NITRITE RESTRICTIONS ON POULTRY

HEARING

BEFORE THE

SUBCOMMITTEE ON DAIRY AND POULTRY

OF THE

COMMITTEE ON AGRICULTURE
HOUSE OF REPRESENTATIVES

NINETY-FIFTH CONGRESS

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THURSDAY, SEPTEMBER 28, 1978

HOUSE OF REPRESENTATIVES,
SUBCOMMITTEE ON DAIRY AND POULTRY
OF THE COMMITTEE ON AGRICULTURE,
Washington, D.C.

The subcommittee met, pursuant to notice, at 10:06 a.m., in room 1301, Longworth House Office Building, Hon. Charles Rose (chairman of the subcommittee) presiding.

Present: Representatives Baldus, Krebs, Jones of North Carolina, Mathis, Volkmer, Jeffords, Kelly, and Hagedorn.

Also present: Representatives de la Garza, Bedell, Wampler, and Grassley, members of the full committee.

Staff present: Fowler C. West, staff director; Robert M. Bor, counsel; William A. Imhof and John E. Hogan, associate counsels; Glenda L. Temple, clerk; Thomas E. Adams, Jr., Bernard Brenner, Robert A. Cashdollar, Joseph R. Crapa, James A. Culver, George M. Dunsmore, Carol Forbes, Gerald R. Jorgensen, Leighton W. Lang, Eugene Moos, and E. Lee Musil.

Mr. ROSE. The Subcommittee on Dairy and Poultry of the House Agriculture Committee will please come to order.

This morning in the space of about 2 hours we would like to cover very quickly 12 witnesses and hear from them on the subject of the impact of the proposed nitrite restrictions on the American poultry industry.

While the jurisdiction of this subcommittee is exclusively jurisdiction as to dairy and poultry, the impact of the proposed nitrite restrictions can by comparison be extended to the red meat industry as well. However, that is not a subject for this hearing. We had hoped to have a joint hearing but, because of scheduling difficulties, that joint hearing with the Investigations and Oversight Subcommittee was not possible. We have decided to go ahead and take testimony from these witnesses today.

Our first witness is the Honorable James G. Martin, Member of Congress from North Carolina.

Congressman Martin, we welcome you, sir. I welcome you as a fellow North Carolinian and, knowing of your background as a chemist, I am especially interested in your testimony.

Mr. MARTIN. Thank you, Mr. Chairman and members of the subcommittee. Although I note the admonition of the Chair that you are dealing here principally with the poultry industry, the timeliness of these hearings is such that what you hear presented during this day will have great impact on deliberations regarding other meats, I am sure, and other considerations.

Mr. ROSE. Thank you, Mr. Martin. Your prepared statement and attachments will be made a part of the record.

[The prepared statement and attachments thereto submitted by Mr. Martin follow:]

Statement of Hon. James G. Martin, a Representative in Congress from the State of North Carolina

Let me thank the Chairman of the Subcommittee for scheduling this very timely hearing. I should also express to the Commissioner of the Food and Drug Administration, Dr. Kennedy, and to the Assistant Secretary of Agriculture, Miss Foreman, my appreciation for their public assurances that no regulation to ban nitrite would or could be imposed prior to the convening of the next Congress. I, for one, was especially concerned that abrupt, premature action might be planned in view of the oft-expresse intention of the Agriculture Department Office of Consumer Services to ban nitrite regardless of the evidence and regardless of the risk.

This hearing can help to establish a vital record on the questions of risks and benefits associated with the use of sodium nitrite for curing various meat products. Protecting consumers from botulism is the principle reason for the use of nitrite. The amount of nitrite needed can be reduced from 120 ppm to 40 ppm if mixed with 0.26% potassium sorbate, but no practical method has yet been found to safely prevent formation of botulin toxin without using any nitrite at all. There is no evidence of any harm or disadvantage associated with the sorbate-reduced nitrite method, but neither is their any evidence of harm from the normal use of nitrite.

The evidence reported so far is inconclusive and far from compelling, except to those who hold the curious view that one molecule can cause irreversible cancer, and that if a chemical causes cancer at any animal dose, no matter how large, then it must be banned at any human exposure level, no matter how small. This has led these government agencies to "protect" you from any detectable trace of nitrosamines. The present level of sensitivity for analytical detection of nitrosaminies is about 5-10 ppb, far below the reported level of their carcinogenic threshhold (1-2 ppm in food), but we can expect more sensitive methods to be developed that could detect the presence of mere parts per trillion. What then?

Those who advocate Absolute Zero Risk would then seek to ban nitrosamines

to 1 ppt, yet one pound of food tainted with an undetectable 1 part per trillion of carcinogen would still expose you to a trillion molecules. So absolute zero is their goal, and that's absolute nonsense.

What is the risk of nitrite, as normally used?

It is very important for members and staff of this subcommittee to examine the Newberne Study, the one experimental finding that indicts, but does not convict, nitrite as a carcinogen. I agree with the director of that research: that it is inconclusive. It is far from compelling evidence that nitrite is a carcinogen or even a promoter except at high doses.

You will want to evaluate the rather critical lab audit reported by the F.D.A., but you will probably conclude, as I have, that the study cannot be overturned on that basis.

Two other features ofthe M.I.T. study are far more important barriers constraining us against too much reliance upon its findings. Until these two defects can be overcome, the case against nitrite will remain inconclusive.

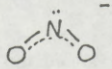
First, while the average lymphoma incidence for all of the test animals (12%) is significantly higher than for the controls (8%), little meaning can be attributed to that since the 8% lymphoma incidence in the controls is unaccountably very high for the Sprague-Dawley strain of rat. Clearly something is wrong with the entire batch of test animals and controls, regardless of the nitrite. Who knows what? A virus? Something they ate?

Secondly, even if you ignore that problem, what meaning can be attributed to the irregular variation in lymphoma versus nitrite dose? In some test series the incidence of lymph cancer increased with increasing nitrite dose. In others it decreased at the highest dose. Still other series show a plateau, a constant cancer incidence over a range of nitrite doses. Beforeyou can claim that this carcinogenic effect is proportional to the dose, even at normally low human exposure, you must first rationalize the clear evidence that it is <u>not</u> proportional to dose at the higher

experimental levels. The damaging truth is that the very reason that 12% lymphoma incidence is reported for the aggregate of all nitrite-fed rats is because no orderly proportionality was found. So, instead, a syncopated meaningless jumble of data were reported en gross.

How, then, can you estimate the cancer risk associated with nitrite?

You must assume that the 4% gross increase in lymphoma is a real number related to sodium nitrite. You must then assume, contrary to the Newberne evidence, that the incidence is proportional to the dose. You must make another unwarranted assumption that nitrite has no carcinogenic threshhold, below which the cancer incidence drops off faster than the dose level is reduced. A summary of the steadily expanding list of known carcinogenic threshholds is appended.



One more dazzling assumption must then be made; namely, that only the nitrite deliberately added to cured meats is hazardous, and that all of the natural bodily exposure to nitrite is somehow conveniently different. Yet, chemically, nitrite (NO_2^-) is a rather simple angular triatomic ion with one nitrogen equally bonded to two oxygen atoms, regardless of its source. So you cannot ignore the nitrite in vegetables, or in your natural saliva, or that formed by digestion of protein in your intestines. It is nitrite, too, and as my Table shows, at least 98% of your daily nitrite exposure comes from the latter two natural sources. It would hardly be practical to ban salivary or intestinal absorption of nitrite; even if you had jurisdiction.

An argument can be made to disregard the intestinal nitrite, but it won't hold up. You can argue that nitrite in the acidic medium of the stomach will form nitrous acid, which will react with secondary amines to form nitrosamines. The flaw in that suggestion is that, as Commissioner Kennedy and Secretary Foreman jointly testified to a Senate subcommittee, nitrosamines, if formed, would typically produce cancers at multiple sites: lung, liver, digestive tract and nervous system--which was not observed.

So the intestinal production of nitrite cannot be neglected. Once nitrite gets into the blood or lymphatic system, it makes no chemical difference how it got there. It's all the same.

The graph accompanying the Table helps put all this in perspective. The areas of the various squares are proportional to the dose ratios relative to the amount in cured meat. The large square (980 square units) represents the intermediate dose fed to many of the M.I.T. rats (0.1% of the diet, or 50 mg per Kg). It is over 20 times greater than the total normal human exposure from all sources (46 square units, or 2.1 mg per Kg of body weight.) The area of the entire page (1470 square units) represents the average dose ingested daily by all of the different nitrite fed rats lumped together.

You are being asked by the advocates of the Absolute Zero Risk principle (a) to ban the one unit of nitrite in cured meats, (b) on the basis of irregular effects at levels of 980-to-1960 relative units fed to cancer prone rats, while (c) disregarding the major natural source of 45 units of nitrites.

That's a lot of baloney.

(The attachments follow.)

Threshhold Effects: List of Substances Found to have Threshhold Effect.

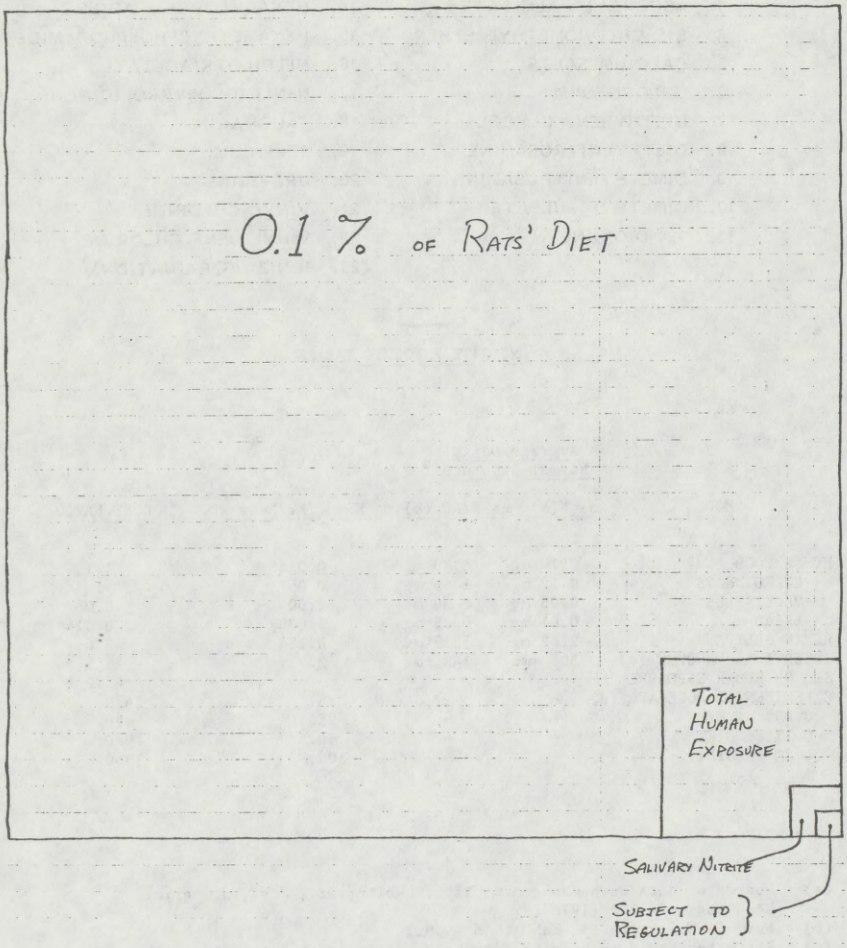
1. 2-ACETYLAMINOFLUORENE
2. AFLATOXIN
3. ASCORBYL PALMITATE
4. BIS-CHLOROMETHYL ETHER
5. CALCIUM SALTS
6. CHLOROFORM
7. DIETHYLENE GLYCOL
8. DIETHYLNITROSAMINE
9. DIMETHYLNITROSAMINE
10. DIMETHYL SULFATE
11. 1,4-DIOXANE
12. ETHYLENE GLYCOL
13. ETHYLNITROSOUREA
14. HEXACHLOROBUTADIENE
15. HEXAMETHYLPHOSPHORAMIDE
16. NITRILOTRIACETATE
17. N-NITROSOPYRROLIDINE
18. SACCHARIN
19. SELENIUM
20. URETHANE
21. VINYL CHLORIDE
22. VINYLIDENE CHLORIDE
(23. IONIZING RADIATION)

NITRITE EXPOSURE TABLES

MODE	Average Daily Normal Exposure as N(a)	as $NaNO_2$(b)	mg $NaNO_2$/Kg Body Wt.	DOSE RATIO
HUMAN FOOD	0.79 mg	3.89 mg	0.056	1.1
-CURED MEATS	0.72 mg	3.55 mg	0.051	1
-VEGETABLES	0.06 mg	0.30 mg	0.004	0.08
-BREAD	0.01 mg	0.05 mg	0.0007	0.014
HUMAN SALIVA	2.62 mg	12.9 mg	0.184	3.6
INTESTINAL PRODUCT (c)	30. +mg	148.+mg	2.1 +	41.5 +
SUM OF HUMAN EXPOSURE				46.2 +
EXPERIMENTAL DOSE-AVG.(d)	-	-	75.	1470.
0.05% of DIET	-	-	25.	490.
0.1% of DIET	-	-	50.	980.
0.2% of DIET	-	-	100.	1960.

(a) Source of data on human consumption: White, Jr., J.W., J. Agric. Food Chem. 24 202 (1976).
(b) Formula Weight ratio, $NaNO_2$: N = 69:14
(c) Estimates based on nitrite/nitrate ratio in large intestine, without regard to much larger nitrite/nitrate ratio in small intestine. Source: Tannenbaum, S.R., et al, Science 200 1487 (1978).
(d) Newberne (MIT), unpublished.

Nitrite Exposure



Mr. ROSE. Before we begin our questioning, I would like to ask that we recess to go to the floor to record our presence on the motion that the House resolve itself into committee. Then we will return immediately. If there is no objection, we will do that at this time.

[Recess taken.]

Mr. ROSE. The subcommittee will be in order.

In the interest of time, I want to announce that I will limit the questioning of our witnesses to 5 minutes in an attempt to reach our goal of 12 witnesses as rapidly as we can.

Are there questions for Congressman Martin? Mr. Wampler?

Mr. WAMPLER. Thank you, Mr. Chairman. I want to commend you and members of the subcommittee for holding this hearing.

Apparently this is the only opportunity that members of this committee will have in this session of Congress to hold hearings on this question of the banning of nitrites, which is extremely important to the entire agricultural industry as well as consumers. It has many far-reaching ramifications that I think this committee has a very deep responsibility to probe.

I regret that the author of the study on which the proposed action is being predicated is not a witness and we will not have an opportunity to cross-examine him.

Again I want to commend you. I realize that the scope of the hearings this morning is somewhat limited, and properly so, to the jurisdiction of your subcommittee.

I do want to commend Congressman Martin for his statement. If there is an expert on this subject in the Congress, I believe we would have to say it would be Congressman Martin because of the fact that he has a doctorate degree in chemistry, has taught in that field, and is recognized, I think, generally as an authority.

When the results of the Newberne study were made known, Mr. Martin and I held a press conference expressing some concerns of ours. We were concerned, among other things, that the FDA and USDA might take some rather precipitous action to ban the use of nitrites before a proper record was written.

While I am not a scientist and I am not in a position to quarrel with the conclusions that were drawn from that study, I would like to ask Mr. Martin a question. As I understand it, in this MIT study a cancer-prone species of rats were used. In order to produce this same small, but I think you described it as "statistically significant," increase it was necessary to feed these cancer-prone rats certain levels of nitrites.

How would this relate to the human consumption? In other words, if we were to eat cured meat that had been treated with nitrites, how could we relate that dosage to what a human being would have to eat to come up with the same levels of exposure?

Mr. MARTIN. Of course, Mr. Wampler, there are several ways to do that. To begin with, you could make the point that to ingest the equivalent amount of cured meat would require a human to consume some 586 pounds of cured meat a day. Of course, you have to recognize that with animal testing, even with a sample as large as this, 1,380 rats, I believe, were used which is far larger than the usual test sample, it is not useful for screening purposes to only test them at normal low dosage. You will not find a statistical number of rats which will develop cancer at the normal, low, human-type dose. Therefore, you must use the large dose.

However, I maintain that the importance of this kind of test is purely for screening purposes, to raise the attention level to those substances which do fail the test. But I maintain that it should not be a basis for a regulatory ban, because it is very, very probable, that the effects on humans at the normal low dose will not be anything in proportion to the effect on the animals at the high dose.

The reason for that is because at the higher doses that are used with this particular experiment, as with the higher doses that were used with the saccharin test, as you will recall, it is very probable that the defense mechanisms of the animals are overwhelmed. It may be that it leads to a different metabolic activity. It may be that the liver, kidneys, and lymph system itself might be overloaded with this substance, making the animal more susceptible to some other carcinogen which might be present which ordinarily it is able to detoxify.

Therefore, I suggest that there is accumulating, abundant evidence—and I have submitted a list of 23 examples—where the carcinogenic effect only occurs at a very large dose, usually at a dose that is associated with some other metabolic disfunction that can be observed.

Mr. WAMPLER. As a scientist, I gather what you are saying is that the results and the conclusions of the MIT study are not sufficient to warrant banning of nitrites.

Mr. MARTIN. That is the conclusion even of the author of the study. I agree with his conclusion that the evidence is inconclusive, not only for the reason that I have just given, but also for the reasons that I cited in my testimony; namely, the meandering of the data. As you increase the dose, the incidence of lymphoma wanders around a bit. That is not very satisfying to someone who works in that field. I believe that is the reason that Dr. Newberne cited it as being inconclusive.

Second, you have the very high incidence of lymphoma among the control animals. I suggest clearly something is wrong that can not have anything at all to do with nitrites.

Mr. WAMPLER. Thank you, Mr. Chairman.

Mr. ROSE. Are there any other questions?

[No response.]

Mr. ROSE. Mr. Martin, we appreciate very much your presence and your testimony. Thank you for making yourself available to us.

Mr. MARTIN. You are very welcome, Mr. Chairman.

Mr. ROSE. Our next witness is Ms. Esther Peterson, Special Assistant to the President, Office of Consumer Affairs.

Ms. Peterson, please come forward.

We have before us a copy of a prepared statement that you have made. We will be happy to receive that in its entirety for the record and would like to request, if you can, that you summarize what you have said in that statement. If that is not possible, we will receive your testimony any way you want to give it to us.

STATEMENT OF ESTHER PETERSON, SPECIAL ASSISTANT TO THE PRESIDENT, OFFICE OF CONSUMER AFFAIRS

Ms. PETERSON. Thank you.

I want to start off by saying I am not a scientist. I come here in the interest of consumers.

I congratulate you as a committee for dealing with this extremely important question that faces us.

From the testimony of other witnesses, from the papers that have been written, the facts appear to be:

One, scientists discovered in the early 1900's that sodium nitrate, identified then as an impurity in salt, was responsible when converted to nitrite for the special flavor and coloring associated with most cured meats. USDA approved the use of nitrites as an additive in red meat products for those purposes in 1925.

Congressman, the reason I am reviewing this is that as I go around I find it is terribly hard for people to put into the proper perspective what we know and what we don't know and what have been the actions. It has been confused. Therefore, I thought for myself, as a nonscientist, I would like to just add up where we are on these questions.

Two, in the early 1950's, other scientists discovered that the color associated with nitrite is the result of a reaction between this chemical and red blood cells, a reaction which also impairs the ability of the cells to carry oxygen.

Three, in the late 1950's and through the 1960's, other scientists developed a steady accumulation of evidence that nitrite combines with other substances called amines to form a chemical substance called nitrosamines. These substances cause cancer in laboratory animals. So it is a long history.

