatory attention they have received. Moreover, the risks from microbiological and nutritional factors are high because they are the result of how each of us chooses, uses, and abuses our food.

The hazards from food additives, pesticide residues, and environmental pollutants are both remote and small; yet in the press, legislative, and consumer groups, they receive the most attention. Micro-

biological and nutritional hazards are clearly far greater but are widely and largely ignored. Yet these most important and disregarded sources of risk are precisely the ones most within individual consumer control. In short, the attention we give these matters is inversely proportional both to their actual importance and to our ability to control them.

Although food chemicals do not thus represent the major human health risk, they have been the subject of a considerable amount of research since 1970. In the past decade, significant advances have been made in toxicity testing and in the interpretation of the results of studies to predict hazards for man. New, revised or proposed guidelines have been promulgated for carcinogenesis testing by the National Cancer Institute (3) for carcinogenesis, mutagenesis, and teratogenesis testing by the Canadian Department of Health and Welfare (4); for testing the toxicity of household products by the National Research Council Committee on Toxicology (5) on behalf of the Consumer Product Safety Commission; for assessing food safety by the Food Safety Council (6); for assessing pesticides by the Environmental Protection Agency (7); and for assessing the safety of chemicals by the NRC Environmental Studies Board (8).

Numerous conferences and workshops have been held to consider conventional toxicity testing protocols (acute, subchronic, chronic, inhalation, dermal, etc.), as well as such newer areas as mutagenesis or genetic toxicology, behavioral or neurotoxicology, immunotoxicology, and various types of target-organ toxicity. The U.S. Senate Committee on Agriculture, Nutrition, and Forestry has examined the topic of food safety (9).

In recent years all levels of government, industry, academia, and society as a whole have become increasingly involved in issues related to the safety of various chemicals, to the Delaney clause, and to food safety policies. There has been extensive debate on many related matters, including the concepts of maximum tolerated dose (MTD)*, threshold dose effect, and the use of safety factors versus risk estimate projections. Related developments during this period include: new re-

quirements for good laboratory practices (GLP) (10); the Occupational Safety and Health Administration (OSHA) guidelines on carcinogenesis (11); and the passage of toxicology related legislation, e.g., the Federal Environmental Pesticide Control Act, a revision of the 1947 Federal Insecticide Fungicide and Rodenticide Act (FIFRA) (12), the Toxic Substances Control Act (TOSCA) (13), the Safe Drinking Water Act (14), and a report on food safety policy (15). These have made the 1970's an exciting, albeit somewhat unsettling, decade in the history of toxicology and have had an impact on food safety evaluation.

In general, methodologies of testing now available seek to evaluate the adverse effects of food chemicals; "Benefits" have proven more difficult to quantify (16). The latter may in the future constitute an important element in the regulatory decision-making process, and adequate methods for assessment of benefits are urgently needed. The Food Safety Council (17) has recently proposed certain guidelines and a framework for the explicit evaluation of benefits of using food chemicals that may be compared with evaluation of risks.

Because valid risk assessments cannot be made without adequate data, toxicologists have taken a closer look at various aspects of testing methodologies. Modifications and improvements of existing methodologies are being made. Additions to existing protocols or proposals for new protocols are being developed. Testing methodologies are being examined in order to improve assessment of risk while reducing expenditures of time, money, and scientific resources. If a given protocol does not improve assessments and reduce expenditures, it will not provide any real benefits to the consumer. Rather, it will merely supplement the traditional approach, lengthen the current list of procedures, and ultimately increase costs. It should also be pointed out that authenticated cases of human injury resulting from the approved use of chemicals in the production, processing, packaging, or storage of food are rare. Therefore, established, effective methodologies should not be abandoned in favor of new approaches that may be attractive only because they are new, different, fast, or relatively inexpensive.

Recent developments and current needs in determining risk assessment of food chemicals are subjects of a study to be published in 1980 performed by the Committee on Food Protection of the Food and Nutrition Board of the National Research Council/National Academy of Sciences. This report is entitled Risk Assessment/Safety Evaluation of Food Chemicals and will include suggested investigative procedures for establishing the toxicity of food chemicals.

In order to restructure present food safety policies, an extremely important first step is to establish the mechanisms for choosing appropriate methods for establishing the toxicity of compounds.

Secondly, the subject of prediction of risk is also a very important factor. The Food Protection Committee report previously mentioned covers the subjects of selection of test procedures, species selection, sensitivity to toxic effects, metabolism, methods of predicting risk, the concept of the uncertainty (previously termed the safety factor), and extrapolation of dose-response data from animals to predict human toxicity.

It is recognized by investigators working with food chemicals that research to refine the validity of extrapolation methods for interpreting animal toxicity data should continue to be conducted.

Thirdly, mechanisms should be developed to permit consideration of both risk and benefit in the food safety decision process.

Finally, a uniform regulatory policy should be adopted that would be applicable to all food components, food additives, and food contaminants.

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*An operational definition to facilitate the chronic testing of chemicals in the National Cancer Institute bioassay program.

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Statement of Bernard L. Oser, Ph. D., Food and Drug Consultant, Forest Hills, N.Y.

Throughout my many years of association with scientists, lawyers and friends in both FDA and the regulated industries, I have had numerous occasions to discuss, in principle, various scientific and technical aspects of the food laws and their implementation. I have lectured and taught on the subject and have been called by a former Commissioner "one of FDA's most constructive critics" in which sense I trust that what I have to say here will likewise be construed.

FDA as well as the food and related industries have devoted more resources and manpower to the reinvestigation of substances which experience in use and previous scientific evaluations indicated to be safe, than to new additives or new uses. This has been due in part to the application of new methods of analytical precision and sensitivity which reveal the presence of hitherto undetected residues, to the more extensive and intensive procedures employed in toxicological investigations and unfortunately, to premature reaction to uncorroborated studies of questionable validity. Illustrative of such cases are the cyclamate, saccharin, Red 2, DES, caffeine and nitrite decisions.

In recent years FDA has tended to show undue haste in reacting to rumors and reports of toxicity of food additives especially when they emanate from abroad. Lay publicity, the pressure of activists, and the resultant concern of industrial users of approved substances, set in motion extensive reviews and expensive studies to refute or corroborate these adverse reports. They engender inconclusive controversy and often prove to be false alarms. Meanwhile, public confidence in the judgement of both FDA and industrial scientists tends to become eroded.

Two former Directors of the Bureau of Foods have described the agency's perception of concern for the various aspects of food safety. Ranked at the head of the list of six potential hazards were food borne infection, followed in sequence by malnutrition, contaminants, naturally occurring toxicants in foods, pesticide residues, and finally "functional ingredients", which include GRAS substances and regulated color and food additives. Reflecting the minor position of food additives in the scale of risks is the fact that of 217 Notices of Judgement reported by FDA in the past year only 8 related to food additives and 3 to color additives.* The others involved unsanitation or contamination with insect or rodent filth, mold and miscellaneous minor substances.

From the viewpoint of consumer reaction however, Commissioner Robert's list of the areas of "sensitivity", as perceived politically and by the public, put food additives first, followed by chemical contaminants, sanitation, nutrition, etc., stating that "these rankings

reflect the negative but ill-defined feelings of consumers about additives, the media exploitation of these feelings, and the attention focused on such problems as PCB's, PBB's, Kepone, and recalls of under-processed foods." In my opinion, consumer concern for the safety of food additives has influenced regulatory, legislative and judicial activity to a degree out of all proportion to the real public health hazard.

Problems of the Toxicologist

In the deliberations which preceded passage of the Food Additives Amendment, it was stated that "safety requires proof of reasonable certainty that no harm will result from the proposed use of an additive". It does not - and cannot - require proof beyond any possible doubt that any harm will result under any conceivable circumstance. Observation of "no effect" in animals does not "prove" the absence of effect in larger groups, in other species (including man) or at lower doses. A finding of "no residue" in a food or feed, by an exquisitely sensitive analytical method, does not rule out the subsequent discovery of a finite amount by an even more sensitive method.

On the advice of an NAS/NRC Advisory Committee, the FDA and the Department of Agriculture some years ago adopted the definition for "negligible residue" as "no amount of a pesticide chemical remaining in or on a raw agricultural commodity . . . . that would result in the daily intake regarded as toxicologically insignificant on the basis of scientific judgement of adequate safety data". More recently, because of recognition of the impracticability of a strict "zero tolerance" concept, the term "virtually safe dose" has been applied in deference to those for whom "toxicological insignificance" is unacceptable. The proposal of FDA to replace the absolute zero by the "sensitivity of method approach"(SOM) (i.e. analytical methods of toxicologically acceptable sensitivity) is in effect acknowledgment of the principle that "de minimis non curat toxicologia".

Notwithstanding the frequent statement of the impossibility of "proving" safety in the absolute sense, FDA, as I will point out later, has taken the position that even if the carcinogenicity of a substance is in doubt, its use may be proscribed on the ground that it has not been "proven safe", presumably to the degree of "reasonable" certainty. But, one may ask, reasonable to whom? This is a highly subjective and unmeasurable criterion. Under the pressures of legalistic necessity and consumer activism, FDA tends to exercise an overabundance of conservatism, far to the right of "reasonable certainty".

The fundamental issue is one of safety - not for rats receiving maximum tolerated doses - but for men, women and children - under conditions of proposed use. It is a scientific question which, in the language of the law, should be judged by experts qualified by training and experience to evaluate safety.

Judgements of safety cannot be rendered with absolute certainty regardless of whether based on experience in use or on "scientific procedures", the latter including, but not limited to, animal tests. Toxicology is not an exact science. It is not only a relatively new combination of disciplines but is in a dynamic state and investigative procedures or parameters of adverse effects are continually being proposed or developed (and, regrettably, adopted in some cases prior to validation for significance or reproducibility).

Animal studies, regardless of how thoroughly they are described by Guidelines for "Good Laboratory Practice", inevitably involve subjective evaluation with respect to design, execution, and interpretation. Investigators do not determine "scientific facts" but make findings (i.e. observations based on planned studies) which are not ultimate truths but open to interpretation, validation, and subjective evaluation in which knowledge, experience, integrity, and intuition play important roles.

The choice of animal species, the mode of administration, the selection of basal diets and dosage levels, the number and type of observations, the duration of the test and the extent of post-mortem examinations, are all matters of decision concerning which there is less than unanimous agreement even among toxicologists. To quote quote from the Food Safety Council's "Proposed System for Food Safety Assessment"

> "Of primary consideration in the choice of test species is whether the animal model is biologically appropriate for the toxicological assessment of possible human risk. This implies, of course, an animal in which the qualitative and quantitative aspects of metabolism and pharmacokinetics of the test substance are identical to man. Nonetheless, whatever metabolic data are available must be considered in the selection of the test animal, as well as in designing the experimental protocol. If it is demonstrated that there is a significant difference, particularly in qualitative terms, in metabolism between man and a proposed test species, the test results may have little relevance to human safety."