Four, 3 years ago, FDA received evidence that nitrite itself could cause cancer. A more extensive study was commissioned to evaluate the relationship between dose of nitrite and response of cancer. The study, by Dr. Paul Newberne of MIT, was completed this year. You know about that.

The Newberne study shows that nitrites produce a statistically significant increase in cancer in test animals. Government scientists have evaluated the methodology and conclusions of the MIT study and confirm that the central finding—that is, nitrite is an animal carcinogen—is valid. The study is being reevaluated and FDA has made the papers available to insure a widespread public and scientific evaluation.

Those seem to be the facts that lead up to where we are today. When the Federal agencies which safeguard our food supply learn of such facts, what responsibility has the Congress assigned to them? From my study of the food safety laws, these facts emerge:

One. The Food and Drug Act and the laws governing meat and poultry inspection, first enacted in 1906 and revised through the years, define an additive which is poisonous or deleterious—one which may render a product injurious to public health—as an adulterant. Under those statutes, the use of adulterants is prohibited.

Two. In 1958, the Congress amended the Food and Drug Act to declare, that, upon showing of accepted scientific evidence, FDA shall permit the use of any food additive which causes cancer in animals.

Both the adulterant clause and the Delaney amendment are sound and prudent public policy. They state that public health and safety has the primary claim on regulator action and that all else is secondary, including economic dislocation. The consumer understands this very well. Even as recently as 1976, a survey commissioned by FDA

found that 97 percent of the public believed that Government should regulate food safety. Three out of four persons said they believe the Government already makes sure packaged, canned, or frozen foods, are safe to eat.

But, the fact that the public hearing is being held in the House, as well as others being held in the Senate, and the introduction of some 22 bills and resolutions pertaining to nitrite indicates that the issue may not be as clearcut as the facts and the law might indicate. There are two complicating factors:

One. Scientists have found that nitrites also inhibit the growth of botulism which produces a toxin that, in some instances, will kill human beings.

Two. The meat industry in the United States produces about $12.5 billion worth of cured meat products each year, most of which now require the use of nitrites.

The facts in the first instances are clear, but the implications are ambiguous. The question is whether nitrite is the only protection against botulism. There is much uncertainty, and uncertainty often leads to fear. This is unfortunate, especially when you consider that in 1972 the U.S. Department of Agriculture convened a special 5-year panel on the problems of nitrites and botulism without producing any new data on the specific nature of the threat of botulism in meat, either fresh or cured.

We can estimate the risk of nitrite as a carcinogen in terms of potential deaths it will cause; we cannot do the same for botulism, not because it is beyond scientific competence, but only because it has not yet been adequately researched.

As a result, neither the Federal agencies responsible for food safety nor the Congress, can make a completely informed judgment. Public officials, including Representatives and Senators, are being forced to weigh a specific hazard against an unknown fear.

We are prevented from evaluating the botulism hazard, even to determining at this point whether nitrite is essential to prevent botulism. We are left to assume that it must be. Do we know, however, the extent to which the hazard is a matter of poor or sloppy practice by food processors and consumers? To what extent is this chemical being used to mask practices which can be eliminated as easily through quality control techniques or through better training programs? To what extent can meat be cured by other means?

Do we know, for example, whether the meat industry as well as the Federal Government, have made any substantial investment of research funds and staff to find other ways to extend the useful life of meat and meat products? The U.S. Department of Agriculture, for example, has doubled funds being directed to nitrite research, especially to evaluate other means of curing meat.

Whether these conditions exist through ineptness or design is immaterial; the fact is they exist. And, because of the uncertainty they generate, we cannot respond to the reasonable questions which the meat industry raises as to the intentions of the Federal Government toward the $12.5 billion cured-meat products segment of their business.

At the present time, the administration is examining whether the law requires an immediate ban on the use of nitrite, or whether a ban

can be imposed over a specific time period. There is no question as to the future of nitrites as a food additive, however. The question is how the ban should be implemented.

While the legal question is being resolved, there are many other things to be done. We must fully explore alternatives to nitrite, both safe chemical alternatives and standard methods such as refrigeration and freezing. We will need new guidelines to ensure proper handling of products which are now processed, distributed, and stored in a more relaxed fashion because of the use of nitrites.

Very importantly, we must develop and implement an extensive consumer education program designed to teach proper methods of selecting, storing, and preparing, nitrite-free products.

I have been around to a number of meetings. I was impressed at Buffalo when I was handed this newspaper article from the Buffalo Courier. It says, "Nitrite-Free Hotdogs Available." It talks about the Britton Central School District. They have replaced the traditional rosey hotdog by a newer pale pink hotdog. I want to read this paragraph to you. I quote from what they say:

> We used nitrite-free hotdogs all last year with very good results. The kids all like them. The paler color, according to reports, has not been a detriment at all. We explained to the children what we were doing and they accepted it very well.

I did not get to ask, but I know that there have been no cases of botulism. It is interesting that there are experiments going on where nitrite-free products have been used successfully. We need to develop the education that has to go with this. I do know from my work within the supermarket industry, how important it is to educate consumers on the use of food.

Many people are unfamiliar with the possible threat of botulism, and consumers need better skills to avoid the potential hazard of mishandling these products. Hopefully, consumer education programs can be implemented in cooperation with stores, the media, schools, and libraries, and with concentration on point-of-purchase information on proper handling, storage, and preparation, of the nitrite-free products.

These actions, however, should be only part of a cohesive program to resolve what appears to the consumer to be a great dilemma in the Nation's food policy. We are told that the continued abundance of food requires the use of chemicals which, on examination, may prove harmful and injurious and, thus, erode confidence in the Government's ability to protect the health and safety of all citizens.

The growing assumption is we cannot have both an abundant and a safe food supply. This leads to a defeatist view: That is, we are exposed to a much higher level of nitrites through natural means than from food additive use of nitrite, thereby somehow making the deliberate addition of nitrite acceptable. These views deeply concern me. A simple survival instinct tells me to minimize as much as is humanly possible, my exposure to any harmful substance.

We do not have, nor can we expect, a sterile food supply or a zero risk environment. However, the deliberate addition of a known carcinogen to some 9.1 billion pounds of meat, poultry, and fish, annually cannot be tolerated.

This is what the Congress said in 1906 when it was faced with the problem of hazardous additives to the meat supply. The Congress has

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underscored its commitment to this view—that is, the Nation's food supply shall be both safe and abundant—each time the question has been asked.

In 1906, the issue raised was whether to allow the meat industry to use the chemical Borax to provide a more aesthetic, palatable color to meat. Congress, in that precedent-setting decision, resolved the issue in favor of consumer safety. Is this Congress willing to do less? I think our responsibility to the American public obligates us to maintain and enforce those standards already established by Congress.

Thank you.

Mr. ROSE. Thank you very much, Ms. Peterson, for your statement. Are there questions by members of the subcommittee? Mr. Volkmer?

Mr. VOLKMER. I would like to thank the lady for appearing. Have you considered the possibility of the additional cost to the consumer, if we do eliminate nitrite with no substitute?

Ms. PETERSON. I am very aware of that. This is why I said in the testimony that we have to consider the cost of not doing it. We get a little afraid sometimes of doing the right thing.

Mr. VOLKMER. I am asking about doing it now, or doing it 1 year from now, or 2 years from now. I am sure if I go out and ask some of my constituents who are approximately the same age as yourself who have had a nice, long life, and have lived with nitrite for this long period of time and who are on social security, if this may cause an increase in cost, if I ask them which they prefer, I think I know their answer, because I think I know my people.

Ms. PETERSON. In my experience I have found so often that cost factors are exaggerated. I have said this and I can say this from my experience, inside business as well as outside. I do think we have to weigh that.

Mr. VOLKMER. It should be determined before we make a decision.

Ms. PETERSON. Under the procedures it looks to me as though there is going to be plenty of time. This is not an overnight thing. It will give us time to look at a lot of these factors.

Mr. VOLKMER. Thank you, Mr. Chairman.

Mr. ROSE. Mr. Wampler?

Mr. WAMPLER. Thank you, Mr. Chairman.

Ms. Peterson, we appreciate your coming today. I would like to pursue the line of questioning of the gentleman from Missouri.

Has your office actually done any economic studies as to what impact this proposed banning of nitrite would have? Do you have any hard figures?

Ms. PETERSON. We have not done an economic study. I do not really feel at this time, that that is our responsibility. We have economists and certainly the departments will be working on this.

As I said before, my responsibility in trying to exert some leadership in this is what is best for the consumer. Certainly when the final decisions are made there will be a lot of these factors that come into it. It seems to me very important that we do not let a lot of those issues cloud over what we think is best for our people. In this case, I think the situation that I have outlined is best. I do recognize that those considerations will be there.

Mr. WAMPLER. I just assumed, as the President's Special Assistant

on Consumer Affairs, that you might have given some study, for example, as to what the cost would be in terms of additional energy that would be required under one of the proposed plans of requiring continuous refrigeration of nitrite-free meat products. If I recall correctly, the food chain with which you were formerly associated does not keep the temperature of its meat cases at 40° F.; is that correct?

Ms. PETERSON. All of these are the kinds of things that I tried to point out can be done. I feel in this society we must not stand still. I accept the technological developments. I really am encouraged by the kinds of things that I see coming technologically. I have great hope that we can do what is best for the consumer. I guess I am an optimist and think that it can be done. I have worked with consumers enough to know that they can accept information, and they can accept taking care of things.

When we went to open dating, people said, "Oh, we can't do that." But when we taught people what it was, they accepted it. Don't underestimate the sophistication of the consumer today. It is terribly important, and I think it is there.

Mr. WAMPLER. But you have no evidence of any studies to share with the subcommittee this morning.

Ms. PETERSON. I have no evidence or studies to share on that, because I really do not think that is the issue this morning.

Mr. WAMPLER. Do you have any evidence of any deaths that have been caused by the use of nitrite?

Ms. PETERSON. I am not a scientist, as I told you before. I have had enough experience in working on standards to know that we do not know thresholds. I worked very hard on radium standards and things of this kind. We do not know what pushes over. My feeling is: why do we deliberately add something that we know about when we know there is already a lot existing? I tried to point that out. That is what is important.

Mr. WAMPLER. Would you favor the banning of leafy vegetables?

Ms. PETERSON. It is in leafy vegetables. It is in water and in all of these things. But we don't deliberately add more. This is the point. We don't know the thresholds. We don't know when it spills over.

I want to say, as I hope, a responsible person in our society, that I don't want my children or my grandchildren to say we are deliberately adding one more hazard that could increase this danger.

Mr. WAMPLER. Congressman Martin who testified just before you came in, said, among other things, that protecting consumers from botulism, which is a very deadly thing, is the principal reason for the use of nitrites. There are many of us, and many in the scientific community, who question the validity of the study on which you and others are predicating the phasing out or the abandoning of nitrite.

Would you agree with me that there is a definite need for further study on this, and that the USDA and FDA should not take precipitous action on the basis of one questionable study?

Ms. PETERSON. I think I pointed out to you that I would like to see lots more research into this. We know so little.

But the other thing I wanted to point out, is that it has been done, and it can be done. I have worked with food technologists and you know what can be done in quality control. We have not explored all the possibilities of the kinds of things that can do this protection.

Of course botulism is terrible, but let's not have the possibility of not acting on full information of what can be done.

Mr. WAMPLER. Probably you and I would agree on one thing—that certainly there is no justifiable basis, scientifically, for the Department at this point in time, to abandon the use of nitrites until we have a great deal more technical data, research, and the possibility of finding a chemical substitute. Would you agree with that?

Ms. PETERSON. The point is that it is going to take time to do. The regular procedures under the Administrative Procedures Act require time. I am positive that there will be time for the leadership to be expressed, and for the Congress to do it, so that we do it in a fair way.

Mr. WAMPLER. Let me conclude with this one question. I think this is a very practical consideration.

Once the regulatory agency, whether you are talking about FDA or USDA, initiates and publishes this rule for comment, then a lot of economic damage is done and displacement is done in the livestock sector of our country. This is something I hope that you and other consumer advocates will consider very carefully because, unquestionably, the threat of botulism is at this point in time on the basis of the known evidence a much greater threat than that of any cancer-inducing properties that nitrite might have. I hope that you will bear that in mind.

Ms. PETERSON. Of course we absolutely must be very careful because botulism is dangerous. Also, let's remember we have great scientists and we have great technologists. We have not thoroughly explored the possibilities of alternate ways of doing this.

Mr. WAMPLER. That is what I am glad to hear you say because I think you and I agree on that.

Mr. ROSE. The gentleman's time has expired. Are there additional questions? Mr. Jeffords?

Mr. JEFFORDS. I would like to ask some philosophical questions on consumerism.

Of course the Delaney clause really does not allow us to consider cost-benefit-type situations. It makes some rather arbitrary decisions.

Speaking from the consumers' point of view, do you believe that it is relevant to consider the additional cost versus the risk in making a determination as to whether or not to preclude consumers from purchasing something?

Ms. PETERSON. It is a factor that is important for us, but I want that to be weighed carefully so that we know what the costs of not doing it are. Too often we jump quickly and hide around not doing sometimes the right thing by saying, oh, the cost. I have had so much experience in this good, long life I have had where that has been used to mask the real question. We have held back very frequently from the policy that we could have advanced in a much better way.

Surely look at it. Surely see that it is important. However, also see the cost from the other side. It has to be weighed.

Mr. JEFFORDS. So you believe that is a relevant factor, though?

Ms. PETERSON. Of course we have to look at cost. I have been working in many of these areas.

I want to be very, very sure because, from my point of view, the cost of a life, the cost of adding the possibilities for our future generations, even adding to it is a tremendous cost that we have to think about carefully.

Mr. JEFFORDS. Certainly. Of course in the nuclear field we have made a decision that we do a cost-benefit association. Even though we do increase the cancer possibilities, we made a decision to go ahead, whereas in this field we have been more or less arbitrary.

I would also like your feeling about the difference between prohibition and warning in these situations. From the consumers' point of view, is it better to warn them, as we have done with cigarettes and other things, rather than just to strictly prohibit? Or do you think that we have to be in a position of making a decision for that consumer that he cannot himself accept that risk determination when he purchases something?

Ms. PETERSON. In the first place, many times the consumer does not know a lot of this. The consumer has to have more information. I am concerned about expecting intelligent decisions without more education and information. I see it in relation to so many of our foods where things are added that people do not understand what that means in the total movement of food.

We need to know from the Department of Justice really what the law says in this case. I would like to be sure that we have a lot of information. In this case, we need to have the legal interpretation of really what the law says, it seems to me.

It is another thing as to whether we say we can do it by just informing. I have felt for a long time that I want information at the point of purchase. I want people to know. However, in this area I am doubtful whether just warning is the thing. I really am doubtful about it. It has not helped an awful lot on cigarettes, has it?

Mr. ROSE. Mr. Kelly?

Mr. KELLY. Thank you, Mr. Chairman

In your testimony you refer to "your responsibility," which would deal with warning people and seeing that foods that are dangerous would not get to the public. That is a fairly restricted area.

According to your testimony, this additive has been used in the food supply for over 50 years. Now suddenly the administration comes galloping up with a flag flying and they are going to save the Nation.

Has the administration briefed you, and do you have any idea, about the ripple impact on the economy if all the people throughout the industry that have millions and billions of dollars invested in processing equipment predicated upon the use of this compound, refrigeration equipment, sales equipment, all of the machinery involved, are suddenly told that after 50 years of experience, because of an experiment that is certainly under very grave question, there is a new day and a new technology and all of that investment is going to be wiped out?

When they get ready to reinvest to apply the new technology, how is it that they are not going to be concerned about whether or not there will be even a better technology or a less resistant breed of rats found? So they might think the best thing to do is just import everything and let the Government support us. Why struggle? Why invest? Why work when there is so much uncertainty because of so many opportunities to do so much good to save mankind from these horrible dangers that you are defending us against at the present time?

Ms. PETERSON. I appreciate your question about that. First, I do not think the administration exactly galloped on this thing. It has been

hanging around for a long time. I have been in this for a long time. When I was in the White House years ago we were talking with industry on what we could do. What bothers me is that there has been footdragging in not understanding that here is a coming problem and why don't we meet it.

My whole feeling in the consumer movement is to be sensitive to the sounds that are coming from people. Anticipate these things. Don't think, oh, it won't happen to me. We have not been galloping; let me say that very, very definitely. This has been around for a long time.

Another thing, Congressman, is that a hazard was identified. We cannot deny that.

Mr. KELLY. Let me ask you one other question that maybe is more specifically in your area because apparently they have not briefed you on the economic impact.

Back in antiquity people used to cook everything to a point where the bugs wouldn't eat it so it was safe. It was hardly fit for humans to eat; it was not very nutritious; it did not taste too good, but it was safe.

Have you weighed and considered this? Are we going to go back to the idea that we don't dare eat anything for fear that the bugs will eat it, too, so we have to kill the bugs, the nutrition, and everything? Have you weighed that?

Ms. PETERSON. It is hard for me to answer that because, may I say, frankly, it is kind of a ridiculous question. It is like asking me to go back to the scrubbing board as a woman. I am not going to do that. I want the advantages of society.

Mr. KELLY. Fine. I can appreciate that. But then where are we going? Do you know where we are going if nitrites are taken out?

Ms. PETERSON. Yes, we do know where we are going.

Mr. KELLY. Where are we going?

Ms. PETERSON. I have seen this direction clear for years. We are going to an abundant food supply that is good for our farmers and that is good for our people. We are going toward an abundant food supply and a safe food supply. We are going to act on the best scientific knowledge we have. As leaders of this society, we are going to try to point it in that direction. It is not easy, my friend.

Mr. KELLY. If we abandon the nitrites today, in the morning when the sun comes up how are we going to handle the situation?

Ms. PETERSON. There is time. Do you mean tomorrow morning?

Mr. KELLEY. Yes. One morning it is going to happen.

Ms. PETERSON. We are working at it. When the administration really meets it, we will have hearings and will work at it. We do not do a quick thing in this society. We have procedures that have been worked out for years.

Mr. KELLY. Certainly the meat industry and the farmers do not want to do anything that is not in the interest of the public. They certainly could not want to do that.

If there is something so obvious as a substitute and it has been around for so very long, then why don't we know what it is and just simply say we are going to stop doing this that is bad and start doing this that is good? If that is the case, tell me when the sun comes up in the morning what we are going to do, because when the sun comes up we are going to have to do something.

Ms. PETERSON. When the sun comes up tomorrow morning, we are still going to have a lot of procedures to work on. The thing that is difficult is that the only substitute we have found is quality control. When you work with food technology, you know that there is a tremendous possibility on that. You know from cases that there has been carelessness in covering up quality control by the strong preservatives. We have to look honestly at this thing.

I think when the sun comes up it is going to be a bright, good, sunny day when we meet these things head on.

Mr. ROSE. Thank you very much. The gentleman's time has expired.

I would be happy to recognize other members, but I would observe that our next two witnesses are Carol Tucker Foreman and Donald Kennedy. I want to bring them on together in order to have them testify and then let you question them together. However, they have 12 o'clock appointments and we may not get to them.

Ms. PETERSON. If you have further questions later, I will be very glad to supply answers for you.

Mr. ROSE. Mr. Hagedorn?

Mr. HAGEDORN. Mr. Chairman, I have a quick question.

You are a Special Assistant to the President with regard to consumer affairs. I know consumerism means quality food products free from any potential injury. Consumerism also means reasonably priced food products.

As I have followed the debate over the nitrite issue, I sense a great deal of distress in rural America. I represent thousands of pork producers. I met with over 300 of them last Friday evening. If you want to insure consumers of an abundant supply of food and fiber in this country, we have to move forward very cautiously and judiciously because the signals these people were sending me is that they were not expanding their hog herds, even at a time when we have an excess amount of feed grains being produced.