There are many other technical points at issue among toxicologists. For instance, there is disagreement as to whether "ingestion" via the diet includes dosage via stomach tube. Pathologists may differ, sometimes significantly, in their interpretation of histological slides. The incidence of cancer in animals is variably expressed as the number of tumors per dosage group, the number of animals with tumors, and even the number of litters containing animals with tumors.

There is considerable controversy over the requirement that the maximum tolerated dose be used in carcinogenicity studies and how it should be determined. The Scientific Committee of the Food Safety Council recommends that the highest dose should be one that

1. Induces no overt toxicity, i.e., appreciable death of cells or organ dysfunction as determined by appropriate clinical pathological, pathological or biochemical methods.
2. Induces no toxic manifestations which are predicted to shorten the lifespan of the animals except as the result of neoplastic development.
3. In two generation studies, is not detrimental to conception rates, fetal or neonatal survival, or postnatal development.
4. Does not retard weight gain during the subchronic test by greater than 10% as compared to control animals.
5. Takes into consideration metabolic and pharmacokinetic data, and if dose-dependent qualitative or quantitative differences occur, at least one test dose should be set above the metabolic shift (provided the level(s) does not exceed the criteria listed above in 1 through 4).

Critical studies by the National Cancer Institute and others have in some instances exceeded these limits but NCI scientists believe it is their purpose to discover potential sources of carcinogenicity even if the test conditions employed exceed those for establishing safety under conditions of use. Despite the fact that regulatory decisions have been and are being based on tests in which animals receive massive dosages prenatally and throughout their lifetime, the validity of the in utero procedure is only now being investigated under the National Toxicology Program.

The Delaney Clause

The Delaney clause and the underlying concept* has turned out to be the vaguest and most controversial aspect of the Food Additives Amendment. This was predicted when it was first adopted but it came into sharp focus following the saccharin ban.

The first and most crucial phrase in the Delaney clause consists of three words viz. "found to induce cancer" which have never been clearly defined for regulatory purposes.

A single feeding study in animals of any species or strain, under whatever extreme conditions of dosage, i.e. regardless of magnitude, frequency or duration, can condemn the use of a substance if cancer is found to occur. The very fact that the next part of the Delaney clause provides an alternative, namely that the test be "appropriate for the evaluation of the safety of food additives" implies that any test employing the ingestion route of administration is, ipso facto, appropriate. Neither the statistical significance of the incidence, the relevance to experience in use, nor the low level or benefit of the substance in use, are mitigating circumstances prescribed by statute or regulations.

The practice of using the maximum tolerated dose (MTD) in carcinogenicity tests arose from the desire of cancer researchers to screen large numbers of chemicals for potential carcinogenicity, not for the purpose of safety evaluation of residues in food. The belief that

massive dosage compensates for the limited numbers of animals under test compared to human populations "at risk" is incompatible with the altered biochemical pathway or pharmacokinetics of absorption and excretion when doses exceed the normal homeostatic capacity of the organism to cope with foreign substances.

Aside from the magnitude of the critical test dose, the very condition of daily ingestion through the lifetime of the animal, contrasted with the intermittent or infrequent intake of most additives by many, increases the margin of safety by at least several orders of magnitude.

Because of marked differences between rodent species and primates in reproductive physiology and in placental structure, hence in the transfer of substances from the maternal to the fetal circulation, it may be questioned whether the rat is a suitable experimental model for predicting prenatal toxicity in man.

The word "cancer" in the Delaney clause was originally construed to refer to the malignant type of neoplasm, described as invasive, metastic, irreversible and lethal, whereas benign tumors were considered to be self-limiting, often reversible, non-metastic and non-lethal. These descriptions appeared in publications of the Joint Expert Committee on Food Additives of the World Health Organization and the Food and Agriculture Organization of the United Nations, as well as the Food Protection Committee of the National Academy of Sciences-National Research Council. However as applied for regulatory purposes, "cancer" now includes benign, as well as malignant, tumors inasmuch as they are regarded as precursors to malignancy, if the animal survives long enough. In discussing the question of whether or not thresholds exist for carcinogens, Dr. John Weisburger, formerly at the National Cancer Institute stated that "there are doses for which no tumors (much less benign ones - BLO) are seen over the average lifespan. Were the animals to live longer, tumors could be predicted to occur".

More recently mutagenicity has been brought under the cancer umbrella because certain tests are believed capable of revealing "suspected carcinogens". However, while FDA has recommended mutagenicity tests as a means of revealing potential carcinogens, which then become subject to chronic tests in animals, it has only last week and for the first time to my knowledge, ruled against a substance (cyclamate) because "the data in the record do not establish that there is a reasonable certainty that cyclamate does not cause cancer . . . . and . . . .<u>heritable genetic damage</u>." (emphasis supplied)

An important advance promises to provide an operational basis for distinguishing "true" genotoxic carcinogens (i.e. electrophilic substances that are believed to react with DNA in the nuclei of target cells) from a variety of other structures, both organic and inorganic, which operate through different and less well-known mechanisms, such as by "immunosuppression, solid state effects, hormonal imbalance, cocarcinogenicity, and promotional activity."

Polycyclic aromatic hydrocarbons, aromatic amines, alkylating agents and certain metals are examples of the genotoxic type of carcinogen, whereas asbestos, estrogens, phorbol esters and certain antisera are among the epigenetic classes of substances. In vitro tests being developed to differentiate between the two classes, may have value in carcinogenicity testing programs.

In view of the foregoing discussion, it would appear that the time has come for reassessment of the Delaney concept to permit discretion on the part of scientists for translating truly relevant tests for cancer-inducing potential to the conditions of human exposure to food additives.

The Sweetener Ban

I have discussed elsewhere, and at considerable length, the basis for my conviction that the Food and Drug Administration erred in precipitately withdrawing cyclamates from its GRAS list, which was admittedly based on studies conducted under my direction by Food and Drug Research Laboratories. Briefly, my reasons were that the agency and its advisors were not in possession of complete knowledge of the study, the test material was not cyclamate but a mixture of cyclamate and saccharin (which itself later came into question), there were many potentially interfering factors whose significance was not then understood, and finally, the preponderance of subsequent studies conducted elsewhere failed to establish cyclamates as the offending factor. During the decade which followed, FDA has vacillated between regarding cyclamate as a weak carcinogen, to possibly a non-carcinogen but of unproven safety (because of testicular atrophy in rats receiving the metabolite cyclohexylamine), to the latest conclusion that studies have "failed to prove that cyclamate does not cause cancer or inheritable genetic damage" -- a philosophically unattainable goal.

With respect to saccharin, in no instance have single generation studies shown it to be carcinogenic in animals. The three 2-generation studies on which FDA relied for its proposed ban involved massive dosage (5 or 7.5% of the diet) to pregnant rats and even more excessive perinatal dosage to the progeny. As stated by the National Academy of Sciences ad hoc committee that reviewed these studies, this in utero procedure was relatively untested and unvalidated.

As stated above the National Toxicity Program for Fiscal Year 1980 has only now begun "to develop techniques for predicting toxicological problems arising from exposure to various agents administered either in utero in the last trimester of pregnancy or to a newborn." Fortunately Congress has extended the moratorium on FDA's saccharin ban.

One could go on and describe the inadequacies of the data which have led to premature adverse publicity and either actual or threatened removal of Red 2, nitrite, DDT, 2,4,5-T, etc. from use in food. However with respect to both the artificial sweeteners, cyclamate and saccharin, I regard the data which induced FDA to ban them, or remove them from the GRAS list, as flawed because the bladder tumors were seen only at a single maximum dose level rather than being graduated to dose. Statistical extrapolation of the data to man resulted in theoretically predicted incidence far too low for epidemiological verification. Both of these sweeteners may be regarded at worst, as "weak carcinogens" for the rat. Since the weakest is about one ten-millionth as potent as aflatoxin, for which action levels are permitted, the hazard to man could be considered negligible and virtually indeterminate under any conceivable use conditions.

Benefit/Risk

Societal and legislative concern for safety of the environment inevitably leads to consideration of benefit versus risk. Neither of these attributes of food additives can be quantified in mutually commensurate units, hence it is futile to attempt to express the relation between them in the form of equations. However benefit and risk may be evaluated in terms of their ratio, i.e. acceptability of risks are warranted only if the benefits are sufficient. Benefit and risk are indeed two sides of a coin and other things being equal, lesser risk is per se more benefit.

The oft-repeated contention of FDA that it has no legislative authority to take benefit into account in assessing the acceptability of risk ought to be corrected, if true. Petitions for food additive regulations require that data be included bearing on the (intended) physical or other technical effect", which implies that the additive must have utility or functionality. Such effects may relate to the enhancement of nutritional content, preservation against deterioration and waste, sanitary handling and packaging, aid in processing, and, especially important from the standpoint of the ultimate consumer, improvement in hedonic values (flavor, texture, color, etc), in convenience in cooking, baking, preparation, etc., and in economy as related to availability (seasonal), variety, and cost.

The specific benefits or purposes served by food additives, as well as their safety, are seldom consciously perceived. However inasmuch as their use is permitted, positive values must be presumed to exist. Perhaps the most generally appreciated advantages of eating foods are

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satiation and enjoyment. Life would be dull indeed if the process of satisfying nutrition and appetite were unaccompanied by pleasure. Sugar, honey, syrups and, in fact, most fruit juices are near the bottom of the scale of nutrition but they rank exceedingly high on the hedonic scale. (The same is true to an even greater degree with respect to artificial sweeteners.)

Assessments of benefit should rest to a large extent on consumer reaction and industrial experience as seen in the market place, rather than on the subjective judgements of officials whose main concerns are for "honesty and fair dealing", safety, and good nutrition. Nevertheless provision should be made for regulatory recognition of benefit as an intrinsic factor in evaluating risk.

*The food additive cases included one each of saccharin, calcium orotate, zinc orotate, calcium pangamate, mandrake root, nitrate, a pesticide residue and an "odor suppressant", while 3 cases involved color additives.

*We sometimes speak of the Delaney concept because of FDA's contention that potential carcinogens have been proscribed not by invoking the Delaney clause but under the general safety provisions of the FDC Act.

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September 16, 1980

It is a pleasure to appear before the House Agriculture Committee to discuss some of the issues underlying basic policies on food additive regulation in this country. My discussion will not encompass all issues but rather will focus on a few that will require extensive elaboration in future hearings. Having worked for a regulatory Agency (FDA) and the private sector, I will briefly discuss these areas both from the perspective of the regulator in FDA as well as the regulated industry.