They are nervous about what USDA, FDA, the Justice Department, or whichever Federal agency intervenes—or even consumers themselves—may do to their economic livelihood. They are not making investments and modernizing their hog-producing facilities because they are nervous from an economical standpoint of moving ahead and as to what kind of Government regulation they are going to get.

I might add that this is one small area. The hog producer today is threatened from a number of other points as well.

Unless we know exactly where you are going from point A to point B and we know we have a suitable substitute that is not going to affect consumer trends, then I would say from my standpoint that we ought to not be issuing rules and regulations which cause alarm and uncertainty among the very people that the American consumers want to produce the food and fiber. Otherwise, we will have more imported meat coming in from overseas, as we see happening today.

Ms. PETERSON. Nothing is as good as our own products. Coming from a good agricultural background myself, I feel very strongly about the importance of this.

We are moving cautiously and judiciously. I agree with you that that must be done and that we must not move hastily. That is why our procedures are that we do this not in haste but in reason.

Mr. HAGEDORN. There are a number of suits in courts concerning the nitrite issue. If the Justice Department were to order tomorrow that nitrites be halted in the use of the curing process, would you support Congress taking action in overruling that and passing legislation which would allow for their continued use?

Ms. PETERSON. Isn't that an iffy question?

Mr. HAGEDORN. No; it is not iffy at all. I am just asking you point blank. If the Justice Department ruled on the basis that consumer groups are contending that nitrites ought to be eliminated and prohibited from being used today, would you favor Congress taking specific action to allow its continued usage? That is not iffy at all.

Ms. PETERSON. I think we have to have a gradual process. It is terribly important that we meet some of the economic considerations that many of you have raised today. No one wants to hurt people. We want to do this in a steady way but I think we have to do it under our legislative procedures. There is time and should be time.

Mr. HAGEDORN. Is it fair to say, then, that you would support Congress stepping in and taking action in the event that a court or the Department of Justice rules it illegal to continue using nitrites?

Ms. PETERSON. Excuse me, but I think that is an iffy question to which I cannot answer yes or no. In the first place, I do not think it would even happen. You people as leaders are far more responsible, as is the Justice Department, the Department of Agriculture, and FDA, to move in that way.

It is dangerous for us to get scare things out. We must convince people that we are moving in a responsible way to help protect the farmers, the consumers, and all of us. I believe in our system of Government enough to know that I think that can be done fairly.

Mr. HAGEDORN. I happen to think that Congress would intervene, too, and that it should.

I guessed as the President's Advisor on Consumer Affairs, and knowing the volatility of this issue, that you would have a position on something like that. It is not exactly an imponderable or impossible thing to occur here in the next few months.

Mr. ROSE. Thank you, Ms. Peterson.

I would ask that our next witnesses please come to the table together. Ms. Carol Tucker Foreman, Assistant Secretary of Agriculture for Food and Consumer Services, and Dr. Donald Kennedy, Commissioner, Food and Drug Administration.

I have been told by our staff that you both are on very tight schedules today. That is why I am asking you to come forward in this manner.

Ms. Foreman, your statement is 21 pages long. We will be happy to receive it for the record.

Ms. FOREMAN. Thank you very much, Mr. Chairman.

In fact, Dr. Kennedy and I have a joint statement and we would appreciate having the statement made a part of the record.

Mr. ROSE. The statement in its entirety will be made a part of the record.

[The prepared joint statement presented by Ms. Foreman and Dr. Kennedy follows:]

JOINT STATEMENT OF CAROL TUCKER FOREMAN, ASSISTANT SECRETARY, FOOD AND CONSUMER SERVICES, U.S. DEPARTMENT OF AGRICULTURE; AND DONALD KENNEDY, COMMISSIONER, FOOD AND DRUGS, U.S. DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

Mr. Chairman:

For some time now, the U.S. Department of Agriculture and the Food and Drug Administration have worked closely together on the very complex problem of regulating the use of nitrite in food products. We appreciate the opportunity to participate in these hearings and to describe the recent activities and plans of the two agencies in this area.

On May 18, 1978, the Food and Drug Administration (FDA) received from Dr. Paul Newberne of the Massachusetts Institute of Technology (MIT) a report that, at the very least, suggests that nitrite, an additive used in many foods, increases the frequency of cancer when ingested by laboratory rats. This study is the climax of several years of increasing scientific concern about the possible dangers of nitrite.

Sources of Nitrite

Nitrites are chemicals formed when living systems act on nitrate salts, which are widely distributed in nature, or on nitrogen in other forms. Nitrates are naturally present in drinking water and in many foods, especially vegetables. Bacteria in the human digestive system also produce nitrite, both from nitrate and from other nitrogen-containing compounds.

Deliberate Addition of Nitrite to Food

For centuries, salt containing nitrate has been deliberately used in the curing of meat to preserve it for later consumption. The modern science of meat preservation has developed in the past 50 years, after scientists discovered that the nitrite formed from nitrate is responsible

for the distinctive characteristics of cured meats. Because it is difficult to control the amount of nitrite produced by conversion from nitrate, meat producers sought to add nitrite directly to meat; in 1925 the U.S. Department of Agriculture (USDA) formally approved this direct use of nitrite in meat.

Today, almost all curing is done by directly adding the active substance in the form of sodium nitrite. Nitrite is used in processed meat and poultry, processed fish, certain imported cheeses, and pet food; it is used for certain minor functions in connection with food production; and it is also used in home curing.

Within the last 40 years, scientists have come to recognize another valuable effect of nitrite in meat preservation. Nitrite retards the growth of the spore-forming bacterium, Clostridium (C.) botulinum and hence formation of its toxin. This toxin causes botulism, a deadly form of food poisoning.

C. botulinum can grow and produce its toxin even without a foul odor or other sign of contamination that might warn the consumer. This unsuspected growth of C. botulinum could occur in any spore-containing product that receives sufficient heat processing to destroy the normal spoilage bacteria, but not enough to destroy the spores of C. botulinum. For example, it could occur in hot dogs and luncheon meats, were it not for the use of nitrite in their preparation. These products receive only limited heat treatment because sufficient heat to destroy the spores would make the products unpalatable.

Concerns About the Safety of Nitrite and Nitrate

Although nitrite and nitrate converted to nitrite prevent botulism, these chemicals also carry their own health risks, and in recent years scientists have become increasingly concerned about them.

Since the early 1960's, it has been known that nitrite can combine with other chemicals, called amines or amides, to form a family of chemical products called nitrosamines. Because many foods contain amines or amides, nitrite may react with these constituents of the foods to produce nitrosamines--either before the foods are eaten ("pre-formed"), or in the mouth or stomach after they have been eaten. Several studies have shown that these nitrosamine compounds cause cancer in laboratory animals.

The U.S. Department of Agriculture and the Food and Drug Administration have concluded that findings of these studies are sufficiently serious to warrant regulatory action to deal with the risk presented by nitrosamines. On September 2, 1977, FDA proposed to require that manufacturers of processed poultry products demonstrate that the products contain no nitrosamines. On May 16, 1978, USDA issued a final rule specifying the amount of nitrite to be added to bacon. On June 15, 1978, USDA began a compliance program that requires that bacon can be free of pre-formed nitrosamines when tested by a method sensitive to 10 parts per billion (ppb), the lowest amount confirmable by present technology. Through the use of potassium sorbate as a preservative.

USDA proposes to reduce the amount of nitrite that may be added to bacon from 120 parts per million (ppm) now to 40 ppm in 1979 in order to assist in nitrosamine reduction, while still maintaining protection against botulism.

Nitrite as a Direct Cause of Cancer

In 1975, an FDA-sponsored study of nitrosamines developed evidence suggesting that nitrite, when fed alone (i.e., 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 MIT for a much larger study to determine whether continuous lifetime exposure of laboratory rats to nitrite induces cancer. In sum, the study and FDA's analysis of the data to date supports the conclusion that nitrites were associated with a statistically significant increase in cancer in the test animals by a mechanism not involving the presence of known nitrosamines, although further analysis is needed. Further analysis is being undertaken by both FDA and outside scientists to resolve outstanding questions that could affect our understanding of the health risks of nitrite consumption.

The MIT study is one of the largest and most comprehensive of its kind ever undertaken; a total of 1,381 experimental and 573 control rats were involved. The study was designed to evaluate the relationship between dose (the amount of nitrite fed) and response (the occurrence of cancer in the animals fed nitrite). Nitrite was fed to the test rats as part of their drinking water or as part of several different well-defined and well-controlled diets. The doses fed to the rats ranged from 250

to 2,000 ppm of sodium nitrite. In view of the different test conditions for different groups of rats, the overall study has greater scope than smaller separate studies.

The results of the study as analyzed to date indicate that nitrite induced a statistically significant increase in cancer of the lymphatic system. The lymphatic system is an interconnected system of spaces, vessels and cells between tissues and organs through which lymph circulates throughout the body. The combined incidence of lymphomas (or tumors of white-blood-cell forming tissues that resemble leukemia) in the groups that were not fed nitrite in their diets was 7.9 percent; the incidence in the combined nitrite-treated groups was 12.5 percent.

Three special features of the results of this study deserve emphasis:

-- Although further analysis is required, the observed pattern of tumors appears to rule out the possibility that the carcinogenic effect of nitrite occurred by the formation of nitrosamines in the diet of the animals. Nitrosamines typically produce cancers at multiple sites: in the lung, digestive tract, liver and nervous system. No nitrosamine is known to produce lymphomas exclusively.

-- Lymphatic system tumors were not the only result of nitrite feeding. Some animals that did not develop tumors showed striking alterations in various parts of the immune system.

-- The observed tumors of the immune system may be sequentially related to other toxic effects of nitrite.

In evaluating these risks, it is reasonable to assume that there is a direct correlation between cancer risk in animals and the same risk in humans.

FDA's analysis of the MIT study took into account the findings of an FDA inspection of the MIT laboratory in January 1977 prior to completion of the study. The inspection was conducted as part of FDA's pilot Good Laboratory Practice program. The FDA inspectors noted a number of problems with the manner in which the study was conducted. These were called to the attention of Dr. Newberne. In some instances, Dr. Newberne provided additional information or explanations about the conduct of his study that satisfied FDA that no problem existed. In other instances, Dr. Newberne undertook prompt corrective action. The Agency is now fully satisfied that Dr. Newberne's study was well conducted and that the results he obtained are reliable.

Review of Nitrite Findings

FDA's conclusion to date that the MIT study shows that nitrites induce cancer in laboratory animals is the result of careful and searching scientific analysis. In addition, the Agency has made the entire report of the study available to the public, so that peer review by the scientific community can begin without delay. FDA and USDA invite comments from

all interested persons on all aspects of the study that bear on the conclusions that may validly be drawn from it. Special briefings have also been held for consumer groups, industry representatives and Members of Congress.

In addition to seeking peer review of the MIT study on nitrite, FDA and USDA have recently formed an Interagency Working Group for Nitrite Research. Scientists from the National Cancer Institute, National Institute of Environmental Health Sciences, FDA and USDA have been appointed to serve on this interagency group, which will review and evaluate the Newberne study and the chemistry, toxicology and epidemiology of nitrites, nitrates and nitrosamines, identify gaps in our knowledge and recommend research to address those gaps. It does not follow, however, that because further research might enhance our understanding of the health risks of nitrite consumption, that regulatory action should be delayed indefinitely.

Legal Status of Nitrites in Poultry Products

Before discussing our plans for future activities, it may be useful in light of this Committee's interest in poultry to explain briefly the complicated legal situation involving the use of nitrites in poultry products.

Nitrates and nitrites have long been used in the curing of several types of poultry products, in some instances for at least 30 years. These uses were previously considered to be covered by "prior sanctions" issued before September 6, 1958 by the USDA under the Poultry Products

Inspection Act (21 U.S.C. 451 et seq.). Under the Federal Food, Drug, and Cosmetic Act, a use of a substance in food that has a "prior sanction" that is, was approved by FDA or USDA before the effective date of the Food Additives Amendment of 1958, is not subject to the food additive provisions of sections 201(s) and 409 of the FD&C Act (21 U.S.C. 321(s) and 348). The use of nitrites in red meat products, including bacon, ham, and hot dogs, was approved by USDA as early as 1925. A "prior sanction" for this particular use of nitrites is clearly established by the long history of their approval by USDA.

While the prior sanction for nitrite in red meat appears to be well-established, there appears to be no similar prior sanction for the use of nitrite in poultry. Considering the fact that nitrite has been used in some poultry products for a number of years, this situation is somewhat anomalous. It is explained by the fact that under the 1958 Food Additives Amendment, a prior sanction for the use of a substance in poultry requires that USDA have approved the use under the Poultry Products Inspection Act, which was passed just a year prior to the 1958 Amendment. Thus, there was only a brief period of time in which USDA could have provided a prior sanction to nitrite in poultry. A records search has revealed no such approval during this short period of time.

On April 22, 1977 and on July 15, 1977, FDA received letters from Ms. Foreman, which concluded that USDA had not offically approved the use of nitrates and nitrites in poultry products under the

Poultry Products Inspection Act before passage of the Food Additives Amendment of 1958 and that, therefore, those uses are not covered by valid prior sanctions. The USDA decision that there is no prior sanction for the use of nitrites in poultry has been challenged in a lawsuit filed by the poultry industry. The lawsuit is still pending.

The clarification by USDA of its position on the prior sanction status of nitrates and nitrites in poultry products prompted a reexamination of FDA's own understanding of the status of these compounds. As part of the examination, FDA published a Federal Register notice on September 2, 1977, in which the legal status of nitrites used in poultry products was discussed and in which it was announced that FDA had established a program to obtain information required to resolve definitively questions about their safe use. The notice also explained that FDA would entertain requests for the issuance of interim food additive regulations authorizing the continued use of nitrates and nitrites in poultry products, if the requests were accompanied by a commitment to conduct testing to demonstrate (1) that the requested uses do not result in the formation of cancer-causing nitrosamines before the food is ingested; (2) that the requested levels of nitrates and nitrites are otherwise safe for human consumption; and (3) that use as a preservative is necessary to prevent the growth of Clostridium botulinum and the resulting production of botulinal toxin in the food.

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As a result of FDA's Federal Register notice two petitions were received from the Special Poultry Research Committee requesting that FDA establish interim food additive regulations for the use of sodium nitrite in canned, shelf-stable poultry products and for the use of sodium nitrite in poultry products in general.

FDA reviewed these petitions and, on April 26, 1978, issued two letters responding to the petitioners. Those letters pointed out several deficiencies in each of the petitions and advised the Special Poultry Research Committee specifically of the type of information needed to resolve those deficiencies.

FDA representatives met with the petitioner on May 30, 1978 to discuss the petition for canned, shelf-stable products. The petitioner submitted additional data which was reviewed by FDA's Bureau of Foods. Our scientists raised some questions about some aspects of it.

FDA officials met with the petitioner on two occasions to discuss the petition for the use of sodium nitrite in poultry products in general. FDA received additional information concerning this petition which is currently being reviewed.

Future Activities

Dr. Newberne's study has undoubtedly raised some of the most complex and difficult regulatory problems that FDA and USDA have ever faced. Any regulatory action that the agencies propose will strike a careful balance between competing health risks. Nitrites have been shown to induce cancer in laboratory-animals and must therefore be considered to present a risk of cancer to humans. Nitrites are also used to prevent the formation of

botulism in many meat and fish products. The addition of nitrite is not the only way to prevent formation of botulism but it is heavily relied upon by a large and diverse industry. Shifting to other methods now available and developing new methods are not simple problems to overcome. We are acutely aware of these competing health risks and they will continue to influence our regulatory activities.

The problem is made even more complex by the fact that the responsibility for regulating the addition of nitrites to our food supply is shared by two agencies, involves three different laws, and numerous provisions within those laws.

Both FDA and USDA are fully committed to cooperate on designing a regulatory approach to the nitrite question. Extensive discussions have already been held and the Commissioner of FDA and the Assistant Secretary for Food and Consumer Services will soon announce the formation of an interagency group to further coordinate our activities on this problem. The group will be jointly chaired by representatives from FDA and USDA.

As you know, the Secretary of Health, Education, and Welfare and the Secretary of Agriculture have asked the Justice Department to consider the acceptability under the laws we administer of different courses of action

that might be followed by USDA and FDA in dealing with this issue. It is a complex legal problem. The Justice Department is considering it in detail. We do not have an opinion from the Attorney General as of yet and cannot predict when they will complete their analysis.

News reports of the Newberne study and speculation about the actions that FDA and USDA intend to propose have abounded since early August. We are aware that based on those news reports some Congressmen have expressed concern about the timing and direction of any regulatory action. There appears to be some fear that nitrite usage will cease overnight. That fear is unfounded.

Final regulatory action by either agency is not imminent. Any action that the agencies might take will reflect President Carter's Executive Order requiring substantial public announcement and participation. We will prepare and publish proposals in the Federal Register. We will solicit public comment on the proposals. Because of the complexity of the issues involved, we will provide at least 120 days for public comments. Then, the agencies will review the comments received, carefully consider the points made and evidence presented, and prepare final regulations. As a rule, final regulations are very unlikely to be ready until 12 - 15 months after we begin the process. The length of time needed to conduct the administrative process appropriately and to provide the opportunity for public debate required by the administrative process make legislation analogous to the saccharin moratorium unnecessary. We believe, in fact,

that the administrative process provides an excellent opportunity for 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 generally.

Some have argued that no administrative action should be taken at this time because Congress has recently mandated a study of food safety policy under the Saccharin Study and Labeling Act. That argument is specious. The food safety study currently being conducted by the National Academy of Sciences/Institute of Medicine is due to be reported in January of 1979. The timetable for the administrative process that I have described above will permit time for all interested parties to evaluate the National Academy of Sciences report before any final action is taken on the use of nitrites. The public debate over the National Academy study will, and should, proceed while the administrative process involving nitrites runs its course.

Mr. Chairman, this concludes my oral presentation. For the Committee's record, I would like to have made part of the record further information on USDA's actions regarding nitrosamines and nitrite-free products.

History of USDA Regulatory Actions Regarding Nitrosamines

In the early 1960's scientists 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 secondary amines, had been previously identified as potent carcinogens. The discovery of nitrosamines in fish led the scientific community to investigate the possibility that carcinogens might also be present in cured meat products as well. Studies revealed that the risk of nitrosamine formation is especially great in bacon products, which are generally prepared by frying at a high temperature. Continued research has shown the problem to be persistent, as recent nationwide surveys continue to confirm the presence of nitrosamines in fried bacon.

Until last year, the Department of Agriculture had been reluctant to take definitive action concerning nitrosamines, although public concern had been mounting steadily. In 1972, the Center for Science in the Public Interest and several other groups petitioned the Department to ban the addition of nitrites to bacon and other foods. The petition was denied. Suit was brought in District Court, but judgment for the Government was affirmed on the ground that the plaintiffs had not exhausted their administrative remedies. Throughout 1972, representatives of the Department held a series of conferences to discuss the recent scientific studies and other information on the role of nitrite in curing and preserving. One of the main purposes of the conferences was to determine what new information was needed in order for the Department to take definitive action.

The continuing discussions on the nitrosamine hazard were given a more formal structure in 1973 when the Secretary of Agriculture appointed an Expert Panel on Nitrites and Nitrosamines to assess the data concerning the presence of nitrosamines in foods, to evaluate the public health significance and specific problems identified with the use of nitrites in foods, and to determine if alternative methods of processing were available. The panel included representatives from the Department, FDA, the academic community, the medical profession, the meat industry, and, during the last 5 months of the panel's existence, from a consumer oriented public interest science group. The panel held 15 meetings during the period 1973-1977 at which it heard and evaluated testimony on the problems associated with nitrosamine formation.