The most important issue affecting the regulatory processes for food additives is the basic public policy as contained in the FD&C Act and amendments of 1958 and 1960. Basically, this Act with subsequent amendments states that no chemical known to be a human carcinogen or suspect carcinogen will be allowed in human foods or in the feed of food producing animals unless in the latter case the chemical will not adversely affect the health of that animal and based on an analytical procedure approved by the Secretary there will be no residues of that chemical in foods produced for human consumption.

This policy now has placed the FDA regulatory process for food additives in an inconsistent situation. The background and development of this policy have been elegantly reviewed by Mr. Peter Barton Hutt, "Public Policy Issues in Regulating Carcinogens in Food," in Regulatory Aspects of Carcinogenesis and Food Additives, F. Coulston, Editor, Academic Press, New York, 1979, pp. 9-23. As noted in his review, the policy in question (and it is policy statement and not a statement of scientific principles) arose in response to the scientific uncertainty about how much or how little of a carcinogen would be required to produce cancer in a human being and how long it would take for the cancer to develop. In light of this uncertainty, Congress concluded that until this uncertainty is resolved, it would require FDA to regulate on the side of caution by not allowing any animal carcinogen in the food supply.

In the 20 years since enactment of this legislation, the scientific uncertainty that existed then has not been unequivocally resolved; if anything, the issues are more confused now. The only real issue now as it pertains to the "Delaney Clause" is to reexamine the relevancy of this policy

in light of present knowledge. Does the policy as espoused in 1960 with its attendant regulatory procedures now serve the best interests of the general public?

The basic intent of the policy was to protect human food supplies from the presence of animal carcinogens. In 1960, it was not anticipated that scientific advances would subsequently demonstrate the presence of trace amounts of animal carcinogens in food nor that some common food substances might be shown to be animal carcinogens. Mr. Hutt (loc. cit) has stated the situation very simply:

> "Virtually every food product on the market today contains some constituent that has been shown to be carcinogenic in at least one animal test. Some of these are unwanted contaminants, such as the aflatoxin in peanuts, corn, and milk, and the nitrosamines in bacon. Some are the result of using chemicals for other important processing purposes, such as the chloroform produced by chlorination of water. Others are natural constituents of food, such as the tannin in tea, the caffeine in coffee, and the safrole in cinnamon. Still others are essential vitamins and minerals, such as vitamin D, calcium, selenium, and tryptophan. Even egg white, egg yolk, lactose, maltose, and charcoal-broiled meat have been shown to be animal carcinogens. It would be difficult to plan a diet for even one day that would be entirely free of animal carcinogens. It would surely be impossible to live for any significant time on such a diet, in light of the utter ubiquity of these substances."
>
> "Thus, although the food safety policy embodied in the current law, and the FDA's implementation of it, may have made good regulatory sense even as late as a few years ago, it is obviously no longer sustainable. It is simply not feasible to remove from the food supply every substance that has been shown to be carcinogenic in test animals."

Vitamin $D_2$, as noted above, is one unique example of a nutrient carcinogen in C3H · $MTV^+$ mice. D. S. Titus et al., IRCS Med. Sci. Libr. Compend., 8, 286 (1980), reported that vitamin $D_2$ possessed estrogenic activity in the uterine weight bioassay which may account for the increased incidence of mammary tumors in mice. With lipids, P. Bernard et al., IRCS

Med. Sci. Libr. Compend., 6, 489 (1978) reported that addition of fat at dietary levels of 10, 20 or 30% decreased the time to tumor and increased the incidence of mammary tumors in this same mouse strain. Even though lipids are not usually considered a critical factor in tumor induction, obesity in humans favors tumor development and high fat diets have been related to cancer induction in the gut, J. H. Weisburger and G. M. Williams, "Chemical Carcinogens," Second Edition, Chapter 6, pp. 84-138, in Casarett and Doull's Toxicology - The Basic Science of Poisons, J. Doull, C. D. Klassen, and M. O. Andur, Editors, Macmillan Publishing Company, Inc., New York, 1980.

Obviously, it is not feasible to regulate vitamin D or dietary lipid under the umbrella of the FD&C Act. These cases are presented simply to reinforce the concept that the human diet cannot be made completely free of chemicals or products that produce cancer in animals.

Further evidence of the regulatory dilemma can be seen by the actions taken by FDA with regard to aflatoxins and saccharin. Aflatoxins, a group of several congeners produced by Aspergillus flavus, are found on many cereal grains and nuts, generally after harvesting. One of these compounds (aflatoxin $B_1$) is one of the most potent hepatocarcinogens known, Weisburger, and Williams, loc. cit. FDA, to avoid banning a large portion of the annual corn and peanut production, determined that aflatoxins were "unavoidable" and hence not subject to provisions of the "Delaney Clause" or other general safety provisions of the act, Hutt, loc. cit. Action levels for residues were established in the low part per billion range. Saccharin is also carcinogenic in animals, M. D. Reuber, Environ. Health Perspectives, 25, 173-200 (1978), even though it may be acting as a promoter, E. Boyland, Nature, 278, 123-124 (1979) and S. M. Cohen et al., Cancer Res., 39, 1207-1217 (1979). The proposed FDA ban on saccharin was met by significant public opposition. Congress ultimately decreed a moratorium along with a call for further study of this specific issue.

The public outcry over the proposed FDA ban on saccharin illustrates however that the general public is willing to accept some risk for at least one potential carcinogen in the diet. This is important and should be considered in any review of the "no risk" philosophy as expressed in the 1958 and 1960 amendments to the FD&C Act. The public seems more willing to accept that there is no such thing as "absolute safety." "Safety" cannot be deter-

mined experimentally. Instead, toxicology evaluates the hazard (toxicity) of a material which is then equated to "potential risk" based on exposure and hazard. The challenge is to decide what level of risk is socially acceptable. This must involve public debate.

These two actions amply demonstrate the dilemma faced by FDA in its attempt to regulate food additives. The agency has in many instances ignored evidence of animal carcinogenicity data for common food components and declined to take action that would be subject to public ridicule, Hutt, loc. cit. Even when actions are taken, the lengthy legal process may be negated by Congressional action as in the case of saccharin. This is not to imply that the Congressional action was inappropriate. However, intervention places Congress in the position of assuming the regulatory function of FDA on a case by case basis. FDA cannot continue to regulate in this environment and expect to retain public confidence. FDA should be allowed to carry out its mission. FDA needs the legislative mandate to permit the agency to function properly. This means a reassessment of the current policy for regulating food additives with the ultimate development of a long-range policy on food safety.

FDA, within its present mandate, has been developing a regulation to establish criteria and procedures for evaluating assays for carcinogenic residues of chemical compounds in food producing animals. Commonly referred to as the "Sensitivity of Method Document," this procedure was republished as a proposed regulation in the Federal Register on Tuesday, March 20, 1979. The proposed regulation is complex in its approach but is unique as a concept and deserving of a thorough evaluation. This approach has not been validated experimentally; moreover, some of its approaches are the subject of vigorous scientific debate. However, the proposed regulations are an attempt by FDA to develop a more consistent regulatory policy for chemicals to be used in food producing animals. This attempt is laudatory.

Briefly, the intent of this regulation is to determine the potential that the proposed use of a sponsored chemical has for contaminating the edible tissue of target (food producing) animals with residues that engender a risk of cancer to humans and then to devise an approach to regulate that chemical to minimize potential risk to humans. Each chemical would be evaluated with regard to its use pattern, residue levels of toxicological concern, and the potential toxicological significance of these

residues. Numerical scores would be assigned to each of these three factors. Individual scores would then be multiplied for a final score "number." If the total number is less than 1,000, general safety provisions of the Act would apply to the chemical. A compound with a score number greater than 1,000 would raise enough concern about the potential contamination of food with carcinogenic residues that the chemical must enter at least the first step of the proposed regulations.

Assuming that a chemical was subject to a complete evaluation under the proposed regulations, the final result would be the approved use of an "animal carcinogen" where the conditions of use (i.e., time from cessation of use to time of marketing), have been established along with the development of an analytical procedure applicable for regulatory surveillance and compliance. The process seems to assure that potential residues of a chemical in edible products will be less than levels calculated by mathematical extrapolation from carcinogenic bioassay data in animals to present no greater than a preselected level of "risk." The approach is conservative in order to provide "maximum" protection of the general public.

The concept appears feasible on the surface but as noted above has not been verified experimentally nor proven to be scientifically feasible.

Another issue in this discussion is to recognize the importance of the reviewer in the regulatory process and to emphasize the need to devote sufficient resources and energy to the recruitment and retention of qualified personnel. The regulatory official labors in an arena where scientific issues, rules and regulations, and public policy and pressure coincide and many times conflict. The regulator is not in an enviable position. On one hand, the petitioner is pushing for an expeditious decision, hopeful for approval; public pressure may be exerted to withhold a decision, withdraw a decision, or to rapidly approve a petition. Congressional authority may be interjected into the regulatory process either in a decision-making or in an oversight role. These competing pressures, although inevitable and not necessarily detrimental, may foster an attitude or an atmosphere that complicates the decision-making process.

For the most part, the regulatory official is a highly motivated individual dedicated to making decisions in the public interest based on the best available science within the content of existing public policy as

exemplified by legislation and accompanying rules and regulations. However, the nature of the position, i.e., desk review of data, may not provide the necessary stimulus to attract, train, and retain highly skilled personnel. The reviewer may not be able to keep up with newer techniques and to participate in and publish the original research necessary to develop a solid scientific reputation. This is a major concern to the young scientist embarking on a scientific career. Regulatory agencies recognize these problems.

Regulatory decisions require the best available scientific data. However, the regulator often will not have all of the information desired since research generally raises more questions than it answers. Moreover, the data will in many cases have been generated over a period of several years, during which time new techniques and/or approaches have been developed. Yet the regulator must make a decision with available data. How long can a decision be delayed waiting for new data?

But more importantly, the regulator must decide what constitutes a properly designed study to determine a toxicity endpoint including carcinogenesis. An experiment conducted 10 years ago may not be considered adequate today. Scientific advances are rapid; new endpoints (behavior, immunology, etc.) are being developed and/or validated. The factors that go into a properly designed experiment are constantly being discussed, unfortunately not always leading to any consensus. The Interagency Regulatory Liaison Group (IRLG) was established to provide a forum for discussion of just such issues but apparently has not yet made a significant impact on approaches to toxicity testing. Consistency between various regulatory agencies appears to be a necessity. FDA and EPA for example approach the problem of carcinogenicity from vastly different viewpoints. The FDA proposes general approaches or guidelines; for example, routes of exposure, at least for food additives, will probably include in utero exposure. In establishing the process for "Cyclic Review of Food Additives," core protocol standards are being proposed, i.e., endpoints or biological indices to be included in the protocol if the results are to be evaluated to have a significant regulatory impact. This general approach provides flexibility and the ability to add other endpoints based on the characteristics of the chemical under test. This approach, although highly desirable, makes the regulatory process more difficult; it places more emphasis and responsibility on the technical abilities of the regulatory official and appears to

presuppose some degree of communication between the regulator and the regulated to establish a protocol prior to initiating a toxicity test including a chronic carcinogenic bioassay.

The EPA also proposed standards for chronic toxicity testing, including carcinogenesis, under TSCA, Federal Register, Vol. 44, No. 91, Wednesday, May 9, 1979. Admittedly, the FDA and EPA regulatory missions differ, but the basic need is the same, that of toxicity-carcinogenic evaluations of chemicals. The EPA standards however appear to be protocols unto themselves stating not only what is to be done but also how and when to do it during the study. Unfortunately, this approach "cookbook toxicology" which is not desired by many toxicologists. The approach may also reduce the role of the regulator to that of a check-list clerk for the purpose of simplifying the decision-making process.

The above amplifies one major theme - inconsistency in testing guidelines required by various regulatory agencies. Consistency is important even though the agencies have different missions or areas of responsibility.

The main theme of this presentation has been to suggest that the basic food safety policy established 20 or more years ago may no longer serve the best interest of the general public and that reevaluation of this policy is essential. If a new policy is needed, a combination of appropriate scientific expertise and public representation should be able to define that policy and the mechanism(s) to implement that policy in the best public interest. In broad terms, any such mechanism must categorize and prioritize the chemicals as to the status of carcinogenicity data, i.e., status as a proven or suspect human or animal carcinogen. It must include an assessment of all available scientific information available on a particular material including the mechanism(s) by which the compound causes an increase in tumor response, i.e., initiation, promotion, etc. It must assess relative risk, alternatives and their risk, and then balance all of this information with the benefits to arrive at a decision that is in the best public interest. Fundamentally, food additive regulations with potential carcinogens will have to accept some form of risk assessment. Only then may it be possible to develop a public policy and an approach that allows the regulator to function in a consistent manner compatible with public safety.

Testimony before the House Agriculture Committee

by

Ira I. Somers
Executive Vice President
National Food Processors Association

The National Food Processors Association (NFPA), formerly the National Canners Association, appreciates this opportunity to testify on the subject of food safety. As a trade association with over 700 members, we represent approximately 90% of the canned foods industry.

It is no coincidence that NFPA should have a strong interest in food safety. This has been one of our major concerns for over seventy years as I shall document. For this reason, NFPA believes that as a trade association, we should assume a prominent role in any discussion of food safety policy at the national level.

As our record demonstrates, NFPA represents an industry responsive to emerging public concerns and attempts to be constructive and imaginative in its response.

In all discussion of food safety one should not lose sight of the fact that our industry provides the safest food supply in the world and that those food safety problems which historically have been greatest already have been eliminated. The "problems" we are dealing with today are not absolute but theoretical or speculative and yet to be proven -- for example, the case against nitrite.

With this introduction, let me review NFPA's historical interest in food safety. The National Canners Association was organized in 1907 just one year after the enactment of the Pure Food and Drug Act. Food safety was a prime factor in the creation of the Association. For example, the early bylaws of NCA contained the following statement: "Any person, firm, partnership, association or corporation engaged in the manufacture or preparation of foods packed in hermetically sealed containers and sterilized by the use of heat alone, free from chemicals for preservative purposes, may become an active member of the Association . . . if and so long as such person, etc., shall maintain a sanitary canning plant, conduct the same in a sanitary manner and use only wholesome raw products." (Emphasis added)

These bylaws were an early recognition of the need for product safety. The reference to exclusion of chemical preservative was a recognition that prior to enactment of the Pure Food Act, unsafe substances such as formaldehyde, copper salts, etc., were added to foods by some packers and the canning industry wanted it known that they did not condone such practices. The industry does of course recognize the use of safe and Government approved preservatives.

NCA Inspection Program: In 1920, the Association put into effect for the canning industry a comprehensive Sanitation Inspection Program. The industry felt at that time that establishment of a uniform inspection service would help to assure consumers of the merit and convenience of canned foods and provide products packed in canneries under the supervision of individuals responsible for seeing that the factories and employees were clean and neat, and that all the food prepared therein was pure, wholesome, and packed under sanitary conditions. This program and philosophy served the consumers of that day very effectively.

NCA Sanitary Code: In 1923, the Association established a Sanitary Code which was published as Bulletin 93A. This code dealt with proper lighting and ventilation, the materials from which walls and ceilings should be constructed for easy cleaning, and criteria for floors, work rooms, washers, scalders, blanchers, etc. It assured that the water used for syrups, brine making, cleaning, and washing would be safe and wholesome. It also dealt with cleanliness of the workplace surroundings (free from waste and rubbish), equipment being operated in compliance with state and federal sanitary laws, proper washing of the product before entering the plant, and removal of damaged or soiled material. It listed a number of requirements affecting employees. It is significant that this code, established in 1923, closely parallels FDA's Good Manufacturing Practices of today.

NCA Code of Ethics: In 1925, the National Canners Association adopted a Code of Ethics which reads: "To assure the consuming public the best canned food that scientific knowledge and human skill can produce, and to establish relations with allied industries and trades on a basis of justice and fairness, the National Canners Association makes the following statement of principles to govern its membership in the conduct of their business and their relations with the public:

1. To use in the preparation of our products only suitable materials which are sound and wholesome.

2. To employ sanitary and hygienic methods and equipment in the operation of our plants, to comply with the Sanitary Code of the Association and all food laws and regulations.

3. To maintain the highest standards of quality.

4. To truthfully describe and represent our products.

5. To fulfill both the spirit and letter of all contracts.

6. To recognize always a paramount obligation to safeguard the interests of the consuming public."

NCA Laboratories: These general programs of the Association were paralleled by the development of research laboratories and a scientific program within the Association. The Washington laboratory was established in 1913. Early work began with the study of the adequacy of food containers. By 1920, thermal processing was a major object of research, aimed at eliminating instances of botulism from underprocessed products. This work led to the development of a truly scientific method for establishing adequate sterilizing processes. It also led in the 1920's to the establishment of two additional laboratories in Berkeley, California, and Seattle, Washington.

Processing studies by the Association served as the building stones upon which current methods of heat sterilization were built. In the late 1920's, an official processing publication, Bulletin 26-L, was made available to the food industry. This publication has been updated periodically and is now in the 11th edition. It contains recommended minimum heat processes for a large number of low-acid canned foods.

In the intervening years, a tremendous amount of research was done by the NCA (NFPA) laboratories on the organism Clostridium botulinum and the procedures and requirements necessary to prevent its growth and development in canned foods and the often fatal illness that it may cause. There have been very few instances of botulism from commercial canned foods over the years. And we are proud of that record. The real botulism threat now lies in a growing number of cases from improperly processed home canned foods.

NFPA processing bulletins for low-acid canned foods in metal and glass containers have had a very salutary effect on industry's safety performance. So has another effort, launched after the occurrence of a single case of botulism in 1971. The Association staff went to work and developed what came to be known as the "Better Process Control Program." We asked the Food and Drug Administration to implement this as a regulation to be applied to the low-acid canned food industry. It is now FDA Regulation 113. It places additional controls and requirements on industry, which, in our view, are necessary to assure against instances of botulism.

Sanitation has long occupied the attention of the industry, and our Association laboratories. In the mid-1940's, renewed emphasis was placed on sanitation, training programs were held and a book on sanitation was published. This effort generally upgraded industry practices.

When organic pesticides came into use, it was obvious that more care was needed in their use than had been practiced in the past. The Association set up what came to be known as the "Protective Screen Program." This was designed to give packers accurate information on any pesticide, and to set parameters which would guide them in the acceptance of agricultural products to which pesticides had been applied. It also included research on methods of washing and preparing products to reduce residue levels. Today, instances of canned product being contaminated by pesticide residues are extremely rare.

The introduction of organic pesticides required new methodology to detect residues. The Association laboratories spent considerable time developing such tests. We organized a Committee of Industry Analysts to whom round-robin samples could be sent to assure that all persons using a standard method were getting comparable results. These procedures have continued and now involve laboratory testing procedures for all kinds of potential contaminants.

Back in the 1930's, when labeling became a concern of the Food and Drug Administration, the National Canners Association developed a Descriptive Labeling Program and prepared a labeling manual to guide industry in the labeling of canned food. This manual has been updated over the years. It lists the information required by regulations as well as helpful supplementary information, to properly inform consumers about the contents of the product within the container. For example, when salt became an item of consumer concern, the Association passed a resolution that members would declare the words "salt added" on their product labels. The labeling manual was changed by our Board to reflect that policy statement. Similarly to reflect this position, the Association agreed to declare all ingredients on the label, even for products with a standard of identity which do not require declaration of all ingredients.

When nutrition labeling came along in 1972, the canning industry immediately began using it voluntarily, until now a high percentage of the canned foods are nutrition labeled including most of the major food items.

All of these activities are good evidence that NFPA and the industry it represents have been interested in producing wholesome, safe products and informing consumers of their composition.

Certainly food safety has an extremely high priority with the canning industry. And, even though our record is good, for which the industry can be justly proud, we are not resting on our laurels. Industry recognizes the need to move forward, to do what is necessary to assure continued safety of the food supply.

With this background, I would like to offer our general views on food safety legislation.

First, we believe that the different existing standards for food ingredient safety, with minor refinements which I will discuss in a moment, are necessary and sound public policy, and that major revisions in the food safety provisions of the Federal Food, Drug and Cosmetic Act (FD&C Act) are undesirable and impractical. The FD&C Act currently provides for somewhat different safety standards for naturally occurring contaminants for food additives and for added substances that are not food additives and that are required in the production of a food or that cannot be avoided by good manufacturing practices. The 1958 Amendments to the FD&C Act imposed stringent safety standards (including the Delaney Clause) for approval of new food additives, but exempted from food additive control those substances which were approved for use in food by FDA or USDA prior to September 6, 1958 (prior sanctioned), or which are generally recognized as safe (GRAS), through either scientific procedures or experience based on common use in food.

It is our view that these different food safety categories constitute sound public policy and should be retained. The exemption from food additive control for prior sanctioned and GRAS substances is based on what would be an otherwise impossible administrative burden of subjecting all food ingredients to comprehensive safety tests and on Congressional recognition that those food ingredients in long use prior to 1958 had been shown to be relatively safe and desirable. Moreover, these substances remain subject to the general prohibition of the Food and Drug Act against the addition of a poisonous or deleterious substance that may render a food injurious to health. Similarly, the different safety standards for naturally occurring contaminants, and for added substances that are required in the production of a food or that cannot be avoided by good manufacturing practice, reflect sound and practical administrative and social judgments.