The panel's first report was published in February 1978, and included eight final recommendations. Two recommendations made by the panel should be particularly noted since they are related to regulatory decisions about nitrosamines.

First, the panel recommended "for any product where carcinogenic nitrosamines are formed during processing or preparation for cooking or eating, the nitrosamine level should be closely monitored and reduced to an undetectable level as rapidly as possible, e.g., within three years." This recommended three-year implementation period was not acceptable because USDA cannot legally allow products containing confirmable levels of nitrosamines to remain on the market.

The Department has a mandate under the Federal Meat Inspection Act (FMIA) to assure that meat products are free from adulterants. Under the provisions of this Act, a meat product is considered adulterated if it "bears or contains any poisonous or deleterious substance which may render it injurious to health." Nitrosamines are undoubtedly "adulterants" under this definition, and USDA has a clear legal obligation to eliminate them from the meat supply. The recommendations of the panel cannot excuse legal responsibility.

USDA also had reservations about a second important recommendation of the panel. It recommended that "the Secretary of Agriculture cause to be announced that the risk of cancer is increased when fried bacon or the rendered fat from it is consumed." USDA's view on this recommendation (supported by a majority of the panel, even though not included as a final recommendation) was that a public announcement on the health risks of bacon would create fears about bacon consumption at a time when the industry was making substantial progress in eliminating the nitrosamine problem. USDA therefore elected not to make such an announcement.

The first step in assuring that the health hazards posed by the presence of nitrosamines in cured meat products are eliminated was taken in October 1977. At that time, USDA published a notice in the Federal Register directing the meat industry to submit data showing ways in which bacon could be manufactured and prepared for consumption without resulting in the formation of confirmable levels of nitrosamines. The deadline for receipt of this information was January 16, 1978, and was

later extended to March 17, 1978. Nitrosamine data for other nitrite cured meat products was requested over a longer time schedule.

USDA has taken two regulatory actions based upon the data submitted by industry. Both of them concern the amount of nitrite that goes into bacon, and they are intended to assure elimination of confirmable levels of nitrosamines in this product. The two regulatory actions are:

1. Immediate Action to Reduce Level of Nitrite Used in Bacon Production

USDA issued a final regulation to reduce the nitrite level immediately to 120 parts per million. This rule, which went into effect on June 15, also required that the reduced nitrite level be combined with the addition of 550 ppm sodium ascorbate or sodium erythorbate. According to industry data, nitrosamines at a level of no more than 9 parts per billion will be formed in bacon prepared in this manner. This is the lowest level of reliable measurement achievable under commercial laboratory conditions.

Representatives of the meat industry have felt for some time that nitrosamine formation would be significantly reduced if ingoing nitrite were reduced to the 120 ppm level and combined with ascorbate or erythorbate. In October 1977, for example, Richard Lyng, President of the American Meat Institute had written to the Administrator of Food Safety Quality Service and stated, "We believe that adequate data have been submitted to demonstrate the effectiveness of reduced nitrite (120 ppm) and increased ascorbate or erythorbate (550 ppm) in producing bacon which when fried contains nonconfirmable quantities of nitrosamines." The

data later submitted by industry on March 17 supported this analysis and became the basis for the May 16 final regulation.

To monitor industry's compliance with the new regulation, USDA plans to begin testing bacon samples for nitrosamines. This compliance program, scheduled to begin on October 16, is the culmination of an intensive compliance effort carried out over the past four months. The implementation of the USDA compliance program has, however, been challenged by the American Meat Institute in a court action. Implementation will depend upon the outcome of that action. Soon after the regulation was published a joint USDA-Industry task force was formed to study bacon processing methods and assist industry in adapting to the regulation.

Processing practices and guidelines have been developed on such matters as the accurate measurement of ingoing nitrite and ascorbate, and the methods of pumping curing solution into the meat.

USDA has also arranged for Government and private laboratory facilities to be available to processors so that they will be able to conduct tests and bring themselves into compliance with the regulation. Products will be detained only after USDA has (1) received a test result indicating confirmable levels of nitrosamines, (2) given the processor the opportunity to bring his product into compliance, and (3) confirmed the presence of more than 10 ppb nitrosamines on a second, more precise test. USDA is not in the business of closing plants, but of preventing adulterated products from reaching consumers.

USDA plans to continue with the regulatory course, announced on May 15, 1978, to eliminate nitrosamines from cured meat. Some modifications, of course, may become necessary in the future to make the regulatory actions on nitrosamines consistent with whatever measures are taken on nitrite. It is important to note that nitrosamines are generally 1,000 times more potent as carcinogens than nitrite. Fortunately, the means for eliminating nitrosamines appears to be at hand and, with continued industry cooperation, the USDA regulatory plan should be successful.

2. Proposed Rule to Reduce Level of Nitrite Used in Bacon Production

On May 16 USDA issued a proposed regulation that would reduce the amount of nitrite permitted in curing bacon to 40 parts per million (ppm) and require it to be used in combination with 0.26 percent (of the weight of the product) potassium sorbate and 550 ppm of ascorbate or erythorbate. The data provided by industry indicates that this formula protects against botulism, while eliminating confirmable levels of cancer-causing nitrosamines. Although industry findings are promising, they were derived from experiments involving relatively small numbers of bacon samples in comparison to the total volume of bacon produced annually. Further research and opinions are required to confirm the initial test results. The public comment period will remain open until November 16, 1978, offering a total of six months for the compilation and submission of additional information. Unless the original test results are disproved, this proposal is scheduled to take effect in 1979.

The Proposal on Nitrite-Free Products

On April 28 USDA published a proposal that had been developed in response to requests from certain cured meat product manufacturing groups to allow the use of traditional product names for meat products cured without nitrite or with reduced levels of nitrite. At the present time, cured meat products may not be called "corned beef," "bacon," "frankfurters," etc., unless they contain nitrate or nitrite. For example, a frankfurter produced without nitrite is now called "uncured cooked sausage" because it does not conform to the regulation which requires nitrite as an ingredient in frankfurters.

Manufacturers of low or no-nitrite products consistently charged that their products were safe and wholesome and posed less of a nitrosamine hazard than products containing nitrite. They further asserted that USDA regulations, which define cured meat products as containing nitrite, unfairly discriminated against their products.

Recognizing consumer preferences and expectations about cured meat products, USDA included in this proposal the requirement that products sold under recognized names -- regardless of the level of nitrite they contain -- must maintain the taste and consistency standards associated with the traditional cured products. To avert any health hazard involving botulism, the proposal establishes several alternative processing methods which may be safely used, such as canning, pickling, drying, and adding salt. To further prevent any risk of botulism that

may arise from consumer confusion in distinguishing between alternative and traditionally cured products, special labeling would be required for the products that must be refrigerated. Products containing no nitrite would be labeled "Not Preserved, Must Be Kept Refrigerated Below 40° F. At All Times." Products containing low levels of nitrite would be labeled "Not Fully Preserved, Must Be Kept Refrigerated At Below 40° F. At All Time."

There is certainly some potential health risk posed by products containing low or no nitrite if they are not made free of that hazard by some other system. Proposal comments with regard to more effective labeling, storage, and distribution procedures will be assessed carefully. Public education programs may also be necessary to further insure proper consumer awareness.

Mr. Chairman, this completes our prepared testimony. I know the Committee has some questions, and we will do our best to answer them.

Mr. ROSE. Thank you.

Ms. Foreman, the National Academy of Sciences report has not been completed, has it?

Ms. FOREMAN. It is due to be made final in January of next year.

Mr. ROSE. When was that instituted and at whose request was it instituted?

Ms. FOREMAN. I believe that it was at the request of Congress as a result of the saccharin labeling action last year. Dr. Kennedy is much more familiar with that piece of legislation and that study than I am.

Mr. ROSE. Dr. Kennedy, do you know what the National Academy report is going to say at this time? You don't, do you? I would assume you wouldn't.

Mr. KENNEDY. No, but I can sketch its scope for you a little more, if you wish.

The Congress asked the Academy to conduct really two studies: First, a study on saccharin and its impurities and to measure the health benefits associated with saccharin and, second, and more encompassingly, a study that would attempt to evaluate some questions essential to food safety policy.

My understanding is that the National Academy of Sciences has had hearings and heard from a number of groups and has done research on case histories of several different compounds that have led to controversial regulatory proposals or posed difficult regulatory dilemmas. Their study will consist ultimately, in addition to this information about saccharin, of some recommendations about food safety policy based on their analysis of these case studies and additional work that I do not know about.

Mr. ROSE. Just briefly, let me tell you that I feel very sympathetic for the position that you two people find yourselves in, somewhat at the focal point in our whole society of the question of risk taking in the food business. You are at that focal point because of laws that Congress has passed, because of laws and regulations that have evolved through the years.

Although I empathize with meat producers who are consumed with fear in this area and tend to take out their fear on you two people personally, I reject that. I do not hold you two personally responsible for the disruption of the meat industry, as some people would like to do.

I hope that we can have through you and your offices a meaningful discussion with the Congress about this whole area of risk so that we, as the supposed policymakers in our Government, can determine whether or not we need new laws and regulations to deal with the new abilities that we have today to judge risks that we might not have had at another time in our past.

Sunshine is a possible cancer-causing agent, but none of us have told the Miami, Fla., Chamber of Commerce that they should require umbrellas for all the people who go on the beaches at any point in time.

Automobiles are risky instrumentalities. We have done quite a bit to reduce the risks of automobiles and of speeding in them, but we have not banned them outright. We have not said with great conviction, as

some people I have heard here today speak with great conviction, "Oh, we're going to allow plenty of time to phase that out."

We are not proceeding to phase out sunbathing. We are not proceeding to phase out spinach or salivating in the mouth. The last, two, we all know, lead to nitrite being present.

In this particular situation with which we are faced, why can't we consider such an alternative as maybe reducing the levels of nitrites, going back and retesting lower levels, giving you the legislative authority to allow lower levels, and maybe accompany that with warnings of some sort? Why can't we be more clever with legislative tools to you than we have been to this point in time?

Dr. KENNEDY. Possibly you can find ways to be that clever, Mr. Chairman. You have made a very fair statement of what all of us find a difficult social dilemma. I would like to pick up on one feature of the way you have posed it because I think it is very central.

It is often argued to us that public policy should not focus strong attention on a hazardous substance when the mount of its addition that we can control is small with respect to some amount that we cannot control. Where risks are nonexclusive, should we take a different view toward controlling them by law than we do risks that are exclusive risks? That puts you at the focal point of this debate instead of me as a lawmaker. I like it better that way.

I would pose to you the problem of deciding what ratio of controllable to uncontrollable exposure you would set as the limit for intervention. I find that a terribly tough problem. Is 50 enough, 20, 1 percent? That is how slippery the slope seems to me.

Mr. ROSE. Thank you for that observation. It is a slippery slope, but I really think that we belong on it. We are the ones who set this whole thing in motion to begin with.

It is unfair for people to blame Carol Tucker Foreman and Donald Kennedy for all of this when we in the Congress have a responsibility to examine this whole question very broadly and not be ashamed or afraid to look at any of the parts of it and then do our business and our homework on the floor.

Thank you. I am sure there are other questions here from members of the committee. Congressman Krebs?

Mr. KREBS. Thank you, Mr. Chairman.

Mr. Chairman, I want to associate myself with your very well chosen comments. You summarize the situation very well. I would like to ask a couple other questions to amplify what you have tried to establish.

Do I gather from what you have said that there has been a certain amount of cooperation between the industry and your office in an attempt to find some modus operandi or some compromise?

Ms. FOREMAN. With regard to the manufacture of bacon where the Department has in fact begun some regulatory action in order to prevent the formation of nitrosamines during the processing of bacon, there has been a great deal of close cooperation.

We have formed, as part of that regulatory process, a joint industry-Government committee. We have asked scientists from the Science and Education Administration and the Food Safety and Quality Service to join with scientists from the industry. They have gone to a

variety of manufacturing processing companies where they process bacon to see how the system there might be adjusted in order to prevent the formation of nitrosamines. We have held some joint conferences with the industry.

Our business is not to put people out of business. Our business is to make sure under the laws of Congress that the product that is offered for sale is not adulterated.

In the bacon issue we have attempted to try to operate in a method that secures a safe product and avoids economic dislocation as much as we can possibly do that.

Over the years, the Science and Education Administration and other agencies in the Department of Agriculture have worked jointly on research on nitrosamins. This is where we thought the problem rested earlier. As we begin a regulatory process on this new issue, undoubtedly we will continue and expand the projects that we already have underway.

The President's Executive order on regulatory reform requires, in fact, that kind of cooperation between interested parties in the development of regulations at the present time. So I would look forward to a great deal more as this process goes along.

Mr. KREBS. The answer that you just gave me would lead me to believe two things, and they may be totally erroneous.

First, of all, the inference that I am drawing here is that the type of cooperation that you have had from the bacon producers has not necessarily extended to some of the other industries. Is that a correct impression or not?

Ms. FOREMAN. No, sir. No. It is because our regulatory actions up to this time have been directed at bacon because that was the product where we had information that showed that nitrosamines formed. Until the MIT study, our data showed that nitrosamines were the problem. Nitrates in and of themselves being carcinogens is a problem we have not dealt with in the past. That is a new problem. It is only because the information we had drew us more closely to working with the bacon industry that we have had that activity at this point.

Mr. KREBS. I am glad to hear that. This brings me to the next question.

It strikes me—and again that might be based on an erroneous impression—that this type of working together with a given industry should really be attempted on as serious a level as possible before the regulatory process is even initiated. If for no other reason, from a psychological standpoint it seems to me that would be much more constructive. Maybe under present laws that is not possible. You may want to elaborate on that.

Ms. FOREMAN. Let me respond briefly that in fact I believe that under the Administrative Procedures Act, under recent court rulings on that act, and certainly under the executive order on regulatory reform, we would be prevented from closing out other people from that process. The public should be aware of what is happening on this issue. It would prevent us from sitting down in a small room with the industry and making decisions about how to proceed.

I would like to take 1 minute to elaborate. When we begin to get into this regulatory process, the President's Executive order requires the

publication of an intent to propose in which you lay out some of the problems with which you are faced and suggest various alternative courses of action. If you have rejected certain courses of action, you have to say why you rejected them.

Under the existing Executive order, we will be required to have a very complete impact statement, not just economic impact but economic, social, and environmental impact statement, prepared not before the final regulation, as we have done in the past, but before the proposed regulation goes into effect. So all the way through the President's Executive order encourages greater and greater information to be made available at the earliest possible time in order to try to prevent unintended consequences of Government action. That is how we proceed.

Mr. KREBS. Regarding the advice or sentiment of the chairman, which I share and which other members of this committee may share, of trying to reach some sort of a compromise in terms of the risk-benefit formula, do you perceive the Delaney amendment as a hinderance in order to achieve this type of a compromise?

Ms. FOREMAN. Congressman Krebs, I do not administer the Delaney amendment. If you would like to speak specifically to that, I think I will defer to Dr. Kennedy.

I certainly think that it is worthwhile to have a public debate on the issue of costs and benefits and the problems involved with chemicals in our society. That is one of the reasons we are happy to come here today to participate in this hearing.

I can promise you that I do not have an answer to that. I do not know to whom in our society you want to assign the responsibility for making the decision about how much of a carcinogen is enough, not enough, or too much. We certainly would not want to close anybody out of that debate.

Dr. KENNEDY. I would like to add briefly to that, Congressman Krebs.

The Delaney clause has had, I think, important value. I do not think it should be cast aside lightly. Congressional concern and public concern today are focused on two respects in which the Delaney clause appears not to be serving us as well as we would like.

One of them is in its failure to deal with very small amounts of things. The other is in its failure to deal with any amount of a thing that yields what many perceive to be a social benefit that would make some level of risk acceptable.

The reason is that at the time that Congress passed the 1958 amendment it did not see anything in the universe of food additives that appeared likely to confer such a benefit and that analytical chemistry was not at the level of sophistication to make these traces of things as important and prominent as they have since become.

I think that is why the Congress asked the Academy to do its study when it confronted the saccharin dilemma a year ago. Working with the outcome of that study and with the agencies that have administered the toxic substances laws of this country, Congress will be prepared next year to undertake what is going to be a very difficult and complicated task of constructing wise public policy. We are anxious to participate as helpfully as we can in that. I think it is going to be a very tough year.

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Mr. KREBS. Thank you very much, both of you.

Mr. ROSE. At this time I will recognize Mr. Baldus.

Mr. BALDUS. Let me read from page 19 of the testimony, which was not read.

> USDA plans to continue with the regulatory course, announced on May 15, 1978, to eliminate nitrosamines from cured meat. Some modifications, of course, may become necessary in the future to make the regulatory actions on nitrosamines consistent with whatever measures are taken on nitrite. It is important to note that nitrosamines are generally 1,000 times more potent as carcinogens than nitrite. Fortunately, the means for eliminating nitrosamines appear to be at hand and, with continued industry cooperation, the USDA regulatory plan should be successful.

I would like you to expand on the means for eliminating nitrosamines. Is that the combination of nitrite and other compounds?

Ms. FOREMAN. Last October we asked the industry to present to us information that showed that they could manufacture bacon using nitrite without having nitrosamines formed at a detectable level. Last March the industry presented us data that indicated that with 120 parts per million [p/m] of nitrite and 550 p/m of erythorbate, bacon manufactured at those levels, when tested after 21 days, showed 10 parts per billion [p/b] or less of nitrosamines. Ten parts per billion is about the best level that we can reliably detect in commercial laboratories around the country at this time.

The Department made final then a regulation that it had proposed in 1975 that set a maximum level of 120 p/m and 550 p/m. However, there are methods that can detect nitrosamines down to 5 p/b. We felt it was important to deal with that. Therefore, at the same time we proposed a regulation that would within a year require that bacon be manufactured using no more than 40 p/m of nitrite combined with 0.26 percent by weight of potassium sorbate.

We have provided a 6-month comment period asking the public to say if this method is acceptable and will that do the job. That comment period, I believe, will end November 16.

The study data that we have to date is very optimistic about that method providing bacon that has no detectable level of nitrosamine and that has the same protection against botulism that 120 p/m of nitrite does. So we are optimistic. If the studies continue to come out the way they have to date, and in the absence of any data that would say that system won't work, we will next year make the regulation final dropping bacon to 40 p/m of nitrite and including 0.26 percent potassium sorbate.

If other methods come up that can be used that have similarly small amounts of sodium nitrite, we would accept those methods probably as well. We are not totally wedded to this one method. It is one method that appears to be successful.

Mr. BALDUS. As a member of both the Agriculture Committee and the Small Business Committee, I can understand where large meat and poultry processors would be able to adjust to the new levels and to testing and assure quality compliance requirements very easily. However, the processing business is very diverse. There are also very many small ones.

Do you anticipate that the smaller processors, meat packing plants, and sausage makers will have problems in complying?

Ms. FOREMAN. Let me point out that this issue right now only deals with bacon and not with sausage. We have not gone beyond bacon yet on the issue of nitrosamine.

Mr. Butler, who is the deputy assistant secretary, could expand if you wish expansion or would expand for the record.

Let me say that so far our meetings with the industry seem to indicate that, much to our surprise, small processors seem to be having less difficulty making adjustments to 120 p/m and 550 p/m than larger manufacturers do. Larger manufacturers have more resources but the smaller ones, because of the way they make bacon in limited quantities, have a little bit easier time shifting their manufacturing methods, at least that is our initial indication from 3 months of work now with the industry during the summer.

Mr. BALDUS. The testing to be sure that they are in compliance, what about that part? Are they equally sure?

Ms. FOREMAN. The Department takes on the responsibility for that testing across the board, if necessary. When we go in, we take a sample. It is kept for a period of time. We then test the sample. If the sample shows over 9 p/b of nitrosamines, or over the accepted level of nitrosamines, then we go into a more sophisticated testing mechanism.

During that period of time the processor has the option of going out on his own and getting additional lots of his bacon tested. If five consecutive lots that he has tested show up below the action level, then we stop our further testing. We drop it at that point. If he chooses not to do that, we go ahead with our testing. Or if he does that and finds that he still has high levels, we go ahead and do our testing.

There is a period of days that is involved in this. During that period of time, our people and the industry task force people will be available to work with the processor in question to see how he might adjust his process in order to avoid having a higher nitrosamine level than is acceptable.

We have worked out with the industry a number of steps in order to avoid that ultimate stopping of production because the nitrosamine level is too high.

Mr. BALDUS. I would judge from your statement that the characterization of this process would be one of cooperation rather than confrontation at this point.

Ms. FOREMAN. At this point I think that both sides would describe it that way. We are certainly attempting, as I pointed out earlier, to keep an adulterated product from going on the market; not to close people down. That is obviously a situation that nobody wants.

Mr. BALDUS. Thank you.

Mr. ROSE. Mr. Mathis?

Mr. MATHIS. Thank you, Mr. Chairman.

Mr. JEFFORDS. May I interrupt? I understood these witnesses had until 12 noon with us. Is that time firm? I am concerned that we are using an unusual procedure here, which is not to let the minority have any questions of these witnesses. I would like to know as to whether or not we will have an opportunity for questioning.

Mr. ROSE. What is your time schedule, Dr. Kennedy and Ms. Foreman?

Dr. KENNEDY. I have a 12:30 appointment which I can probably manage to be a little late for. In fact, the explanation that I will make is one that has worked before.

Mr. ROSE. "Congress," I assume. [Laughter.]

We will recognize Mr. Jeffords at this time.

Mr. JEFFORDS. I am very pleased to be recognized, Mr. Chairman. I will yield to the distinguished gentleman from Virginia, our ranking member of our committee, Mr. Wampler.

Mr. WAMPLER. I thank the gentleman for yielding.

Ms. Foreman, when did you consider that the Department of Agriculture had sufficient evidence to take action against nitrites as a danger to human health?

Ms. FOREMAN. When the material from the Massachusetts Institute of Technology study was presented to the Food and Drug Administration and we began to have discussions with them, it became clear that FDA views that the substance sodium nitrite will fall prey to the Delaney clause and to their adulteration clause.

If a substance is an adulterant under the Food, Drug, and Cosmetic Act, it is, according to our attorneys, also viewed as an adulterant under the Meat Inspection Act.

Mr. WAMPLER. The fact of the matter in what you are saying is that it wasn't until the results of the MIT or Newberne study were made available; is that correct?

Ms. FOREMAN. That is correct. We were aware of an earlier study done for FDA that raised these questions, but it was certainly not until this very extensive study was presented to them that we began to consider the need for action.

Mr. WAMPLER. In other words, you had not made up your mind prior to that time; is that correct?

Ms. FOREMAN. With regard to nitrites?

Mr. WAMPLER. Yes.

Ms. FOREMAN. Yes, sir.

Mr. WAMPLER. Let me refresh your memory a moment. I have here a newsclipping service, the Bureau of National Affairs, Inc., Washington, D.C. On January 10, 1978, it credits you with stating at the Women's National Democratic Club on January 9, 1978, that—and I am quoting their words: "USDA presently is moving towards regulation of nitrites and nitrates, substances used as preservatives in bacon, ham, and processed meats such as hotdogs."

It quotes you as pointing out to the Democratic Women on January 9 that consumers would not be able to "leave bacon on the kitchen shelf overnight," and that you added, "You won't be able to take hotdogs to the beach, leave them unrefrigerated for hours, and then warm them only a little."

Reading those words which you made almost a year ago, and well in advance of the release of the Newberne study, how could you say that you had not made up your mind? Don't you have a built-in prejudice against nitrites and have had for many years?

Ms. FOREMAN. No. sir. In the context of my speech the comments were made specifically with regard to the effects of nitrites in causing nitrosamine formation. I was quite clear, I believe, and have been

each time I have talked about this before the MIT study, that the problem with which we are dealing was the issue of nitrosamines. In the case of bacon, nitrosamines do form.

I went on to say that if there are nitrosamines in these other products, then we will have to deal with the use of nitrite in those products as we are dealing with the use of nitrites in bacon products. That was all in the context of the role of nitrite in causing the formation of the cancer-causing nitrosamines.

Mr. WAMPLER. Could you give me or cite to me any test prior to the publishing of the Newberne study that had indicated nitrite by itself was a possible carcinogen and therefore was unsafe as a meat preservative? Do you know of any study such as that?

Ms. FOREMAN. There were the studies done earlier for FDA that raised some question about that. There are studies that have been done at the National Cancer Institute that seem to indicate that nitrites might cause the formation of nitrosamines in the body rather than preform nitrosamines and that these might be a problem. Those are the studies that I have been aware of before the MIT study. None of those seemed to be advanced enough to require regulatory action.

Mr. WAMPLER. But you did have this knowledge and you were hoping that is what the MIT study would show, so that it would carry out your natural prejudice, weren't you? Haven't you demonstrated that repeatedly?

Ms. FOREMAN. Mr. Wampler, I do not believe that I have a prejudice on the subject. I was sworn by the President of the United States to uphold the laws of Congress, and I have attempted to do that.

Mr. WAMPLER. In the hearing that was held recently in the other body, you pointed out that you had fears that some Congressmen—and I assume you were referring to me and others that introduced legislation after the publishing of the Newberne study—had unfounded fears about the timing and direction of any regulatory action that you might take. I do commend you for putting on the record today the timeframe in which you intend to act in this matter.

However, if it is shown reasonably that the Newberne study is not valid, what would you do then? Would you tend to reverse your proposed regulatory action?

Ms. FOREMAN. If it were proven 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 a course of action.

Mr. WAMPLER. I notice you used the word "specious" rather freely here this morning. I looked up the definition. I thought I knew what it meant. I think you referred to Mr. Martin, and me and others. Among other things, "having a false look of truth or genuineness, is the definition.

I want to assure you that I am concerned about this. I have never been more serious about any matter since I have been in the Congress. I have been here 14 years.

I do not know whether you have traveled as much through the country as I have. I assume that you have. The one message that I get from the people of this country is that they are fed up with

big Government. They are fed up with overregulation and needless regulation.

In the scientific community itself, from those with whom I have talked, the Newberne study itself is subject to very serious questions from a sound scientific basis. This is why I hope that both you and Dr. Kennedy haven't closed your minds to the possibility that there can be those who can refute it scientifically.

Another thing that is concerning people in this country is that every time there is study such as this, the results are made public, the mass media spreads it across this country, and it scares the daylight out of people. There is an interesting parallel between this and Aesop's fable about crying wolf. If you cry wolf long enough, then when there is a significant finding made, people are going to tend to ignore it.

We are all scared. We can't breathe anything; we can't eat anything; we can't touch anything; we can't drink anything for fear of cancer.

Dr. Kennedy and I have discussed on an informal basis the need for a national cancer risk assessment policy. I think the chairman and others addressed themselves to that this morning. There is a bill pending before the full Committee on Agriculture to help establish a framework under which we can get a reasonable assessment of risk and benefit. This is what I am afraid you have overlooked through the narrow definition of the law and also on the scientific validity of this test. Again, as I have been told by those whose judgment I respect, there is serious question about the scientific validity of this test. Even Dr. Newberne himself, I think, has suggested that.

Dr. KENNEDY. Let me try to deal with the two parts of the problem you raise.

I spent 25 years as a scientist, publishing papers on subjects much less interesting to most people than the toxicology of nitrites. I think my record for being confirmed was pretty good, but I surely got argued with a lot.

Science is an activity that ultimately proves itself through debate, through open debate. You point out that the media has a way of dispensing these concerns before they are fully ripe. Unfortunately, the alternative to that is to keep them secret. Quite apart from the question of whether It would be a desirable policy for any Federal agency to keep secret the knowledge that a potentially serious hazard existed about which a rather thorough experiment had demonstrated a risk, apart from that question, there is the question of how one would get the kind of open scientific debate that works in our community without that kind of public exposure.

I certainly agree with you about the hazards of crying wolf. No one could be more poignantly aware of the social cost of that than I. On the other hand, I am afraid that to do otherwise would give us something much worse.

Mr. WAMPLER. I appreciate what you say. For example, would you be willing to withhold any precipitious action until the Congress has a chance to work its will in the next session on the question of a national cancer risk assessment policy to give you more meaningful guidelines within which to work so that you can on the one hand weigh risk against benefit?

Dr. KENNEDY. The purpose of scientific review is a little different. The purpose of scientific review is to establish the firmness with which a presumption of risk emerges from this study of Newberne's.

The additional question, whether a new national policy on cancer risk assessment is needed, is one that the Congress made a promise to itself that it would undertake when the Academy reports on the study that the Congress mandated it to do.

Ms. Foreman and I have tried to indicate, both in our testimony in the Senate the day before yesteray and here to you this morning, that the regulatory process, with its layers of due process, provides the Congress with ample time for doing exactly that.

Mr. ROSE. The gentleman from Vermont's time has expired. I will recognize the gentleman from Georgia, Mr. Mathis.

Mr. MATHIS. Thank you, Mr. Chairman.

Ms. Foreman, you responded to a question from the gentleman from Virginia relative to earlier tests. Could you identify those tests that have occurred or those scientific studies to which you alluded in answering Mr. Wampler?

Ms. FOREMAN. One was the test done for the Food and Drug Administration at MIT in 1972, I believe.

Dr. KENNEDY. It was completed in 1974 and reported to us in 1975.

Mr. MATHIS. What did that specifically deal with?

Dr. KENNEDY. May I respond because it was to my agency?

Mr. MATHIS. Certainly.

Dr. KENNEDY. Thank you, sir.

It was a study originally designed to demonstrate whether or not nitrites fed in the diet with substances that could form nitrosamines with those nitrites in the stomach, but not in the food, in fact presented risks. As a part of that kind of study, several control groups of animals were fed nitrites alone in diets that did not have any amines or amides that could lead to nitrosamine formation. That is a necessary control in a study where you are trying to put two things together.

Mr. MATHIS. How do you do that? How do you get all those amines out of a body?

Dr. KENNEDY. You can create a diet of known composition that contains none in the food.

Mr. MATHIS. Food is the only way that it can be obtained?

Dr. KENNEDY. No. Some components of the food could be converted in the stomach or the intestine by bacteria, but one cannot control for that. In the study that Newberne first did for us, there was a comparison being made between cancer rates and types of cancer in two groups. The experimental group had nitrites plus different deliberately added amounts of amines and amides in the food. The control group had nitrites alone.

The interesting thing was that in that control group a pattern of cancers arose that suggested that nitrites themselves were doing something. There was an excess of cancers of the lymphatic system in those control animals. Although the data were not complete enough to convince us that there was a basis there for regulatory action, there was certainly a basis for suspecting that something was going on. As a result, we contracted for a much larger study with Newberne directed at exactly that question. That is the study we are talking about.

Mr. MATHIS. That is the study that we have just received.

Dr. KENNEDY. That is correct.

Mr. MATHIS. I ask this obviously purely as a layman. Tell me the difference between experimental and control rats.

Dr. KENNEDY. At the beginning of the experiment there is no difference at all. They are selected to be as nearly identical as possible in terms of their genetic background, their age, weights, and other features. They are made into a pool and then randomly withdrawn to compose groups that are going to be managed differently during the experiment.

The control group does not get the treatment about which we are inquiring. The experimental group does get the treatment about which we are inquiring.

Mr. MATHIS. I am not sure that I follow that. The control group does not get what treatment?

Dr. KENNEDY. Suppose that we are trying to——

Mr. MATHIS. Let's talk about the specific test.

Dr. KENNEDY. Suppose we are talking about nitrites. The control group receives a diet that is the same as the experimental group in all respects except that it does not contain any nitrites.

Mr. MATHIS. So the control group of 573 rats was not given any food that contained any form of nitrite?

Dr. KENNEDY. That is correct.

Mr. MATHIS. 1,381 rats were involved in the experiment all together. Of that 1,381, 573 were not given nitrites and the remainder of that 1,381 was given nitrites.

Dr. KENNEDY. It is a little more complicated than that, sir. In this experiment there were actually half a dozen different experiments. The diets were different. The control diet in some cases was an auger diet. In some cases it was——

Mr. MATHIS. What kind of diet?

Dr. KENNEDY. An auger diet in which the main constituent is a component actually derived from a plant which turns out to be a diet that is free of many of the contaminants or complex substances found in more conventional laboratory diets.

The purpose for having several different groups in the Newberne experiment was to make certain that one was observing the effects due to nitrites alone and not due to some complex chemical combinations of nitrites with other components that might be in the diet.

In one of the experiments the nitrites were given in the water instead of in the food. They were all variations on the same theme but the diets differed somewhat.

Mr. MATHIS. Were any of the rats fed bacon?

Dr. KENNEDY. No.

Mr. MATHIS. Are you at this point absolutely certain of the validity of the findings of the Newberne study?

Dr. KENNEDY. No; no one is.

Mr. MATHIS. No one is?

Mr. GRASSLEY. Have you ever said that before?

Mr. MATHIS. I would yield to the gentleman for that question.

Mr. GRASSLEY. Is this the first time you are saying that statement?

Dr. KENNEDY. It is the first time I recall ever being asked the question, so perhaps the wording of my statement is a little different, but I

have said repeatedly that that study requires and will receive scientific review. I have said since the beginning that there will be confirmations of the pathology. Anyway, absolute certainty is not possible, certainly not at this stage of the evaluation of a scientific experiment.

Mr. MATHIS. Dr. Kennedy, if that is the case, this is the only study, as I understand it, upon which regulatory action against nitrites is based. Is that correct? You say that the earlier study in 1972 and other things that have happened really have no bearing, that the only study that is complete enough—am I misstating that now?

Dr. KENNEDY. Yes. What I said was that by themselves they were inadequate to take regulatory action, but they were certainly adequate to create a significant doubt about the safety of nitrite. They triggered the much larger study about which we are talking now.

Mr. MATHIS. On the basis of that study what regulatory action has been taken?

Dr. KENNEDY. None.

Mr. MATHIS. I believe the Department of Agriculture has put out some——

Dr. KENNEDY. No. Those proposals dealt with nitrosamines and dealt with a hazard recognized much earlier.

Mr. MATHIS. Let me ask you this specific question because I am running out of time.

Are you willing to say at this point that based on a combination of these studies nitrite causes cancer?

Dr. KENNEDY. I am willing to state that at the present level of evaluation of this study it appears highly likely that nitrite causes cancer, and that is certainly the legal standard for regulating for safety. It is less than is required, in my view, to initiate the very long process that ultimately leads to regulations.

Mr. MATHIS. I stipulate the things that you have said but, when I ask you, does nitrite cause cancer, can you say yes or no?

Dr. KENNEDY. I say probably.

Mr. MATHIS. Then I find in your statement on page 10, at the bottom of the page, under the heading "Future Activities":

"Nitrites have been shown to induce cancer in laboratory animals * * * "

When you say that you cannot say that it definitely does, but that it probably does, how then can you turn around and be a party to this statement that says, "Nitrites have been shown to induce cancer * * * "? This, Doctor, I would submit, is inflammatory. It scares people.

Dr. KENNEDY. When scientists talk about a result that has not yet received confirmation but is itself at the present level of evaluation a clear and decisive result, and that is the way I view this result at present, they often refer to demonstration or showing that something is the case.

To make the reservation that no scientific truth is absolute truth until it is confirmed repeatedly is a fair reservation to make. However, I would argue that the language in our statement is not irresponsible language. It reflects the way scientists normally talk about good data that are not yet fully confirmed by independent experiment or independent audit.

Mr. MATHIS. But, Doctor, you understand, as do I, that there is no way that the 10 minutes of colloquy that you and I have had will be

reported tonight on the 6 o'clock news or the 11 o'clock news. It is not going to appear on the front page of the Washington Post tomorrow morning with your saying flatly that you cannot say that nitrite causes cancer. What very likely will be on the 6 o'clock news or on the front page of the Washington Post is a statement that is attributed to you that nitrites have been shown to induce cancer.

I suggest, Doctor, that that is inflammatory. I suggest that perhaps the scientific caution that you have just displayed in colloquy with me might better serve not only the agency, but the consumers of this country.

Thank you, Mr. Chairman.

Dr. KENNEDY. May I respond just briefly, Mr. Chairman?

I would encourage you to look carefully at the press reports announcing our initial findings, our statement of the need to take action. I think that in this instance even most of the newspapers got it quite right and did attach the appropriate cautions to it.

I would, in fact, be a little more concerned that in this instance the media have raised more than the usual amount of challenge to the study on grounds that I am not sure are convincing. In other words, if you just look at the history of the way this story has been handled, I think it has been handled pretty cautiously. I think that is because we were careful and responsible about what we said.

Mr. ROSE. Thank you very much, Dr. Kennedy. Mr. Hagedorn?

Mr. HAGEDORN. Mr. Chairman, I have a question for both of the witnesses.

I just want to get into the worse case there is. Suppose that the Justice Department rules that nitrites can no longer be used under whatever legislation you want to look at that is already on the statutes. What would the position of both the FDA and the USDA be in that event?

Ms. FOREMAN. If the Justice Department were to say that the substances fall prey to the Food, Drug, and Cosmetic Act and the Federal Meat Inspection Act, the prohibitions on adulterants, then we would begin a regulatory process that would lead—might lead—in the end to their prohibition.

That would involve publishing in the Federal Register a notice of intent to propose, laying out the scientific and legal information that we have and various alternatives available. Then there would be publishing of the proposed regulation. Comments would be taken on that. There would be public hearings. It would involve going through debate over the various issues and perhaps finally coming to a final regulation.

Mr. HAGEDORN. Dr. Kennedy, what would the position of FDA be? As I understand it, your procedure works differently. You have to immediately halt the use of a particular chemical such as that; is that correct?

Dr. KENNEDY. No. We have to go through the same Federal Register notice, comment, and rulemaking procedure. There is an opportunity to request a hearing and so forth. Actually the description of the cadence of the regulatory process that Ms. Foreman has just given us would be similar.

Mr. HAGEDORN. Would either of you support congressional action at that time to impose a moratorium on the ban in the event that the Justice Department were to rule that?

Ms. FOREMAN. At what time?

Mr. HAGEDORN. When Congress reconvenes January 20 or so, 1979. Would you support congressional action which would allow for the continued use of nitrites rather than immediate phaseout?

Ms. FOREMAN. I do not think it would be necessary, sir. We would then probably be just at the beginning of the process of getting public comment on the intent to propose some regulations. We would not have had very much time. I am not even sure we would have a proposed regulation out by that time. Certainly a notice might have been published by then. There is a great deal of time for the public to go through this debate, which will include, as Dr. Kennedy pointed out, the opportunity for further challenge to the validity of the Newberne study.

Mr. HAGEDORN. Then you think it is all irrelevant and that any action that the Government might take through the legal process is a waste of time and money.

Ms. FOREMAN. Sir, I don't know how in the world you could come up with that from what I have just said.

Mr. HAGEDORN. You said it wouldn't make any difference whether the courts ruled, that you still had to go through the same process that you are going through now. So it would be irrelevant.