As this Committee is aware, there have been several widely publicized proposals for a major overhaul of the food safety provisions of the FD&C Act. These include proposals to abolish the different statutory provisions for various categories of food substances, to create a single safety standard applicable to all food ingredients, and to provide for risk assessments and/or risk-benefit evaluations of all food substances. NFPA strongly opposes these proposals. They would impose enormous costs and administrative burdens on FDA (and the regulated industry), and

would create a prolonged transition period of substantial uncertainty. Moreover, by eliminating the current adequate protections for prior sanctioned, GRAS, naturally occurring, and environmental contaminant substances, these proposals would also have a potential major adverse impact on large elements of the food industry, the food supply, and on consumers.

Second, we also strongly oppose the recent proposals for risk-benefit review of new food additives. This would add greatly to the cost, complexity, and delay of reviewing new food additives, and would give FDA unwarranted discretion to deny approval for lack of benefits. As Congress recognized in 1958, the benefits of new food additives should be determined in the marketplace by the companies that process and distribute them, and by the consumers who buy them.

Within the framework of the existing food safety provisions, we would recommend two changes. First, we support explicit authority for FDA to phase out the use of valuable food or food packaging ingredients discovered not to be safe for which there are no suitable alternatives. The Department of Justice rendered an opinion last year, at the request of HEW, in which it ruled that FDA has no discretion to phase out the use of a potentially unsafe food ingredient, regardless of the value of that ingredient, or the cost or indirect adverse health consequences of its peremptory ban. We believe that this imposes an unjustified restriction on FDA's enforcement discretion. Accordingly, we support explicit phase-out authority to avoid disruptions in the food supply from the immediate ban of valuable food and food packaging components for which there are no suitable alternatives.

Finally, we support some refinement and clarification in review of food additives under the Delaney Clause. The recent advances in analytical methodology with greater sensitivity, coupled with the continuing controversy over the interpretation of animal feeding study results, make it essential that FDA act only on an informed scientific basis in restricting the use of a food additive. Accordingly, NFPA suggests that the Delaney Clause be expanded to assure sound scientific decisions. First, FDA should be required in each instance to consult with qualified experts in cancer causation. Second, with the assistance of those experts, FDA should be required to prepare a full factual analysis of the scientific data upon which FDA and those experts have reached their conclusions. They should then be required to provide a detailed explanation of the basis upon which it and those experts have scientifically concluded, from a fair evaluation of all the available data, that a food additive is not safe. These supplementary requirements for the application of the Delaney Clause would contribute to scientifically sound decisions, would avoid continued controversy and possible litigation, and would reduce both unwarranted consumer apprehensions and loss of public confidence in food safety determinations.

Certainly, had a procedure been followed in dealing with the nitrite issue consistent with the principles we have just outlined, the confusion associated with that episode could have been avoided.

In closing, we wish to reemphasize that the NFPA represents a forward-looking industry which is responsive to new emerging public concerns in food safety. We believe our program offers a constructive response to these concerns.

AMERICAN ASSOCIATION OF MEAT PROCESSORS
Presented by Ms. A. Joan Dannelley

My name is Joan Dannelley. I am Project Coordinator for the American Association of Meat Processors, the trade association representing the nation's small to medium size independent meat processors. We appreciate the opportunity to present testimony on the federal government's handling of the controversy surrounding the use of nitrates and nitrites in cured meat products.

With me today is a representative of the Virginia Association of Meat Processsors and owner of a small Virginia meat business, Mr. Frank Parrish of Manassas, Virginia. Although Mr. Parrish is not directly involved in the curing of meats, he sells cured meat products to his customers and thus is typical of the type of owner/operator that AAMP represents. Mr. Parrish is a past president of the American Association of Meat Processors and of the Virginia Association of Meat Processors. The Virginia association is one of 27 state and regional organizations affiliated with AAMP, the others being: Alabama Meat Packers & Processors Association, Arkansas Meat Processor & Locker Association, California Association of Meat Processors, Meat & Poultry Association of Hawaii, Idaho State Meat Packers Association, Illinois Association of Meat Processors, Indiana Meat Packers & Processors Association, Iowa Meat Processors Association, Kansas Meat Processors Association, Kentucky Association of Meat Processors, Maine Independent Meat Packers Association, Maryland Association of Meat Processors, Michigan Meat Provisioners Association, Inc., Minnesota Association of Meat Processors, Missouri Association of Meat Processors, Nebraska Association of Meat Processors, New York Association of Meat Processors, North Carolina Meat Processors & Country Ham Curers Association, North Dakota Freezer & Meat Processors Association, Northwest Meat Processor's Association (representing Oregon and Washington), Ohio Association of Meat Processors, Oklahoma-Texas Meat Processors Association, Pennsylvania Association of Meat Processors, South Carolina Frozen Food Locker Association, South Dakota Association of Meat Processors and the Wisconsin Association of Meat Processors.

Since the time industry first recognized a possible problem with the use of nitrates and nitrites in cured meat products and the USDA's establishment of the Expert Panel on Nitrites & Nitrosamines, we have closely followed this issue. It is of vital concern to us because over 75% of AAMP's members cure and/or smoke meat and have been directly affected by the USDA's actions on nitrites.

We shall not take the time here to review the history of the controversy surrounding the nitrite issue as these facts are well-known. Suffice it to say, the governmental agencies responsible for the safety of food are guilty of gross mishandling by taking action to ban nitrite and other food additives without having a solid scientific basis for doing so. The impact this has had has been disasterous. Consumers were needlessly frightened and industry suffered untold losses in terms of lost sales and increased costs. The M.I.T. study that FDA and USDA used as a spring-

board for their attempted ban on nitrite has now been discredited, but the consumer suspicion and distrust lingers on.

In spite of the fact that the government has backed off from its nitrite banning efforts, the cured meat industry is still facing some major nitrite-related problems. Although there is no proof that nitrites cause cancer in humans, bacon is being subjected by the U. S. Department of Agriculture to increasingly burdensome regulations. Dry cured bacon is the latest product to be added to this list. The USDA has proposed that dry cured bacon be subjected to the same monitoring program that is currently being applied to pumped bacon, but with added requirements having to do with brine concentration and water activity.

Dry cured bacon is produced largely by small operators each of whom sell their products to a local clientele that has a preference for their product's distinctive flavor. If the Department's proposal is put into effect, dry cured bacon as its fanciers know it will no longer be available. This is because the product will be so dry and so salty as to be virtually inedible. Why? Because, on the basis of one set of yet to be duplicated test results, the USDA has decided that dry cured bacon needs to reach specified levels of dryness and saltiness in order to protect the product and its consumers from botulism. The proposal completely ignores the health risks of high salt levels. Meat scientists from at least four universities have reviewed the tests upon which the USDA is basing its dry cured bacon proposal and they do not consider them to be broad or conclusive enough to warrant the USDA's action.

The USDA's dry cured bacon proposal is another example of a governmental agency promulgating regulations without having an adequately-proven scientific basis. In addition, in this instance, the USDA is also telling dry cured bacon producers that their product will have to meet standards which no one in government or anywhere else knows how to meet. Forseeing this possibility, AAMP wrote a letter to Carol Tucker Foreman on December 20, 1979, asking for the Department's cooperation, both technical and financial, in conducting further research on dry cured bacon. The answer came six months later in the form of the dry cured monitoring proposal.

Let us make one thing perfectly clear. The American Association of Meat Processors supports the concept that government has a responsibility to insure the safety and wholesomeness of food for the benefit of the consuming public. But, we consider most of the actions that the FDA and USDA have taken in regards to nitrite as being irresponsible by imposing restrictions on the use of certain additives without having an adequate scientific basis for doing so.....and without making sure the scientific know-how is available to accomplish what is proposed. We, therefore, call on Congress to take the necessary legislative action to require that food regulatory agencies not only use a common-sense evaluation of risks versus benefits before taking any action but also to insure that whatever action is taken is based upon evidence that is broadly recognized in the scientific community as being valid.

Statement

by

Joseph G. Sebranek

Associate Professor of Animal Science and Food Technology
Iowa State University

I welcome this opportunity to appear before the Committee and express my feelings concerning the nitrite issue and food safety policy in general.

My involvement with this hearing has come about for two reasons; first, I have been directly involved in nitrite research for almost 10 years and second, I served as chair of a special Iowa State University committee of scientists that reviewed and provided public comment on the Newberne report. The Iowa State committee report was released in early September, 1978 and was one of the first scientific evaluations of the Newberne work.

Our review raised many of the questions subsequently pointed out by other groups. Certainly, the recently completed review by Universities Associated for Research and Education in Pathology has further substantiated our position. However, our greatest concern, following the review, was not the scientific quality of the Newberne work but rather the simultaneous regulatory proposals that were advanced. These proposals were based on what we felt was, at best, an inconclusive report and, at worst, perhaps even erroneous research.

The following two years since the release of the Newberne work have represented a tremendous amount of effort and input to resolve the nitrite issue. I am very encouraged by the testimony here today and by the attitude of this committee that, as a result of all this effort, we may indeed be moving in the right direction.

The nitrite issue has pointed out the need of a broader concern for food safety laws in general, and for the ability to inject an element of scientific judgment into these laws.

To accomplish this, let me emphasize two points; 1) there is absolutely no substitute for thorough scientific review of research by qualified scientists especially when this research is likely to influence regulatory decisions. The professional credentials of a scientist in research live or die by scientific review. Certainly, food safety decisions that may be based on research results warrant, at least, an equivalent evaluation. Therefore, it seems to me that clear cut procedures should be established for both internal and external review by the regulatory agencies of any research that has bearing on a regulatory decision. This review must be completed and considered before any releases, decisions, etc. are made concerning the original research data.

Secondly, it seems that current food laws such as the Delaney Clause need to be rewritten or restructured to allow a greater involvement of scientific judgment. I applaud the several members of this committee who have expressed the opinion that this needs to be done and I hope that the legislative steps to accomplish such a revision are initiated. It might be argued that inserting "judgment" into the "law" is an open invitation to emotional appeals. However, thoroughly reviewed, scientific judgments do not allow emotional involvement.

Much of the justification expressed for what transpired in the nitrite situation has been based on the fact that a very rigid, inflexible regulatory reaction was dictated by law. This could very well be corrected by proper revision of the law. However, even in the present situation, food laws are certainly intended for application to factual situations and adequate scientific review to confirm potential facts is again a necessary prerequisite.

Therefore, revision of present food laws is certainly needed and I hope this hearing results in initiation of some change. However, the establishment of a thorough, effective and comprehensive research review procedure is most critical and would make even the present food laws more workable.

CONGRESS OF THE UNITED STATES,
HOUSE OF REPRESENTATIVES,
*Washington, D.C., September 29, 1980.*

JERE E. GOYAN,
*Commissioner, Food and Drug Administration,*
*Rockville, Md.*

DEAR MR. COMMISSIONER: I understand that the FDA is in the final stage of reaching its decision on whether to permit nitrites to be exempt from the color additive provision. Because the FDA has proposed that nitrites act to fix, not impart color in food items such as bacon and other meat products, I would urge a speedy resolution to this matter and recommend that the Agency decide in favor of allowing such an exemption.

Thank you for your attention in this matter.

With best regards,

DAN GLICKMAN.

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STATEMENT OF HON. CHARLES E. GRASSLEY, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF IOWA

It is clear from this nitrite fiasco that some major changes need to be made in the regulatory decision process involving chemical food additives. That is the purpose of the legislation I co-sponsored with Mr. Wampler, H.R. 6521, and I join him in urging hearings on the bill as soon as possible.

From the beginning, many of us were concerned about the Newberne study and the way it was handled. We became more concerned when it appeared that the Food and Drug Administration would accept the results of the study without scientific review and verification. To me, this is the most disturbing part of the whole affair. If no one had raised a fuss about it, the Newberne study might never have received close scrutiny at all. Only after questions were raised did it become evident that the Food and Drug Administration had not followed ordinary review and study procedures. In May of 1978 the Commissioner of the FDA directed that the usual FDA review procedures which lead to regulatory action be omitted. He substituted an informal review with a task force composed of FDA personnel which he chose. This action led to many routine scientific safeguards being ignored or bypassed.

In August 1978, the Secretaries of Agriculture and Health, Education, and Welfare announced the results of the Newberne study at a joint press conference. Incredibly, at that time the validity of the study had not been seriously examined. It was only after serious questions were raised about it that the Food and Drug Administration decided a closer look might be in order.

In mid-September 1978, responding to an earlier request from me, a team of Iowa State University scientists presented a preliminary analysis of the Newberne study. They found major problems.

In early October 1978, members of the Council of Agricultural Science and Technology met with some of us here in a news conference to outline their criticisms of the study.

Shortly thereafter, I initiated a letter of request, signed by six of my Colleagues, to the General Accounting Office to investigate the circumstances under which the Newberne study was conducted and the methods and procedures within the Food and Drug Administration for evaluating it. That report, when it was released in January of this year was highly critical of the way the study was conducted and the results were handled. It contained a number of recommendations for improvement.

Mr. Wampler asked the Library of Congress to conduct a review of the handling of the study within USDA and FDA. That review found abandonment of normal procedures on the part of those agencies.

Finally, under severe outside pressure, USDA and FDA initiated a "slide-by-slide" review of the Newberne study, the results of which have just been made public. The conclusion is "insufficient evidence * * * to support the conclusion that sodium nitrite per se fed to rats causes cancer, based upon the MIT study."

All this points up some very serious deficiencies in federal regulatory processes. Two years of confusion, doubt, uncertainty and bureaucratic muddling have ended with a whimper, and I have yet to see any indication that the Food and Drug Administration has changed its procedures in any way as a result of this fiasco.

This is a grave disservice to the American public—to consumers and producers alike. It should not be allowed to occur again.

STATEMENT OF HON. VIRGINIA SMITH, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF NEBRASKA

Mr. Chairman and Members of the Agriculture Committee: These oversight hearings on the nitrite issue are certainly in order as a result of the recent action of the Food and Drug Administration and the Department of Agriculture to all but reverse their previous phase-out and/or ban on the use of nitrite and to decide instead not to initiate any further action at this time to remove nitrite from food.

Those of us who have been involved in the battle to lift the ban since it was first imposed almost three years ago, are gratified over the recent decision. It has been a long time coming.

We have had to formally protest to the Food and Drug Administration and to the Department of Agriculture. We have had to introduce legislation to impose a moratorium on the proposed ban. We have had to hold hearings before congressional committees, and we have had to come forward with scientific studies to counter the study that launched this whole business in the first place—the Newberne Study. This is the one that has now been found, after extensive review, void of sufficient evidence for removing nitrites from the U.S. food supply.

The cart has been before the horse all this time. The agencies of government—FDA and USDA—condemned nitrite as a cancer-causing sustance and proposed to phase it out and ban it even before they had the results of the extensive slide-by-slide review of the Newberne Study. When those results came in, the ban could not be justified. It became a case of act now, repent later.

There must be a better system. This proposed ban without an acceptable substitute for nitrite could have wrecked an entire industry. Most of the bacon-processing plants in the nation would have been closed with attendant dislocation of the nation's pork producing and processing industry at a cost to the farm economy of $1.5-billion per year. Over and above this monetary loss would be the ever-present botulism threat to the consumers who would have to depend upon meat products improperly preserved in the absence of nitrite.

This whole procedure has been painful, costly and disruptive. It points up the importance of taking steps to make sure it doesn't happen again. Everyone appreciates the zeal of the Federal agencies in carrying out their responsibilities to protect American consumers from products and substances that carry a genuine, documented health risk. There is no excuse, however, to rush for judgment without the benefit of conclusive scientific evidence. Otherwise, we get the same kind of situation we have now.

That's why these hearings are so important, Mr. Chairman. First, in setting the stage for an examination of the Delaney Clause. At the present time, it is too inflexible. It treats all cancer-causing materials the same and permits decisions to be made on the basis of dosages to laboratory animals far in excess of what a normal ingestion would be.

Another result of the hearings should be to call for an examination of the tests used to make the determination about the cancer-causing properties of a substance. Once the test procedures are improved, they should be subject to an ironclad review process before any action to ban the substance is put into effect. In this regard, I subscribe to the proposal espoused by the gentleman from Virginia, Mr. Wampler, who seeks to establish a National Science Council of eminent scientists to evaluate the evidence and decide the risk to human health.

This would be a big improvement over the system in use now. The next Congress should lose no time in advancing the necessary legislation to make the change in the laws that are creating problems like the nitrite scare and the saccharin scare.

It we learn from these mistakes and do something about them, all of the difficulty we went through in getting the Department of Agriculture and the Food and Drug Administration to back away from banning nitrite as a food preservative will not have been in vain. The opportunity is before us and the time is right.

JAMES ABDNOR
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COMMITTEES:
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VETERANS' AFFAIRS

AGING

# Congress of the United States
## House of Representatives
### Washington, D.C. 20515

September 16, 1980

Thomas Foley, Chairman
Committee on Agriculture
U.S. House of Representatives
Washington, D.C. 20515

Dear Mr. Chairman:

You are to be commended for directing the Committee's attention to the deplorable state of federal policies with respect to nitrites and other food additives. I had planned to appear today, along with a spokesman from the South Dakota Pork Producer's Council, to testify on this important issue. South Dakota is fortunate to be represented by Mr. Bill Buller, however, who is president of and testifying on behalf of the National Pork Producers Council. Since the witness list is already long, please accept these brief comments as my statement of position for the official hearing record.

It is somewhat heartening that USDA and FDA have finally acknowledged the error of their ways in attempting to use the results of the Newberne study to justify a ban on the use of nitrite as a food preservative. It is not encouraging that it took so long for such an obvious conclusion to be reached, though, and it is unforgivable that these agencies-particularly USDA, which is supposed to be the spokesman for agriculture-have paid so little heed to the adverse impact upon meat producers. The lack of regard of FDA for the best interests of agriculture may be understandable, but for USDA to have taken on such an apparent "anti-farmer" bias is neither understandable nor justified.

You and I have both worked to overcome efforts to weaken USDA's role as a spokesman for agriculture. We have won the battle in forestalling the transfer out of USDA such-agencies as the Soil Conservation Service, Forest Service, and Farmers Home Administration, which are vital to USDA's basic mission; but it appears we are losing the war. It is not just the federal government in general, but USDA itself which has taken on a decided "consumer" tilt. The result is bad not only for agriculture but for consumers, too. The unfounded biases of federal nutrition policies against meat, dairy and poultry products are bad for consumers as well as for producers for three basic reasons:

First, the overwhelming bulk of evidence is that meat, dairy, and poultry products are wholesome and valuable components of a well-balanced diet. Raising unsubstantiated fears against these products tends to induce consumers to shy away from them.

Second, if these policies have the intended effect of reducing consumption of meat, dairy and poultry products, production must be reduced as well. If this occurs without a corresponding reduction in production expenses, which is most unlikely, the unit cost of production will be forced upward. Not only will more farmers be driven out of business, but consumers will pay more.

Third, caution is justified when reliable evidence warrants it, but implementation of policies based only upon the prejudices of the regulators tends to destroy the credibility of both the policies and the process by which they are determined. The federal government has cried "wolf" too often. Many consumers no longer pay any attention, but enough do so that producers cannot afford to ignore these policies regardless of their lack of merit.

The Committee is as aware as I am that the handling of the nitrite issue is but one example of how the federal government appears to be warring against the interests of agriculture. Farmers do not expect that they will carry the day in every instance, but they do expect to be treated fairly. Whether it is because the President wants to punish the Soviets or because the regulatory bureaucracy is biased against meat, dairy and poultry products, farmers demand that their interests at least be considered and that policy decisions be based upon a responsible weighing of the facts.

Mr. Chairman, I submit that neither have the interests of farmers been adequately considered nor the facts properly weighed, with respect to nitrites in particular or federal nutrition policy in general. For the good of consumers as well as producers, the Congress must act to restore integrity to the process by which federal nutrition policies are determined, and I strongly urge that the Committee recommend such action without delay.

With best wishes,

Sincerely,

Jim Abdnor

JAMES ABDNOR
Member of Congress

JA/alk

HOWARD WOLPE
MICHIGAN
3RD DISTRICT

COMMITTEE ON
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# Congress of the United States
## House of Representatives
### Washington, D.C. 20515

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September 24, 1980

The Honorable Thomas Foley
Chairman, House Agriculture Committee
1301 Longworth House Office Building
Washington, D. C. 20515

Dear Mr. Chairman:

A number of pork producers within my district have recently brought to my attention the recent reversal of the nitrite ban directive of the Food and Drug Administration and U.S.D.A., consequent upon the discrediting of the Newberne study that had underpinned the original nitrite decision. I want to commend you and the membership of your committee for undertaking the oversight hearings into the regulatory history of this unhappy affair.

One thing is clear: no one -- neither the consumer nor the affected food industries -- have been helped by the confusion surrounding the nitrite issue. Clearly, the industry has been negatively impacted by the publicity attendant upon the original release of the Newberne study and the announcement of the nitrite phase-out. Now, with the questions that have surfaced about the validity of the Newberne study and with the subsequent reversal of the nitrite phase-out order, the credibility of the entire regulatory system is in question -- to the detriment of the very consumer confidence the regulatory system seeks to instill.