Ms. FOREMAN. It is not before the court. We have asked the Justice Department for comment on various actions that we might take and whether or not they are legal under the laws that Congress has passed, under the existing laws.

[Additional information submitted by Ms. Foreman follows:]

DEPARTMENT OF AGRICULTURE
OFFICE OF THE SECRETARY
WASHINGTON, D. C. 20250

OCT 23 1978

Honorable Charles Rose
Chairman, Subcommittee on Dairy
and Poultry
Committee on Agriculture
House of Representatives
Washington, DC 20515

Dear Mr. Chairman:

On September 28, 1978, I testified concerning the use of nitrates and nitrites in meat and poultry products. Certain questions were raised at that time concerning the interpretation of the Federal Meat Inspection Act in relation to the Food, Drug, and Cosmetic Act with respect to the use of nitrates and nitrites in meat products.

For purpose of clarification, I am transmitting herewith for the record a copy of my letter to the Attorney General dated August 22, 1978, which was drafted by the Office of General Counsel of this Department. This letter fully explains such matters in detail.

Sincerely,

Carol Tucker Foreman

Carol Tucker Foreman
Assistant Secretary for Food
and Consumer Services

Enclosure

AUG 2 2 1978

Honorable Griffin B. Bell
Attorney General
United States Department of
Justice
Washington, D. C. 20530

Dear Mr. Bell:

Subject: Request for an opinion regarding nitrates and nitrites in meat and poultry products

This is to request your opinion regarding legal considerations with respect to actions which may be taken concerning the use of sodium or potassium nitrates and sodium or potassium nitrites in meat or poultry products.

Section 1(m) of the Federal Meat Inspection Act (FMIA)(21 U.S.C. 601(m)) and section 4(g) of the Poultry Products Inspection Act (PPIA) (21 U.S.C. 453(g)) contain identical clauses specifying circumstances under which meat and poultry products would be adulterated. Meat products (carcasses, parts thereof, meat and meat food products) found to be adulterated under one or more of the clauses would not be eligible to bear the marks of inspection and could not be sold or distributed under the FMIA (See 21 U.S.C. 601(m), 604, 606, and 610). In this connection, the inspection provisions of the FMIA (21 U.S.C. 604 and 606) provide that federal inspectors shall mark, stamp, tag, or label as "Inspected and passed" all meat products found to be not adulterated and shall label, mark, stamp, or tag as "Inspected and condemned", all such meat products found to be adulterated; and all such inspected and condemned meat products are required to be destroyed for food purposes by the official establishment involved in the presence of the inspector. It is a crime under the FMIA to sell or distribute such adulterated meat products (See 21 U.S.C. 610, 676). Similar provisions with respect to poultry products are contained in the PPIA (See 21 U.S.C. 453, 455, 457(a), 458, 461).

Provisions in the first three clauses of the definition of "adulterated" (21 U.S.C. 601(m)(1), (2), (3) and 453(g)(1), (2), (3)) must be considered in connection with determinations as to whether the addition of nitrates and nitrites would cause meat or poultry products to be "adulterated" under the FMIA or the PPIA.

The second clauses (21 U.S.C. 601(m)(2) and 453(g)(2)) provide, among other things, that a meat or poultry product is "adulterated" if it bears or contains a "food additive" which is "unsafe" within the meaning

of section 409 of the FFDCA (21 U.S.C. 348) or bears or contains a "color additive" which is "unsafe" within the meaning of section 706 of the Federal Food, Drug and Cosmetic Act (FFDCA) (21 U.S.C. 376). In this connection it should be noted that under the "Delaney clause" contained in the "color additive" provisions in section 706 of the FFDCA (21 U.S.C. 376) and the "food additive" provisions of section 409 of the FFDCA (21 U.S.C. 348), a "color additive" or "food additive" is unsafe if found under certain conditions to induce cancer when ingested by man or animal.

The term "food additive" is defined in section 201(s) of the FFDCA (21 U.S.C. 321(s) as follows:

> The term "food additive" means 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 (including any substance intended for use in producing, manufacturing, packing, processing, preparing, treating, packaging, transporting, or holding food; and including any source of radiation intended for any such use), if such substance is not generally recognized, among experts qualified by scientific training and experience to evaluate its safety, as having been adequately shown through scientific procedures (or, in the case of a substance used in food prior to January 1, 1958, through either scientific proce dures or experience based on common use in food) to be safe under the conditions of its intended use; except that such term does not include--
>
> (1) a pesticide chemical in or on a raw agricultural commodity; or
>
> (2) a pesticide chemical to the extent that it is intended for use or is used in the production, storage, or transportation of any raw agricultural commodity; or
>
> (3) a color additive; or
>
> (4) any substance used in accordance with a sanction or approval granted prior to September 6, 1958 pursuant to this chapter, the Poultry Products Inspection Act (21 U.S.C. 451 and the following) or the Meat Inspection Act of March 4, 1907, as amended and extended; or
>
> (5) a new animal drug.

Nitrates and nitrites are not pesticide chemicals, are not new animal drugs, and are not listed by the Food and Drug Administration (21 CFR Part 182) as generally recognized as safe for use in meat or poultry products.

We have been advised informally by FDA that nitrates and nitrites are not "color additives" within the meaning of the FFDCA (See 21 U.S.C. 321(t)) when used in meat or poultry products in that any color use is only an incidental use. Therefore, the question remains as to whether nitrates or nitrites used in meat products or poultry products are "food additives" within the meaning of the FFDCA. For the reasons set forth in a letter and attachments from Carol Tucker Foreman, Assistant Secretary for Food and Consumer Services, USDA, to Sherwin Gardner, Deputy Commissioner of FDA (copy enclosed), there is a "prior sanction" for the use of nitrates and nitrites in meat products and therefore, nitrates and nitrites are not "food additives" when used in meat products. 1/ However, in a letter from Ms. Foreman to Phillip C. Olsson (copy enclosed), the reasons are set forth for the conclusion that there is no "prior sanction" for the use of nitrates and nitrites in poultry products. 2/ Accordingly, it appears that nitrates and nitrites are "food additives" when used in poultry products.

Consequently, assuming the validity of the conclusions stated above, FDA has jurisdiction with respect to the use of nitrates and nitrites in poultry products merely to determine whether they are safe or unsafe "food additives" within the meaning of section 409 of the FFDCA and has no jurisdiction with respect to determinations concerning the use of nitrates and nitrites in meat products. 3/

1/ The permitted use of nitrates and nitrites in meat products including issues relating to "prior sanction" have been challenged in the case of Public Citizen, et al. v. Carol Tucker Foreman, et al. U.S.D.C. D.C. (Civil Action No. 78-1064). This case is still pending.

2/ The decision with respect to the absence of a "prior sanction" for the use of nitrates and nitrites in poultry products has been challenged in the case of Tyson Foods, Inc., et al. v. United States Department of Agriculture and United States Department of Health Education and Welfare, U.S.D.C., W.D. Ark., Fayetteville Division (Civil Action No. F-77-5059). The Government has taken the position that the decision with respect to "prior sanction" is not ripe for review because additional opportunity will be given to the packers and other interested persons to submit evidence regarding this matter in connection with an FDA proceeding regarding the status of nitrates and nitrites in poultry products and plaintiffs are not adversely affected because no action has been taken by USDA or FDA to ban the use of nitrates and nitrites in poultry products. This case is pending decision on the government's motion to dismiss.

The first three clauses of the adulteration provisions also provide that a meat or poultry product would be adulterated

> . . . (1) if it bears or contains any poisonous or deleterious substance which may render it injurious to health; but in case the substance is not an added substance, such article shall not be considered adulterated under this clause if the quantity of such substance in or on such article does not ordinarily render it injurious to health;
>
> (2)(A) if it bears or contains (by reason of administration of any substance to the live animal [poultry] or otherwise) any added poisonous or added deleterious substance (other than one which is (i) a pesticide chemical in or on a raw agricultural commodity; (ii) a food additive; or (iii) a color additive) which may, in the judgment of the Secretary, make such article unfit for human food . . .
>
> (3) if it consists in whole or in part of any filthy, putrid, or decomposed substance or is for any other reason unsound, unhealthful, unwholesome, or otherwise unfit for human food 3/

With respect to considerations concerning the use of nitrates or nitrites in meat and poultry products, these statutory provisions must be construed in light of the recent study performed for FDA which indicates that

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3/ The FFDCA specifically provides in 21 U.S.C. 392(a) that: Meats and meat food products shall be exempt from the provisions of this chapter to the extent of the application or the extension thereto of the Meat Inspection Act, approved March 4, 1907, as amended.

Since the FMIA contains detailed provisions with respect to circumstances under which meat products would be adulterated and there has been a long standing prior sanction and regulations with respect to the use of nitrates and nitrites in meat products under the Meat Inspection Act, it is clear that Congress intended USDA to exercise exclusive jurisdiction with respect to these matters, except where otherwise specified, i.e. determinations as to whether a "pesticide chemical", a "food additive", or a "color additive" is safe or unsafe.

4/ Even if FDA determines that a "color additive" or "food additive" is safe, provisions relating to circumstances of adulteration, other than those relating to "color additive" or "food additive"

nitrites induce cancer when ingested by laboratory animals (nitrates are also used as a source of nitrites). Further USDA and FDA administrative officials have determined that nitrites when combined with certain amines form nitrosamines, some of which are carcinogenic. It should further be noted, however, that we have also been advised by such officials that nitrites have been found to prevent the growth of Clostridium botulinum, a natural contaminant of improperly preserved meat products and which produces an extremely potent poison usually fatal to man; that there are no other substances that could be utilized on a sufficiently broad scale to prevent botulism in commercially processed meat products; and that without nitrites common usage of such products as hot dogs and ham would not be possible without severe health hazards.

USDA has concluded that nitrates and nitrites in meat products are poisonous and deleterious substances which should be eliminated from the food supply as soon as possible where the public health can be otherwise protected. However, in determining whether such substances in meat products would be considered adulterants under the provisions of the FMIA cited above, it must also be determined that such substances may render the meat products injurious to health or cause them to be unhealthful or otherwise unfit for human food. In making such determinations, it is our view that the possible harmful effects of nitrates and nitrites must be balanced against the beneficial effects in preventing toxin formation of Clostridium botulinum. In weighing the relevant considerations in this instance, it is our view that nitrates and nitrites used in meat products at those levels necessary to prevent botulism would not cause the products to be "adulterated" within the meaning and purposes of the FMIA. In fact, the elimination of such substances from meat products would create severe health hazards. This interpretation appears to be in accord with the congressional statement of findings and the provisions in the FMIA clearly indicating that the major purpose of the FMIA is to protect the public health.

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status, must be considered independently by USDA with respect to ingredients in meat or poultry products. In this connection a proviso in the second clauses relating to adulteration states that:

> Provided, that an article which is not adulterated under clause (B), (C), or (D) shall nevertheless be deemed adulterated if use of the pesticide chemical, food additive, or color additive in or on such article is prohibited by regulations of the Secretary in establishments at which inspection is maintained under title I of this Act;

See also Chip Steak Co. v. Hardin, 332 F. Supp. 1084 (1971), rehearing denied, 467 F. 2d 481 (1972), cert denied, 411 U.S. 916 (1973).

It is the position of USDA that the amount of nitrates or nitrites used should be at the lowest level possible under conditions and procedures that will not subject consumers to health hazards such as botulism, and that the level of nitrates or nitrites used should be reduced and eliminated as technology and procedures are developed to accomplish this end without subjecting consumers to botulism or other health hazards.

We would appreciate your opinion as to whether our interpretation of the adulteration and other provisions of the FMIA with respect to the use of nitrates and nitrites in meat products is sound.

Further, in the event that it is ultimately determined that nitrates and nitrites are "food additives" or "color additives" in meat or poultry products, the Delaney Clause would be applicable. In this connection, we would appreciate your opinion as to what actions must be taken under the relevant statutes if such substances were found to be "food additives" or "color additives" in meat or poultry products.

Your prompt attention to this matter would be greatly appreciated.

Sincerely,

Carol Tucker Foreman

CAROL TUCKER FOREMAN
Acting Secretary

Enclosures

Mr. HAGEDORN. And if the Justice Department then were to say——

Ms. FOREMAN. Under other laws passed by the Congress, the Administrative Procedures Act specifically, we are required to go through a certain administrative process to avoid precipitous action and to make sure that the Government does its decisionmaking in a rational fashion. I think we would be just in the middle of that rational decisionmaking process.

Mr. HAGEDORN. Dr. Kennedy, do you subscribe to the theory that if there is 1 molecule of suspected cancer-causing substance in 1 billion molecules of another substance we ought to ban the whole substance?

Dr. KENNEDY. I would like to restate it, if I may. We cannot make any general statements about the precise number of molecules of a cancer-causing substance, of the total that someone might ingest that would be necessary to cause formation of a cancer. What I do say is that, because we know of no threshold for cancer, we know of no point below which in concentration a substance acts, then we have to treat small concentrations seriously.

Mr. HAGEDORN. Do you consider that serious?

Dr. KENNEDY. Yes.

Mr. HAGEDORN. Then you would support a ban if you found 1 molecule in 1 billion molecules.

Dr. KENNEDY. No; that does not necessarily follow. It would depend on the total dose. It would depend on what one knew scientifically about the situation in other respects as well.

You can imagine a situation in which you knew about a substance, that it worked through some secondary process, and that there was a concentration that did not measurably affect the secondary process.

As we learn more about how carcinogenesis really works, we may reach a point at which we can treat small concentrations more sensibly. However, at the moment I think we have been well served, and continue to be well served, by a zero tolerance law for known carcinogens.

Mr. HAGEDORN. Do you know of any circumstances where you would not ban a suspected carcinogen?

Dr. KENNEDY. I don't know of any at the moment, although there are plausible possibilities that you may not want to hear about at the length I would have to take to describe them.

Mr. HAGEDORN. In the case of nitrites, Dr. Kennedy, do you consider them to be a carcinogenic agent to, for example, a strong degree, a mild degree, or a very slight degree?

Dr. KENNEDY. On present evidence, they are a moderately weak carcinogen—on present evidence.

Mr. HAGEDORN. Would that be a very slight degree then, of the three choices? Very slight degree and moderately weak must be in the same category.

Ms. Foreman, I have read some of your testimony earlier and heard it said by you that you feel the consumers are demanding nitrite-free products. Is that correct?

Ms. FOREMAN. There appears to be a demand for nitrite-free products by some people, yes.

Mr. HAGEDORN. Could you supply for the record the number of consumer groups by name and address, along with the number of individual consumers each group officially represents in the United States,

and a fairly accurate number of individual consumers who have contacted your agency as of this date demanding nitrite-free products?

Ms. FOREMAN. I think we can provide some data along those lines. It would probably also be worthwhile for you to inquire of the Food Marketing Institute what kind of inquiries have come to them from their member retail stores requesting information about availability of such products because their customers have been asking for them.

I think there are other witnesses here today who may feel that there is a demand for it.

Mr. ROSE. The record will be held at this point to receive that information.

[The material submitted follows:]

For the months of November 1977 through March 1978, we have located 51 letters opposed to the use of nitrites in foods. These were from individuals, and were sent to us directly or were received through a member of Congress.

In April of 1978, we issued a proposal that would permit, without altering the basic product name and with certain safeguards, reduced levels of nitrite or no nitrite in products in which higher levels of nitrite are traditional.

In response to this proposal we received comments from the following consumer organizations:

(1) *Arcata Co-op, 747 13th Street, Arcata, Calif.*

The Co-op serves 5000 members of the community. The members have put pressure on the Co-op to discontinue carrying products containing nitrites and nitrates. They support the proposal as is.

(2) *Center for Science in the Public Interest, 1–55 S Street, NW., Washington, D.C.*

The Center is pleased to see a proposal banning the use of nitrite and nitrate in baby, junior, and toddler foods. They endorse the proposal to allow traditional products to be made without nitrite and/or nitrate and yet be called by the traditional names. They point out that this would be consistent with the past practice of allowing baby foods to use traditional names for uncured products.

(3) *Consumer Cooperative of Berkeley, Inc., 4805 Central Avenue, Richmond, Calif.*

Owned by more than 90,000 member-families and operates 13 supermarkets. They support the proposal including the requirement of warning statements as the labels for safe handling.

(4) *Community Nutrition Institute, 1910 K Street, NW., Washington, D.C.*

A public interest organization whose primary emphasis is on consumer nitrition issues, especially those related to low income groups and individuals. This is not a membership organization, but it has a "subscription list" of 5000 people.

They support the proposal on the basis that nitrites and nitrates are carcinogenic and toxic and unnecessary.

They claim that the requirements to use nontraditional names for uncured products results in confusion and deception of the consumer.

They would like to see warning statements on cured products, stating that the cures are dangerous. They would like to see handling statements on all fresh products, such as pork sausage, as well as on the uncured generic products.

(5) *New Mexico Public Interest Research Group, 139 Harvard SE., Albuquerque, N. Mex.*

The group supports the proposal in allowing nitrite-free products to be made with traditional names.

They state that the products are already being made under different names and have not caused any illness.

They urge the Government to find a substitute for nitrate and nitrite instead of reducing the amounts.

(6) *Virginia Citizens Consumer Council, Springfield, Va.*

Member of Conference of Consumer Organizations, Consumer Federation of America and National Consumers League.

They support the proposal to allow nitrite-free products to be marketed under traditional names as long as they are labeled with special storage and handling requirements. The apparent safety of products already on the market shows that the public will handle them carefully. They support the ban on infant foods and hope the industry will move to further limit the use of nitrates and nitrites itself.

In addition to comments from consumer groups, we received from individuals identified as consumers:

24 favoring the use of nitrites.

155 favoring banning of nitrites.

112 favoring the proposal for low and non-nitrited traditionally named foods.

Mr. HAGEDORN. I yield my time to Mr. Jeffords.

Mr. JEFFORDS. Thank you. I have a couple of questions.

One which is of concern to me is this. I know, Ms. Foreman, that certainly in the dairy area you have a bias against cholesterol and have been promoting diets without dairy products, substituting margarine for butter. Now I come across a couple statements in the nitrite area which give me concern. I would like you to comment on them.

It has been reported that at a recent USDA news conference you indicated that the Federal Government would no longer purchase meat products containing nitrites. I wonder if that was accurately reported to us.

Ms. FOREMAN. Sir, I would like to go back to the first part of your statement. I do not believe that I have ever advocated a cholesterol-free diet. There is no record of my having ever done so because I just simply would not agree with such a statement.

Mr. JEFFORDS. Maybe that was an overstatement, but you recommended a substantial lowering of dairy products in the diet.

Ms. FOREMAN. I do not believe that I have ever suggested a substantial lowering of dairy products. If you can present me with statements to that effect that I have made, then I would certainly be surprised.

Mr. JEFFORDS. We will do that.

Ms. FOREMAN. I have never toured a District of Columbia school lunch facility, I would also like to point out.

At a recent press conference with the Secretary of Agriculture on commodities used in the school lunch program the question was asked as to whether or not the Federal Government purchased processed meat products that have nitrite in them for use in the school lunch program. My answer was, no, we have never purchased such products through the commodity purchase program. We do purchase a great deal of dairy products, of course.

Local school districts do purchase processed meat products. The Federal Government has never attempted to prohibit the use of products purchased by individual school districts unless those products were declared to be unsafe for some general reason accepted under the law. I cannot imagine that we would take any action to initiate that kind of action we have never taken before. I am sure that local school districts will continue to purchase these products.

Mr. ROSE. The gentleman's time has expired. Mr. Volkmer?

Mr. VOLKMER. I have several questions. I would first like to ask Dr. Kennedy a question following up Mr. Mathis' question.

Will you or will you not use the MIT study as the sole basis for regulation prohibiting nitrite at this time?