I would hope, at a minimum, that the nitrite controversy will be a catalyst for the development of new procedures that will insure that proposed regulatory initiatives flow from solid and credible scientific data and judgements. In this connection, the proposal of Mr. Wampler (embraced in HR 6521) to establish an independent council to decide questions of scientific fact -- in advance of new regulatory initiatives -- would appear to be deserving of serious consideration.

Again, thank you for your attention to this matter.

Sincerely,

HOWARD WOLPE
Member of Congress

HW/ang

STATEMENT OF
THE NATIONAL BROILER COUNCIL
TO THE
COMMITTEE ON AGRICULTURE,
HOUSE OF REPRESENTATIVES

RE: NITRITE OVERSIGHT HEARING

September 16, 1980

The National Broiler Council ("NBC") is the trade association representing the producers and processors of broiler/fryer chicken. NBC's members produce and process more than 75 percent of the broiler/fryer chicken consumed in the United States.

In these times of rapid inflation, poultry makes available to the public nutritious and extremely economical food products. Nitrite-cured poultry products enable broiler firms to utilize all poultry parts, eliminating waste and providing good value to consumers. Broiler firms can thus spread production and processing costs over a large volume of products assuring continued economical prices to consumers.

NBC is pleased with the results of the recently completed review of the Newberne/MIT study by the Universities Associated for Research and Education in Pathology (UAREP) which led to the Food and Drug Administration (FDA) and the United States Department of Agriculture (USDA) conclusion that there is no need to initiate action to remove nitrite from food at this time. NBC also believes that the agencies' decision to contract with the National Academy of Sciences to assist in a review of all existing and relevent data regarding nitrite is the only prudent and orderly way to proceed before any further action is contemplated by USDA and FDA.

It is unfortunate that the initial actions taken by FDA and USDA were, in part, dictated by the simplistic and outdated provisions of our food safety laws. The Delaney Clause, which directs food safety policy regarding alleged carcinogens, is bound up in the black and white either/or language which allows no scientific evaluation of the actual hazard of a particular substance. The Attorney General has even stated that the current national food policy is inflexible; a food additive deemed by one researcher to induce cancer must be banned and eliminated from the food supply, not only pursuant to the Delaney Clause, but also in accordance with the general adulteration provisions of the Poultry Products Inspection Act and the Federal Meat Inspection Act.

The recent nitrite incident demonstrates that we need a food safety policy which responds to the recommendations of scientists and other experts, rather than forcing premature and perhaps unwarranted conclusions that a substance is or is not a hazard. Provisions are also needed allowing checks and balances in the evaluation of health risks including peer review of scientific research. Regulators should also be allowed to weigh the relative risks of using or not using a particular substance; to compare the risk of using a substance or using some alternative; and to evaluate how much risk is posed by a particular use which supplies only a small portion of the total intake of a substance.

In summary, NBC believes that a revised statute is needed to allow the federal agencies and outside experts to quantify the hazard or risks associated with various foods and food additives, and to evaluate whether those risks are significant before regulatory action is taken.

Respectfully submitted,

George B. Watts

George B. Watts
President

Statement of

NATIONAL COUNCIL OF FARMER COOPERATIVES

The National Council of Farmer Cooperatives is a nationwide association of cooperative businesses which are owned and controlled by farmers. Its membership includes 124 regional marketing and farm supply cooperatives, the 37 banks of the cooperative Farm Credit System, and 31 state councils of farmer cooperatives. National Council members handle practically every type of agricultural commodity produced in the U. S., market these commodities domestically and around the world, and furnish production supplies and credit to their farmer members and patrons. Five out of six U. S. farmers are members of one or more cooperatives. The National Council represents about 90 percent of the more than 7,500 local farmer cooperatives in the nation, with a combined membership of some 2.5 million farmers.

Our broad Nutrition and Food Policy reads in part:

> "The National Council of Farmer Cooperatives endorses the attention being focused upon human nutrition and a food policy that will insure the availability of an adequate supply of safe, wholesome, nutritious food at reasonable prices while insuring a fair return on investment to farmers, processors and retailers.
>
> "We urge that studies of nutritional value and safety be conducted on a practical basis, with due consideration being given to consumer health and well-being, but with matters of availability, cost and other pertinent factors also being given due weight."

Saccharine, nitrites and 2,4,5-T are just three recent controversies that come to mind as issues that will go down in the annals of bureaucratic hegemony for years to come. The nitrite issue is just the latest example to show just how important it is to have all the facts, determined by careful scientific evaluation based on sound research criteria, before federal regulatory agencies make far-reaching conclusions about food-health questions.

Currently there are six federal agencies administering at least 21 federal laws that regulate chemical carcinogens. Although there have been some attempts to coordinate agency efforts, there continue to be too many inconsistencies and too little coordination in the determination of cancer risk assessment and regulations related thereto.

First, the NCFC urges that Congress seek the development of a uniform cancer risk assessment policy. It is our hope that such a policy could avoid some of the controversies and unnecessary agency actions that have caused so much confusion, fear and disruption to the food industry and consumer alike during the past decade and more.

Secondly, we see a particular problem with the language of the Delaney Amendment to the Food, Drug and Cosmetic Act in light of the philosophy of "zero tolerance" in the carcinogenicity of food additives expressed therein. With increased technological advances in the ability to detect the most minute traces of a potentially carcinogenic substance, the "zero tolerance" philosophy of Delaney is hopelessly unrealistic. The NCFC still adheres to the basic philosophy behind the amendment, however, and would urge simply a reassessment of the "zero tolerance" language. We would urge that Congress and federal regulatory agencies, along with an impartial scientific commission, work together to establish a realistic cancer risk assessment policy and determine tolerance levels of chemicals used in agriculture which will effectively protect the public health, while at the same time make possible continued abundant production of food and fiber. We would also

urge that federal regulatory agencies be given reasonable discretion, again with the concurrence of an impartial scientific commission, in interpretation of the results of animal experimentation as it relates to human health. The NCFC has always supported and continues to support reasonable regulations. We must insist, however, on reasonable balance and assessment of risks versus benefits.

Thirdly, we support the formation of an independent scientific commission. Most of the food or chemical policy resolutions drafted over the last 15 years by the NCFC have included references to such a body that would be totally impartial, independent of any federal agencies, and comprised totally of the most outstanding, competent scientists specializing in the various areas of oncology, toxicology, etc., that could be brought together.

An example of the need for such a commission was recently shown with the involvement of an independent group of pathologists in reviewing the MIT (Newberne) study. It was the Newberne study that led the FDA and USDA, in 1978, to seriously consider totally banning the use of nitrites as a preservative in cured meats and poultry. Enough concern was expressed about the validity of the study, however, that such drastic measures as a total ban on nitrite use was never taken. However, many industries, particularly the poultry and pork producers and processors, have been severely injured by the cloud of suspicion that has hung, for several years now, over the use of nitrites.

With all the controversy over the Newberne study, the USDA and FDA requested an interagency peer review of the study to determine whether further study was warranted. The agencies themselves determined the need for a "thorough outside review" of the MIT study. As you well know, only now, after over two years of confusion and serious concern, have the two agencies, based on the findings of the impartial group of pathologists, determined there is no need to initiate action to remove the use of nitrites in food preservation at this time. However, the National Academy of Science has been asked to review all scientific data regarding nitrites.

The EPA banning of 2,4,5-T is a similar case in point. Acceptance of studies such as Alsea II and restricting the use of 2,4,5-T on that basis has been a mistake, in our opinion. Further studies have disproved earlier ones. Once again, we believe that had a process for independent scientific study been instituted prior to agency decisions to restrict, suspend or cancel use, or phase out a chemical, less unnecessary fear and certainly less disruption in the food producing or processing chain would have resulted.

Congressman William Wampler (R-VA) has introduced HR 6521 calling for the creation of a National Science Council which would decide questions of scientific fact that arise in agency adjudications involving restricting the use of certain substances that may be harmful to human health. The National Council of Farmer Cooperatives concurs wholeheartedly with the concept expressed in the bill and would encourage its use as a vehicle by which Congress could meaningfully address the problems facing us in the areas of food and environmental health.

Such an independent, impartial "blue ribbon" panel of scientists could work with Congress to determine some standards for cancer risk assessment. A National Science Council, coupled with a modification in the language of the Delaney amendment to the Food, Drug and Cosmetic Act would go far in alleviating the problems that have caused so much confusion and disruption not only to industry, but also to the consumer during the past several years.

We were gratified, Mr. Chairman, to note your introduction sponsorship of HR 12. Dr. Jere Goyan, FDA Commissioner, appears to share your concern about the zero tolerance philosophy expressed in the Delaney Clause.

We hope, Mr. Chairman, that you will seriously consider holding more in-depth hearings on HR 12 and HR 6521.

* * * * * * *

STATEMENT ON FOOD SAFETY ISSUES

Submitted by

THE NATIONAL SOFT DRINK ASSOCIATION

The National Soft Drink Association (NSDA) submits these comments for the hearing record of the U.S. House of Representatives' Committee on Agriculture in its consideration of recent Department of Agriculture/Food and Drug Administration announcements on nitrites and related food safety issues.

NSDA is the national trade association representing the soft drink industry in the United States. The industry is comprised of approximately 2,000 soft drink manufacturers throughout the U.S., of which over 70 percent are active members of the Association. These members account for more than 90 percent of the soft drink production in this country. In addition, the vast majority of soft drink franchise companies who manufacture concentrate syrup, and many of whom own soft drink manufacturing plants, are associate members of this Association.

NSDA commends Chairman Foley and the House Agriculture Committee for focusing on recent government actions dealing with nitrites, and on related food additive policy issues. It is not only timely but indeed critical for the Congress to review current food safety policy in this country and to consider changes which will assure public health protection without jeopardizing the production of an adequate, wholesome, and economic food supply. Such changes are appropriate in order to conform food safety laws with modern scientific research capabilities and to end the unnecessary inflexibility which exists in the regulatory process.

In 1979 a Congressionally mandated report on food safety policy by the National Academy of Sciences (NAS) proposed that the food safety laws be amended to give the Secretary flexible authority to consider relative risks as well as other factors in determining the regulation of food additives. The NAS study recommends that Congress overhaul the present food regulatory system which "has become complicated, inflexible, and inconsistent in implementation." Many individuals in academia, the food

industry, the Congress, and in FDA and USDA have endorsed the NAS view. The Food Safety Council has not only embraced the need for a modernization of food safety law but also has developed alternative procedures for accomplishing such a change.