Dr. KENNEDY. We will begin to propose Federal Register notices based on the MIT study; that is correct.

Mr. VOLKMER. Right now, the Delaney amendment only says food additives. What if we said food and food additives?

Dr. KENNEDY. If Congress said what, exactly, Mr. Volkmer? I am sorry.

Mr. VOLKMER. Any detectable cause of carcinogenic—food or food additives. Where are we then?

Dr. KENNEDY. We would find ourselves doing without a very large fraction of the food supply, Mr. Volkmer. As you know, corn, peanuts, and several others are contaminated with aflatoxin unavoidably. There are some poisonous, deleterious substances that unavoidably become part of the tissue, for example, of fish caught in lakes or the ocean. If we had a zero tolerance for everything, they would have to be eliminated as well.

Mr. VOLKMER. If we ignored threshhold and said there is no threshhold, we could hardly eat anything, could we, or very little?

Dr. KENNEDY. I do not think that is quite true but I think we would have to do without considerable portions of the food supply. Fortunately, Congress was wise enough to restrict its prohibitions to deliberate food additives.

Mr. VOLKMER. Anything I eat is deliberate.

Dr. KENNEDY. Congress addressed its rules to the people who put them into the food, not the people who put the food in themselves. [Laughter.]

Mr. VOLKMER. Ms. Foreman, I believe you testified to this but I did not hear it all. What is the detectable level at this time on nitrites?

Ms. FOREMAN. It varies according to products in which it is used, sir.

Mr. VOLKMER. I mean in the scientific community. It is about one part per what—thousand or billion?

Ms. FOREMAN. I am sorry, but I don't understand the question.

Mr. VOLKMER. Detectable nitrosamines—does anybody know?

Ms. FOREMAN. "The detectable level," is that the question?

Mr. VOLKMER. Yes.

Ms. FOREMAN. Five parts per billion.

Mr. VOLKMER. Five parts per billion.

What if that went to 1 part per billion? Would you go down to that level, also?

Ms. FOREMAN. I think that we would probably have to find some way to cope with that, yes, sir.

Mr. VOLKMER. What about 1 part per trillion?

Ms. FOREMAN. Perhaps.

Mr. VOLKMER. Without even worrying about what it actually does?

Ms. FOREMAN. No. I think that Dr. Kennedy has pointed out that there may come a point at which you then have to change your concerns. There might come a point when Congress might want to alter the law, but the law doesn't——

Mr. VOLKMER. That is where we are now. When we started on the Delaney amendment we were not where we are now in the scientific community in detection, either, were we?

Ms. FOREMAN. Certainly not.

Mr. VOLKMER. Is that correct, Dr. Kennedy?

Dr. KENNEDY. Absolutely. Absolutely.

Mr. VOLKMER. That is why we have to review Delaney. For those who say don't touch Delaney and don't review it, I think, are going to lead us down some very bad roads.

Dr. KENNEDY. Mr. Volkmer, I don't think most people are advocating that Congress never touch Delaney. I advocate that it be examined very, very carefully with the results of the Academy's study.

You have called attention to some troublesome problems that exist with our ability to detect substances at very low concentrations. On the other hand, the nitrosamines are very potent carcinogens, much more potent than nitrite by itself. I would not want hastily to adopt the idea that some amount of nitrosamines—say 10 parts per billion—is not to be worried about just because that sounds like a small number.

Mr. VOLKMER. I will go back to my peanuts, vegetables, and everything else then, too. I will ask you then: Shouldn't the scientific community start examining those things to determine whether those things can cause cancer or other organic deficiencies just as much as additives?

Dr. KENNEDY. The scientific community certainly should examine them because I think we want to find ways of eating more wisely and in more health-promoting ways. However, I am not sure that Congress would ever want to consider regulating the natural constituents of food in the same way that it regulates purposeful food additives. I think that Congress was wise in 1958 to make that distinction.

Mr. VOLKMER. The Congress will have to make that determination.

Dr. KENNEDY. Yes.

Mr. VOLKMER. I would like to ask the last question of Ms. Foreman.

Have the same rules that apply to bacon and in the future to other meats, poultry or whatever, also applied to all foreign imports?

Ms. FOREMAN. Yes, sir.

Mr. VOLKMER. What action have you taken so far with companies that are now bringing food into this country, especially bacon?

Ms. FOREMAN. To my knowledge, none of them are represented on the industry-government committee. Perhaps they should be.

Mr. VOLKMER. Have they been advised?

Ms. FOREMAN. Oh, yes. Our assumption is that people who export to the United States are aware of our rules and regulations regarding acceptable safety and quality levels for meat products. They have to meet exactly the same ones. It is my presumption that they are aware of the fact now of 120 parts per million. I am not aware that we import any bacon. We do not seem to import any bacon into the country. We do import some canned hams.

Mr. VOLKMER. We don't import canned bacon into the country? I have bought it a couple of times and have taken it camping. I don't know where it came from I think it was Denmark.

Ms. FOREMAN. Small amounts of canned bacon will have to meet the same requirements as any domestically produced bacon when the final regulations are made.

Mr. VOLKMER. All products will?

Ms. FOREMAN. All products.

Mr. VOLKMER. As you know, some time ago we had another hearing with the food policy people. I asked a question about heptachlor in

use in Mexico and whether they had studied that as far as beef coming in from Mexico. I have never received an answer.

Ms. FOREMAN. We do a substantial amount of residue testing on imported meat.

Mr. VOLKMER. I asked to be supplied the information and never did get it.

Ms. FOREMAN. Sir, I am very sorry. I was not aware of that. I will make sure that it is supplied.

Mr. VOLKMER. Thank you.

Mr. ROSE. Congressman Wampler?

Mr. WAMPLER. Thank you, Mr. Chairman. I have one more question.

I want to be fair about this. Any bias I have I want it to be directed at each of you equally.

You both have testified that the Newberne study that was conducted at MIT is the legal basis on which you are proposing this regulatory action; is that correct? Do you agree with that? That is the scientific study on which you are predicating this action; is that correct?

Dr. KENNEDY. That is correct.

Mr. WAMPLER. Correct me if I am wrong on this because I am a layman and I am having trouble grasping a great deal of this. What we have in the Newberne study is a compilation of test data that has not thus far been independently, scientifically confirmed or validated, as you expressed that, Dr. Kennedy, in the normal scientific process. Is that a correct statement?

Dr. KENNEDY. Not quite. It has been reviewed internally by FDA scientists. It is being reviewed by an interagency group and in other parts of the Government. However, it has not had the kind of external scientific peer review that is associated with——

Mr. WAMPLER. Peer review was my next question because, in the normal use of the term, "peer review" is what you want in order to really remove any doubt about the validity of test data and the conclusions drawn from it; is that correct?

Dr. KENNEDY. For scientific purposes, yes.

Mr. WAMPLER. To the extent that the Newberne study will be subjected to independent, scientific review, confirmation, or validation by those outside of the bureaucracy, and if that study in effect cannot be substantiated, then would you be in a position to change your mind on using that data as the basis for your regulatory action?

Dr. KENNEDY. Absolutely, Mr. Wampler. We don't want to base Federal regulatory action on defective scientific data or conclusions. If we miss something and it is pointed out to us convincingly by external critics, I will be eating some crow and we will be withdrawing our action.

Mr. WAMPLER. Ms. Foreman, would you comment on that?

Ms. FOREMAN. I think Dr. Kennedy said it very well.

Mr. WAMPLER. I would like to yield to Mr. Jeffords.

Mr. JEFFORDS. I have one additional question, Ms. Foreman, to clear up the record. I am trying to get rid of all the rumors that are running around here.

There is another one that is going around that you either have or about to issue a directive to the USDA not to purchase any meat products containing sodium nitrite. I wonder if you would comment on that.

Ms. FOREMAN. Will you repeat the question?

Mr. JEFFORDS. It has been brought to our attention, at least some people feel, that you either have or are about to issue a directive to the USDA that they will no longer purchase any meat products containing sodium nitrite.

Ms. FOREMAN. I am sorry, I thought I answered that, sir. The only purchase that I am involved with are those purchases in the commodity distribution program for the school lunch and school breakfast programs.

Mr. JEFFORDS. What about other Federal purchases, such as the military installations or other Federal agencies?

Ms. FOREMAN. We don't purchase and I have no authority over that.

Mr. JEFFORDS. Have you made any recommendations to them not to purchase?

Ms. FOREMAN. Of course not.

Mr. JEFFORDS. Thank you.

Mr. ROSE. Mr. Grassley?

Mr. GRASSLEY. Thank you, Mr. Chairman.

First of all, I would like to ask unanimous consent to have incorporated in the record an analysis of the Newberne study by some scientists at Iowa State University that I have had copies of since about 2 weeks ago. I would like to have that submitted for the record, along with a copy of a letter from Dr. Lee Kolmer, dean of the school of agriculture.

Mr. ROSE. Would the gentleman yield?

Mr. GRASSLEY. Yes.

Mr. ROSE. Is that the study that was requested by Congressmen Grassley and Bedell?

Mr. GRASSLEY. Yes.

Mr. ROSE. We have a copy of the report and of the letter that were submitted by Congressmen Grassley and Bedell. Without objection, it will be a part of the record.

Mr. GRASSLEY. Thank you very much.

[The material referred to above follows:]

IOWA STATE UNIVERSITY
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Ames, Iowa ~~50010~~ 50011

COLLEGE OF AGRICULTURE
EXPERIMENT STATION - EXTENSION SERVICE

September 13, 1978

Honorable Charles Grassley and
Honorable Berkley Bedell
House of Representatives
Washington, D. C.

Dear Congressmen:

Several weeks ago each of you requested that Iowa State University scientists examine and assess the methodology and findings of the MIT report "Dietary Nitrite in the Rat." A team of ISU scientists has evaluated the report and the report is attached to this summary letter.

The MIT report "Dietary Nitrite in the Rat" as released by the FDA and USDA includes experimental data and interpretations made by the principal investigator. Methodologies, however, are incomplete and therefore, the report was difficult to evaluate on a scientific basis.

The report is not written in the format that might be expected of a paper submitted for scientific review and was probably not written with that intent since it is a report under an FDA contract. Additional information on methodology and pertinent literature were probably included with the contract proposal and, if that was the case, those sections of the proposal should have been included with the report for scientific comment. In spite of these problems, the Iowa State University evaluation committee had the following comments regarding the MIT report.

Despite several points of concern about methods which cannot be resolved from the report alone, a point that may be derived is that the data show evidence for increasing lymphomas in rats with increased dietary nitrite. However, the principal investigator expresses caution by describing the results as being "suggestive" and "somewhat less than convincing."

The mechanism involved in the increase of lymphomas is not clear and we do not agree with the FDA-USDA conclusion on page one of their statement that "the mechanism is clearly distinct from that of nitrosamines." The report itself makes no such conclusion and no nitrosamine analyses were included to remove the possibility of nitrosamine formation. This is a major error in the interpretation of the results by FDA-USDA. The mechanism involved in increased tumorigensis is, however, extremely important. The protection of public health requires knowledge of this mechanism in view of the large contribution of naturally occurring nitrate to the human diet and the relative ease of nitrate conversion to nitrite in the human body. Recent reports (Council for Agricultural Science and Technology Comments - August 1, 1978) indicate that only about 2% of human exposure to nitrite is derived from cured food; thus it is impossible to remove more than a minor amount from the diet by elimination of nitrite as a food additive.

While the trend for increasing lymphomas with increasing dietary nitrite is present, the degree of statistical certainty the author expresses in the results is overstated due to the inappropriate statistical methods used. The experimental unit is incorrectly identified as an individual rat rather than the pregnant females. Furthermore, there are apparent statistical complications in the randomization of the animals and in the housing of the treatment groups. Rats born and shipped at different times were assigned to a subset of the treatments (not to all treatment groups), thus confounding treatments and shipment time. In addition, there are indications that treatment groups were isolated in separate locations (as evidenced by spread of disease within some groups) which confounds environmental influences with treatments. If this interpretation of the randomization scheme is correct, one must be cautious in assigning the effect to the proper causation factors.

It should be strongly emphasized that this report does not clearly establish carcinogenic activity by nitrite itself. The data merit attention but it is essential that this work first be carefully repeated. Such a study should investigate the mechanism involved since it may be extremely important in formulating recommendations for the reduction of any potential hazard. As an example, if a nitrosamine mechanism was involved, then dietary ascorbate might be effective in eliminating or reducing the suggested carcinogenicity of dietary nitrite. This approach is being taken in the current regulation for the use of ascorbate with lowered levels of nitrite in bacon (Federal Register 43(143):32136, July, 1978).

We hope the attached report will be useful to you and your colleagues in your further discussions of this important issue.

Sincerely yours,

Lee Kolmer

Lee Kolmer
Dean

LK:f
cc Senators John C. Culver
Dick Clark

Representatives
Michael Blouin
Tom Harkin
James Leach
Neal Smith

House of Representatives Agriculture Committee Members

Report by the Iowa State University Committee for Evaluation of "Dietary Nitrite in the Rat" as released by FDA-USDA, August 11, 1978

Chairman: Joseph G. Sebranek, Depts. of Animal Science and Food Technology

Jacqueline Dupont, Dept. of Food and Nutrition

John Hathcock, Dept. of Food and Nutrition

Donald Hotchkiss, Dept. of Statistics

Allen Kraft, Depts. of Food Technology and Bacteriology

David G. Topel, Depts. of Animal Science and Food Technology

Homer Walker, Depts. of Food Technology and Bacteriology

Due to the nature of public reaction to the August 11 joint FDA-USDA statement released with the MIT study, a need exists for sound scientific evaluation and comment on the work. Furthermore, since the FDA-USDA is currently assessing "several options" (FDA-USDA joint statement, August 11, 1978) to provide "maximum public protection," it seems appropriate to comment on regulatory action in light of a careful evaluation of the MIT report.

First of all, a review of the joint FDA-USDA statement itself requires comment. On page one, the statement concludes that the mechanism of suggested nitrite-caused tumors is "clearly distinct from that of nitrosamines." No evidence is available to support this statement since the MIT study did not include any nitrosamine analyses of feed components or stomach contents of the experimental rats. It is well known that nitrosamines are most readily formed in acid conditions as would occur in the stomach (Mirvish, S. S. 1975. Formation of N-nitroso compounds. Chemistry, kinetics and in vivo occurrence. Toxicol. Appl. Pharmacol. 31:325-351). Nitrosation of food components

(secondary amines from protein) in the stomach by nitrite from feed or water could have occurred. The lack of tumors known to be characteristic of some nitrosamines is insufficient evidence to conclude that no nitrosamines were present. Analytical data should have been developed to support or refute this point.

The principal investigator interprets a plateau in the dose-response curve (nitrite-lymphoma) at 1000 ppm as being consistent with a promoting effect (page 13). This plateau was not established statistically yet probably led to the questionable FDA-USDA interpretation of the mechanism being different from that of nitrosamines since the nitrosamines would give a continuous dose-response curve without a plateau.

Neither the author nor the FDA-USDA have pointed out that the data can also be interpreted as consistent with a nitrosamine mechanism. It is plausible that in this test of nitrite "alone," a plateau in the dose-response curve could indicate only that endogenous secondary amines or other similar compounds were more limiting than nitrite in the production of nitroso compounds such as the nitrosamines. A plateau in the dose-response curve for nitrite could be caused by exhaustion of a particular reactant by the 1000 ppm dietary nitrite.

The second point in the FDA-USDA statement that requires comment is also on page one in which 20% of the human dietary nitrite exposure is attributed to cured food. Recent reports (Council for Agricultural Science and Technology Comments - August 1, 1978) show that dietary exposure from cured food is more on the order of 2% of the total. The major source of nitrite is derived from microbiological conversion of various nitrogenous substances to nitrate and nitrite in the intestine. A second source is dietary nitrate (vegetables, etc.) that is converted to nitrite in the saliva. The third source of dietary nitrite

is from cured foods and represents much less nitrite than either of the other two. In addition, the portion of dietary nitrite from cured foods is being reduced (Federal Register 43(143):32136, July 25, 1978 - Use of 550 ppm sodium ascorbate required with 120 ppm sodium nitrite for bacon) and other protective mechanisms such as the use of ascorbate supplementation is being implemented. Therefore, human exposure to nitrite from cured food is slight and elimination of this source would remove a very small portion of the total nitrite (nitrate) from the diet.

The initial reaction of the evaluation committee to the MIT study is that the report itself is not written in the format that might be expected of a paper submitted for scientific review. For example, there is no literature review which might have included specific previous work which has suggested no nitrite-related tumor production during chronic feeding of nitrite. Methods of handling animals and animal diets are rather vaguely described and there are some discrepancies between information discussed in the manuscript and that summarized in the tables. This contract report was probably not intended for scientific review by itself. Literature citations, as well as specific descriptions of methodology, were probably included in the contract proposal. If this is the case, it would have been very helpful to have included those sections of the contract proposal with the final report for scientific comment.

The specific concerns that arise from review of the report are as follows:

1) There is some confounding of treatment groups in the handling of animals. In one instance, treatment groups are confounded with starting times of the experiment (page 4). Rats were assigned to treatment groups such that any one shipment of rats was utilized for only 4 of the 18 treatment groups. It might have been better to avoid such confounding and assign eight pregnant females from

each shipment to each of the 18 treatment groups. In another instance, there is a suggestion of confounding with location. On page 7 and 8, the "illness" experienced by group 13 suggests an isolation from other groups. Likewise, the "infection" of group 1 females (p. 8, section B) is further suggestion of group isolation. If isolation of groups were necessary, it would have been advisable to distribute rats from each of the 18 treatment groups among all locations.

2) The experimental unit used in this study should be the pregnant female rat. The investigator has treated the individual rat (the offspring) as the experimental unit thus indicating that about 135 experimental units were present for each group (treatment). The report, however, states that each dam was fed the experimental diet during pregnancy, which would make the 34 litters the experimental units for any one treatment. Furthermore, if the offspring were housed and fed in pens (not individually), the pen of rats would be the experimental unit. The proper statistical analysis would be made using the transformed fraction of animals exhibiting tumors in each pen. Identifying the proper experimental unit will not deny the trends that are displayed in the data, but will change the probability level associated with the declared level of significance.

3) The diets described do not include any indication of when or how often nitrite was added to the formulations. Table 12A documents the well known nitrite instability in both feed and water. The time lapse between formulation and consumption then becomes a concern. There is the possibility, particularly at high nitrite concentrations, of detectable nitrosamine formation in the feed before consumption. This was found to be the case in nitrite-spice premixes where nitrite

concentrations were relatively high (N. P. Sen, et al., 1974. Effect of additives on the formation of nitrosamines in meat curing mixtures containing spices and nitrite. J. Agr. Food Chem. 22:1125). Consequently, the lack of nitrosamine analyses decreases the scientific value of the data.

4) Nitrite or nitrate concentrations in the drinking water before any additional amounts were added is another point that is not addressed in the report. Water very often contains some nitrate but there is no indication, in this case, of whether or not the water source was examined for nitrate or nitrite content.

5) There is a decreased survival of treatment groups on a powdered casein diet (groups 13 and 14) both with and without nitrite (page 7). Thus, there is some outside influence affecting these groups that is not clear. The report does not suggest any possible causes for this differential response.

6) There are some discrepancies between the discussion in the manuscript and the summary data tables. On page 11, the percentage of lymphomas is declared statistically significant for group 16 when compared to control (group 15). This cannot be duplicated from table 9 using the chi square statistic at $P \leq .05$. Further discrepancies in table 9 includes the total incidence of tumors summed across sites and sexes combined for group 13 where the tabular data indicate a total of 13 and not 12 as reported. Also in table 9, summing over the "control" groups gives a total of 46 (or 45 if the group 13 total is taken as 12) instead of 48 as reported on page 11. Finally, table 4 reports the median age of death for each group which is not in agreement with the 50% survival time reported on page 7.