## DEVELOPMENT OF FOOD SAFETY LAW

Food safety law has evolved gradually over the course of history, reflecting both societal concerns and available knowledge of the time. Societal concern about food safety existed at least as long ago as Biblical times and persisted through the Middle Ages, but probably never before reached the level existing today. Food safety control in the early United States was based on English Common Law and until the 20th Century, largely functioned at the local level. Although the Department of Agriculture was established in 1862 and became an executive department in 1889, food safety throughout that time was still largely considered a local matter. Codification of food safety law and federal control first came with the enactment of the 1906 Federal Food and Drugs Act and was followed in 1938 by the Federal Food, Drug, and Cosmetics (FD&C) Act. The 1938 Act reflected the beginnings of the national character of the food production and distribution system which is so much a part of our lives today. Together with the Federal Meat Inspection Act and Poultry Inspection Act, the FD&C Act currently provides the primary basis for federal control of the food supply.

Although amended several times, the FD&C Act was significantly changed by the 1958 food additive amendments. These amendments, providing the basis for current regulation, shifted much of the responsibility for food safety from the government to industry. They established pre-marketing clearance requirements for new food additives while continuing approval of existing ingredients under a generally recognized as safe (GRAS) or "prior sanction" status. More importantly to current debate, the 1958 amendments incorporated the controversial Delaney Clause. The Delaney Clause was also incorporated in the color additives amendments of 1960 and, in modified form, in the animal drug amendments of 1968.

In enacting the 1958 food additives amendments, Congress considered food additives in a quite different light than, for example, drugs. It was required that food additives be demonstrated to be "safe" under specified conditions of use. In addition, any additive "found to induce cancer when ingested by man or animal" was specifically prohibited by the Delaney Clause. The Congress in effect made a policy decision for the nation, apparently at that time deciding that no conceivable attribute of an additive could balance any perceived risk to man, especially a risk of cancer, no matter how small that risk might be.

Although the Delaney Clause is the center of debate whenever food safety or the more general question of regulating potential environmental carcinogens is discussed, the policy questions go far beyond this controversial provision.

## THE LAST TWENTY YEARS

Continuing regulatory dilemmas, typified by saccharin, cyclamate, aspartame, pesticide residues, food animal drug residues, and nitrite, together with the associated public concern about food safety, indicate that a carefully considered revision of the FD&C Act and associated food safety laws could well serve the public interest and contribute to the formulation of a rational U.S. public health policy. In order to put such revision in perspective, it is useful to assess the FD&C Act against developments during the last twenty years since the passage of the food additive amendments.

Many aspects of U.S. life have changed dramatically since the passage of the 1958 Food Additives amendments. Urban population concentration, changing life styles, and concentration of agricultrual production have created new demands for food variety, convenience, and aesthetic appeal. These changes have produced new constraints not only on the nature of the food supply, but also on the assurance of its safety and economy. Technology has responded to those demands and science has advanced apace. For example, analytical chemistry, capable of identifying food constituents at the parts per million level twenty years ago, is now approaching parts per trillion. Toxicology has greatly

broadened its capability to identify potential adverse effects with expanded chronic testing including in utero exposure, reproduction and teratology tests and an expanding battery of mutagenic tests.

A direct consequence of the scientific advances has been identification of hitherto unrecognized trace amounts of packaging constituents migrating to foods, of animal drug and metabolite residues in meats and poultry, environmental contaminants in fish and impurities in various food ingredients. Expanded toxicological attention has associated potential risk with many of those same substances, at least at high levels of exposure, and has, at the same time, associated potential risks with long-familiar ingredients of food. Food safety policy, however, has not kept pace with food science and therefore these scientific developments have produced concern on the part of some consumers and skepticism on the part of others. Such public attitudes are well-illustrated by the reaction to the proposed banning of saccharin and the unprecedented successive congressional moratoriums on that proposal. The more recent association of potential adverse effects with the use of nitrites in cured meats and poultry has elevated both the concern and the skepticism.

Absolute safety for food, whether processed or natural, is of course, impossible, for there is virtually no consitituent of food that under some condition is without some adverse effect to someone. This is recognized by FDA itself in the Code of Federal Regulations (21, CFR, Section 170.3 (i)):

> "It is impossible in the present state of scientific knowledge to establish with complete certainty the absolute harmlessness of the use of any substance."

In past years, consumers and scientists alike considered only the acute toxic effects of food, and in the absence of such effects, assumed safety. Scientific advances, especially in the last twenty years, however, have led to the recognition of much more subtle toxic effects -- deriving not only from added ingredients but also from those naturally present in foods such as the

mycotoxins, (e.g., alfatoxin in peanuts and corn). As a result, attention has turned from the question, "Is there a risk?" to "What is the type and extent of risk involved?" and "What factors other than risk are involved that should be considered in deciding on appropriate regulatory control?"

As a concept this approach is not a totally new idea, but in fact, is already present in regulatory law. For example, in addition to the drug section of the FD&C Act in which Congress implicity acknowledges that there is no such thing as a "safe" drug, there are implicit acknolwedgements of such considerations in the food sections of the Act. Specifically, Section 406 of the Act, in referring the "unavoidable" contaminants, states:

> "In determining the quantity of such added substance to be tolerated in or on different articles of food, the Secretary shall take into account the extent to which the use of such substance is required or cannot be avoided in the production of each such article ..."

Thus, rather than banning corn and peanut products for example, a tolerance of aflatoxin in these foods is permitted by law -- the implication being that the minimal risk involved is outweighed by the availability of food that would otherwise be illegal.

With respect to pesticide residues, the law again provides for the establishment of tolerances by regulation, stating in part:

> "... the Secretary shall give appropriate consideration, among other relevant factors, -- to the <u>necessity for the production of an adequate, wholesome, and economical food supply</u> ..." (emphasis added)

Again, the evaluation of food availability in relation to some risk is implied.

In the animal drug amendments of 1968, the Delaney Clause was again incorporated but this time with a qualification, that:

> "... no residue of such drug will be found (by methods of examiniation prescribed or approved by the Secretary) in any edible portion of such animals after slaughter ..."

One could conclude, therefore, that the availability of these products outweighed whatever risk might be imposed by an undetected drug or metabolite residue. The problem in enforcing this section of the Act, however, has been in answering the question, "How sensitive must the detection method be?" With the ever advancing capability in analytical chemistry within the confines of the current act, FDA has struggled unsucessfully for several years to answer that question.

Public sentiment is now tending toward acceptance of the fact that absolute food safety is impossible and that even when some potential risk is identified, freedom of choice should be considered. Congress should not have to intercede on a case-by-case basis to provide such freedom. Rather, the FD&C Act and related statutes should be revised based on the well-founded concepts already present in some parts of the Act.

NSDA endorses the development of a consistent food safety regulatory policy which will assure rational public health protection while not abrogating the public interest relative to the production of an adequate, wholesome and economical food supply.

The evolutionary development of food safety control should be continued to reflect not only the changes in the nature of lifestyles and the national food supply, but also the much more dramatic changes in science that have occurred since 1958. It seems apparent that such evolution should reflect the impossibility of absolute safety, should provide adequate consumer information and freedom of choice, and should assure the availability of an affordable food supply. In addition, it appears from recent government actions dealing with nitrites, that a suitable mechanism must be provided to assure the validity of scientific information on which regulatory decisions must be based.

National Turkey Federation

SERVING THE NATION'S TURKEY INDUSTRY

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October 10, 1980

The Honorable Thomas S. Foley
Chairman
Committee on Agriculture
U.S. House of Representatives
Washington, D.C. 20515

Dear Mr. Chairman:

The National Turkey Federation (NTF) is the only national trade association representing the turkey industry in the United States. The grower/processor members of the National Turkey Federation are responsible for the production and marketing of the major portion of the nations's turkey crop. NTF members support government attempts to protect the public from harmful substances that threaten the wholesomeness of food products. However, we have been dismayed by the inclination by government to act upon insufficient data. Such a premature action was taken by the Departments of Agriculture and Health and Human Services after receiving the findings of Dr. Paul Newberne's study on nitrites.

The interpretation of the Newberne study as a reason to seek a ban or phase-out of nitrites was a political decision unsupported by scientific fact. The nitrite issue was handled in an adversarial manner. Scientific considerations were not given a prominent role in the decision making process.

Industry was unnecessarily placed in an adversary position in its efforts to show that the use of nitrite does not lead to the formation of carcinogenic nitrosamines. Industry rose to the task and demonstrated that products cured with nitrite do not produce unsafe levels of nitrosamine residues. However, such efforts by industry should not have been necessary. The premature announcement of the intention to ban or phase-out nitrite without the benefit of scientific review of the Newberne study was a political decision devoid of proper procedural considerations. Industry was forced to fill the information gap while urging government to proceed with a scientific peer review of Dr. Newberne's findings.

We agree with the testimony presented by Norman Borlaug, Nobel Laureate geneticist. In testimony before the House Agriculture Committee, Dr. Borlaug noted,

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"an unusual increase of fear of cancer" in the absence of a cancer epidemic. Furthermore, we endorse his assessment that the Delany Amendment should be changed to give the FDA more flexibility. However, the current wording of the Amendment should not be used as a shield against scientific review of studies commissioned by the government.

The National Turkey Federation endorses the proposal for scientific evaluation proposed by the American Industrial Health Council in testimony presented by Dr. William McCarville. Scientific evaluation of studies, such as the one conducted by Dr. Newberne, should have these objectives: 1) that scientists of the highest qualifications perform the evaluation; 2) that objectivity is maintained by separating the scientific evaluation from the regulatory function and 3) that all agencies have access to all relevant data. By following these recommendations, we should be able to avoid the abuses committed by the Departments of Agriculture and Health and Human Services in connection with the Newberne study. Scientific reviews, such as the one recently completed by the Universities Associated for Research and Education in Pathology (UAREP), should be standard procedure before grave announcements are made by the government.

We feel that the most uniform, sensible and cost effective manner to institute the procedures necessary to resolve scientific controversies concerning the safety of food chemicals is outlined in the Wampler Bill, HR6521. Congressman Wampler suggests the establishment of an independent National Science Council. The Council would institutionalize the review procedure and provide a credible body to carry out the process.

The public, as well as industry, should be protected against unproven theories and hasty government pronouncements. Nitrite is an example of the government pointing the finger of blame in a haphazard fashion. Prudent judgment by the bureaucracies involved would have saved industry from unnecessary expenses incurred in opposing an incorrect assessment of the Newberne study. Mandatory regulatory review procedures should be developed to prevent the reoccurrence of similar episodes in the future. Such action would not only bridle in a hyperactive government but should prevent unfounded accusations about the wholesomeness of food products from reaching the consumer.

Respectfully submitted,

NATIONAL TURKEY FEDERATION

G.L. Walts
Executive Vice President

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