7) The term "lymphoma" is used in the report to describe all tumors in table 9. This term is defined by Dorland's Illustrated Medical Dictionary as "a general term applied to any neoplastic disorder of lymphoid tissue," and does not distinguish between malignant and benign lymphomas. It is also pointed out in Dorland's dictionary that benign lymphoma is rare, thus, presumably the term "lymphoma" is being used in the report to denote malignant lymphoma. This should be made clear in a report that is released to the public especially since tumors in other organs are discussed as malignant or benign.

8) The choice of nitrite levels was determined when the objectives of the study were established. However, nitrite levels actually ingested by the human from cured food do not approach the lowest level of supplemental nitrite used in this experiment. Consequently, any estimation of potential risk from cured food, if it does exist, requires extrapolation from high dosage to low dosage and proper interpretation of such an extrapolation. Toxicological studies with food additives commonly utilize high doses which are necessary for statistical evaluation to increase "the power of the test" with relatively small groups of animals. This allows researchers to involve a manageable number of animals (at low doses the required animals might number a million or more) but may produce problems not accounted for in the test (Kraybill, H. R. 1978. Proper perspectives in extrapolation of experimental carcinogenesis data to humans. Food Technology 32(8): 62-64).

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Despite the difficulties in evaluation caused by the nature of the report as discussed above, there are trends in the data for increasing lymphoma with increasing dietary nitrite although these trends are not consistent in all groups nor are they consistent with dosage level (dose-response).

It is extremely important in view of the lack of a clear dose-response relationship that this work be very carefully repeated before any precipitous action is taken. This is especially true when one considers the author's own statements which include "While the results do not permit assigning nitrite a proximate carcinogenic role," "Despite the somewhat less than convincing case that nitrite is lymphogenic," "the data are only suggestive" and "the biological significance of nitrite associated lesions of the lymphoreticular system is unclear."

Many considerations must become a part of any final decision on the use of nitrite for curing food. It must be established that nitrite itself is a carcinogen and is not nitrosating some component of the rat diet to form a nitrosamine. This possibility increases with increased nitrite concentrations and could be overcome by low levels of nitrite combined with ascorbate.* Benefits of nitrite usage (anti-botulinal effects and others) must be balanced against whatever risks are determined to be present in the final analysis.

It is imperative that the regulatory agencies base their decisions on unequivocal, sound, repeatable scientific information. Decisions, hastily made, will confound, not resolve, the issue of nitrite as a curing agent.

* Regulations have been established to control nitrosamines in some products. Federal Register 43(143):32136, July 25, 1978.

Mr. GRASSLEY. Following up where Mr. Wampler left off, on three or four occasions before in this meeting you have been pretty emphatic about the Newberne study being the basis for the administrative action that both Departments are taking on the banning of nitrites.

The last paragraph of the Newberne study says:

> While these observations require some consideration, the data are only suggestive and the biological significance of nitrite-associated lesions of the lymph system is unclear.

Based on statements like that and also comments regarding the Newberne study by the people at Iowa State University, just what sort of basis for a ban is that? It seems to me like it runs totally contrary to the whole direction that we have prided ourselves on in the university community of seeking the most definitive, scientific, scholarly research almost beyond question before we would take actions. We have not even reached the point where we would even say that it ought to be unquestioned because the author himself is raising the question.

Dr. KENNEDY. Mr. Grassley, the author himself raised those questions in a portion of his contract report to us in which he discusses the results. It is common in scientific papers for authors in the discussion section, as opposed to the section in which they present their results, to discuss the biological significance of those results in cautious fashion.

The fact of the matter is that, if you do the statistical comparisons between treated and untreated animals in his study and you do the aggregated statistics and you analyze those statistics also for the groups in which you add immunoblastic cell lesions to the lymphomas, most of the groups reach significance by themselves. The aggregate group reaches significance by itself.

In other words, the basis for regulatory action depends upon the results and not the author's interpretation of them. The author is properly cautious. We think the results speak for themselves. We think that, unless some very significant and at the moment unknown challenge to the way in which the study was conducted, to the statistical evaluation of the results, or to the author's reading of the slide arises, then we would under the law be obliged to take the action that we are beginning proposals on, in our view.

Mr. GRASSLEY. Don't you have leeway in your administrative decisionmaking to wait until more information is in?

Dr. KENNEDY. The information will be coming in as the external scientific community evaluates that study. What we are talking about here, as Ms. Foreman tried to make clear, is the initiative of a process that cannot possibly reach finality in less than 12 to 15 months. We are working to put together the proposals while that scientific review takes place.

Mr. GRASSLEY. My question is: Can't you wait before that administrative procedure is instituted until you get some more information?

Dr. KENNEDY. I do not believe (a) that it would be wise or (b) that I have that leeway. If I had it, I think it would not be appropriate to use it because the study as it stands creates a sufficiently strong presumption of risk for us to initiate the steps that we must take.

Mr. GRASSLEY. You are saying what the author says about his own study is not of significance?

Dr. KENNEDY. No, I am not. We have asked him for clarification and he has given us further clarification. That clarification is on the public record. If you would like to hear it, I would be happy to read it into the record of this hearing as well. May I do so?

Mr. GRASSLEY. Yes.

Dr KENNEDY. He says to us in a letter of August 25 in which we asked him to explain that reservation and the one he made in some statements in the press:

> It is my view that the positive results of the earlier as well as the more recent MIT studies justify a phase in of a ban on the addition of nitrite to food products, particularly where it is not needed to prevent botulism. The strongly suggestive nature of the results of the recent MIT study and the established role of nitrite in the formation of nitrosamines, in my view, leaves no responsible alternative except to attempt to substantially reduce nitrite as a food additive or, if feasible, to eventually eliminate it entirely.

That quote is not complete. A sentence has been left out of the middle. We will supply the complete statement for the record.

Mr. ROSE. The record will be held open at this point to receive that.

[The material submitted follows:]

MASSACHUSETTS INSTITUTE OF TECHNOLOGY,
Cambridge, Mass., August 25, 1978.

DONALD KENNEDY, PH. D.,
Commissioner, Food and Drug Administration,
Rockville, Md.

DEAR DOCTOR KENNEDY: Recent reports in the news media have either misquoted me or have misinterpreted my comments regarding the results of the nitrite study conducted at M.I.T. under contract to FDA. This letter is to reconfirm that I am in agreement with the spirit of the reasoned and rational statement issued jointly by FDA and USDA on August 11 relative to the results of the study.

It is my view that the positive results of the earlier as well as the more recent M.I.T. studies justify a gradual phase-in of a ban on the addition of nitrite to food products, particularly where it is not needed to prevent botulism. This course of action should however take into account the need not only to safeguard the public from botulism but to minimize disruption of food production and distribution systems while industry and the public adjusts to the nitrite ban. The strongly suggestive nature of the results of the recent M.I.T. study, and the established role of nitrite in the formation of nitrosamines in my view leaves no responsible alternative except to attempt to substantially reduce nitrite as a food additive or, if feasible to eventually eliminate it entirely.

The initiation of a phase-in of a ban on nitrite need not in my opinion await results of further animal studies. Additional studies in other strains of rats and in other species should however be done concomitant to and in parallel with a ban phase-in.

The results of the M.I.T. studies, as I pointed out in the text of the report, clearly show that lymphoreticular tumors are increased in all groups of animals exposed to nitrite. While the incidence was not sharply increased, the fact that it was increased and that there was a trend in all treated groups causes concern.

The statements referred to by the press about "the somewhat less than compelling case that nitrite is lymphomagenic in Sprague-Dawley rats" and "while these observations require some consideration the data are only suggestive" are the usual cautionary notes and reflects the scientific conservatism of many of us in academia.

A detailed report of the study is in prepartion for submission to a scholarly journal for publication. I hope that these comments help clarify my position on the results of the study. If you have further question please bring them to my attention.

Sincerely,

PAUL M. NEWBERNE,
Professor of Nutritional Pathology.

Dr. KENNEDY. My point is only that both here and in what he has to say in the discussion of his study he is going beyond the results to make some statements about their significance. It is the statistics and the data that we have to look at.

Mr. GRASSLEY. I hope you will take into consideration the look that the committee at Iowa State University gave to these studies. In the closing paragraph of Dean Lee Kolmer's letter to me he says, in the first sentence of that paragraph:

> It should be strongly emphasized that this report does not clearly establish carcinogenic activity by nitrite itself. The data merit attention but it is essential that this work first be carefully repeated.

Is there going to be any effort to repeat this?

Dr. KENNEDY. Not pending a regulatory action because such lifetime chronic feeding studies take 3 years. There is no requirement in law, and indeed the courts have repeatedly ruled that repetitions of studies are not necessary in order to take regulatory action to protect the public health. Had Congress written the requirement that every result be confirmed before it is made the subject of regulatory action, it would have done so. However, Congress did not, and the courts have repeatedly ruled that a single study adequately reviewed and adequately convincing is an aprropriate basis for regulatory action to protect the public health.

Mr. GRASSLEY. I yield to Mr. Wampler.

Mr. WAMPLER. I am interested in the latter statement you made. You said "adequately reviewed," and what were your other words now? You said "adequately" what?

Dr. KENNEDY. The reporter will have to read back because I don't remember.

Mr. WAMPLER. You clearly expressed that it had to be validated, isn't that correct? It has to be independently reviewed and validated; is that what you said?

Dr. KENNEDY. No, I did not say "independently." We have a place in the form of the interagency committee an adequate review mechanism. Of course, there will be other public comments that we will look at. That is part of notice-and-comment rulemaking.

Mr. WAMPLER. The point I am making is that there is probably some court of law that is ultimately going to have to decide whether you acted properly and within the framework of the law. I think the real test here is whether or not the Newberne study and the test data revealed therein has been sufficiently, thoroughly, independently reviewed and validated; otherwise, as I understand it, you are not on legal, sound ground in implementing this action. Is that a correct statement?

Dr. KENNEDY. I think that if serious and unanswered scientific challenges to the study had been made and ignored at the time our final regulations were promulgated, we would be very vulnerable to a lawsuit; yes, sir.

Mr. WAMPLER. That is the point.

I thank the gentleman for yielding.

Mr. GRASSLEY. On the point of your discussion with Congressman Mathis on the difference between the banning of nitrites as op-

posed to the problem of nitrosamines, the Iowa State University study says in regard to that:

On page 1, the statement—meaning the statement of Newberne—

> Concludes that the mechanism of suggested nitrite-caused tumors is "clearly distinct from that of nitrosamines." No evidence is available to support this statement since the MIT study did not include any nitrosamine analyses of feed components or stomach contents of the experimental rats. It is well known that nitrosamines are most readily formed in acid conditions as would occur in the stomach.

Then there is a reference there.

> Nitrosation of food components in the stomach by nitrite from feed or water could have occurred. The lack of tumors known to be characteristic of some nitrosamines is insufficient evidence to conclude that no nitrosamines were present. Analytical data should have been developed to support or refute this point.

I only say that to supplement and I guess to contradict to some extent what you told Congressman Mathis, if in fact I interpreted what you told him correctly.

Mr. ROSE. The gentleman's time has expired. Mr. Jeffords?

Mr. JEFFORDS. I just have a personal message that I want delivered to Ms. Foreman.

Our good Senator Aiken, whom you may remember, was a great defender of the dairy industry. I just talked to him the other day on the telephone. He is now 88 years old and had just come back from his physical.

He said:

> When you get the first opportunity down there, you tell them that I eat all the eggs and butter I can and I still eat all the bacon that is possible. I just came back from my physical and, not only did they find that I was within tolerance on cholesterol, they couldn't find any cholesterol in my blood. The first opportunity you get to bring that message back, you tell them all that cholesterol stuff is bunk.

I am just delivering that on behalf of the good Senator. I hope you will take that back with you.

Thank you very much, Mr. Chairman.

Ms. FOREMAN. I am sure that all of us would join in wishing Senator Aiken the longest possible life.

As a matter of fact, Congressman, I have been invited to make the Aiken lecture at the University of Vermont next spring. I certainly hope that he is still going to be there to greet me when I come. I was promised that he would be.

Mr. JEFFORDS. I believe he will. He is doing fantastically well. I know everyone is happy to hear that. He is going around lecturing and doing everything, just like he always did. He is a great man.

Dr. KENNEDY. Since we are pronouncing benedictions, Mr. Jeffords, you could do him a tremendous favor by inviting him to visit another doctor because, if they can't find any cholesterol in his blood, he's in trouble. [Laughter.]

Mr. ROSE. Thank you both for being present today. We may have some questions that we will submit for the record. We will excuse you both now.

We would like to hope that some people at FDA and USDA are studying why people are healthy and will help us to explore how we can use them as role models for making more healthy people, rather

than constantly looking at the cancer-causing agents, although that is a responsibility that we in Congress have certainly given them.

Our next witness is Dr. Steven Tannenbaum, professor of food chemistry, Massachusetts Institute of Technology, Cambridge, Mass.

Dr. Tannenbaum has a statement titled, "Relative Risk Assessment of Various Sources of Nitrite."

Dr. Tannenbaum, we are already an hour over our time limit for the hearing. Therefore, may we take your statement for the record and ask you to discuss the high points of it with us and any other comments that you might like to make in reaction to what has been said or asked here today?

Dr. TANNENBAUM. I would be happy to do that, Mr. Chairman.

[The prepared statement submitted by Dr. Tannebaum follows:]

RELATIVE RISK ASSESSMENT OF VARIOUS SOURCES OF NITRITE

Steven R. Tannenbaum
Professor of Food Chemistry

Department of Nutrition and Food Science
Massachusetts Institute of Technology
Cambridge, MA 02139

SUMMARY AND CONCLUSIONS

Nitrites are thought to pose a health hazard by virtue of their ability to form nitroso-carcinogens, and the argument has been made that their discontinued use as food preservatives would greatly reduce or eliminate this risk. This is an admirable goal but, on the basis of current knowledge, an unattainable one, since evidence is accumulating that sources of nitrite other than that ingested in cured foods make much larger contributions to the total body burden. These additional sources of nitrite, which are natural in the normal healthy person, include saliva and the contents of the intestines.

It is difficult to make accurate estimates of total daily nitrite exposure from the body's natural processes, but magnitude estimations are feasible for the stomach compartment and for the intestinal compartment. Thus, about 10 times more nitrite enters the stomach daily from reduction of nitrate in saliva than from nitrite in cured meats; probably thousands of times more nitrite is formed in the intestine than is contributed to the intestine from pre-formed nitrite in the diet.

An average approximate balance sheet for total daily exposure of an adult is:

Source	mg/day	%
food additive nitrite	3	3
salivary nitrite	15 (10- 20)	15
intestinal nitrite	90 (65-100)	82

This balance does not take into consideration several other known sources which cannot be quantitatively estimated:

cigarette smoke and polluted air
dehydrated foods
refrigerated fresh vegetables
industrial and agricultural products
infections in stomach or bladder

Furthermore, mitigation of the influence of dietary nitrite on gastric synthesis of N-nitroso compounds may result from the concomitant presence in the stomach of components of food which block nitrosation, such as ascorbic acid. Exacerbation of the effects of salivary nitrite may occur when it enters into an empty stomach lacking blocking agents such as ascorbic acid.

The effects of dietary nitrite on the blood would be trivial compared to intestinally-formed nitrite, because of the much greater exposure to intestinal nitrite and because dietary nitrite is mostly decomposed in the stomach. In addition, intestinal nitrite has now been shown to contribute to the daily exposure to N-nitroso compounds.

Recent measurements on human blood indicate the presence of volatile nitrosamines at levels of 0.1 to 1 ppb. Based upon the nitrosamine levels in blood and feces, I have estimated the total daily exposure to dimethylnitrosamine to be on the order of 500 to 5000 µg. This may be compared to recent estimates of consumption of pre-formed volatile nitrosamines in meat products in the UK as approximately 0.5 µg per day, the exposure to dimethylnitrosamine from consumption of 30 cigarettes to be approximately 0.6 µg per day, and unknown amounts of exposure to other nitrosamines in cosmetics and in the workplace.

In conclusion, the risk that could arise from the use of nitrite according to present and proposed USDA regulations would be miniscule compared to those resulting from the body's natural processes. It should be possible to establish this as fact with further research on animals and man consuming cured meat products.

As a scientist faced with the discovery that man is exposed to large quantities of nitrite and N-nitroso compounds through entirely natural processes, I am mystified by the action of government officials who call for the ban of a valuable preservative which is a trivial addition to the natural burden. The moral and ethical issues are clear: we can be certain that if nitrite is precipitously removed deaths will result from botulism. On the other hand, the risk of cancer from nitrite in cured meat is vague and arguable.

How much more could be accomplished with a positive program of orientation of the population to consumption of a balanced and prudent diet than the negative approach of banning with no alternative? The amount of attention being accorded nitrite as a meat additive is out of proportion with its public health significance and is not in the best interest of the consumer.

INTRODUCTION

Man is exposed to nitrite through several different routes. It is the purpose of this document to place in perspective the relative contributions of the different forms of exposure in the formulation of an assessment of the importance of nitrites as possible health hazards.

A. SOURCES OF EXPOSURE

1. Pre-formed Nitrite

a. Food Additive: Meat, Cheese, Poultry

Nitrite is currently added to meat, cheese and poultry, but the major source of exposure is in its use in cured meat products. With a residual nitrite concentration of 10 to 30 ppm, the average daily intake of nitrite from meat products would be on the order of 3 mg for an adult.

b. Inadvertent Contamination

Nitrate is present in virtually all biological materials and an opportunity exists for enzymatic or bacterial reduction of nitrate to nitrite in almost any food product. It would be extremely difficult to estimate the intake from this source because it would be highly variable and dependent upon the method of processing and storage of the product. An extreme example is spinach, which when stored in the refrigerator may accumulate hundreds of parts per million of nitrite after only a few days time. Therefore, this form of exposure may be

significant under selected circumstances. A second source of inadvertent contamination occurs in certain types of dehydration processes, where air is heated directly by flame or combustion. In this case, the nitrogen oxides which are formed in the heated air may ultimately be deposited in the food substance as nitrite. This has been documented for foods such as milk or soybean protein preparations which have been dried in the aforementioned manner. This source of exposure is also difficult to estimate since it would be highly variable. Concentrations of tens of parts per million of nitrite have been detected in diverse dehydrated food products.

2. Salivary Nitrite

The existence of nitrite in saliva has been known for about 100 years, but this fact escaped all of the early reviews on N-nitroso compound formation. The nitrite in saliva arises from nitrate by bacterial reduction. The saliva entering the mouth via the salivary glands contains nitrate but not nitrite. The bacteria responsible for the process of reduction are bacteria which inhabit the oral cavity of all normal, healthy individuals. The amount of nitrite formed in saliva is related to the amount of nitrate which is introduced into the mouth via the salivary glands. This in turn depends upon the exposure of the individual to nitrate, which could come either directly from the food supply or indirectly by a process of endogenous synthesis. This process takes place in the intestine: it will be

discussed later in this paper. Nitrate ingested in food is cleared from the body via the kidney in 24 to 48 hours, depending upon dose. The maximum nitrate concentration in saliva occurs approximately three hours following the meal, and may reach hundreds or thousands of parts per million for an individual consuming large amounts of nitrate in the form, for example, of vegetable juices.

The calculation of the amount of exposure of an individual to salivary nitrite is commonly conducted using data which we published in the Journal of the National Cancer Institute in 1974. At the present time, I believe that a conservative estimate of the amount of nitrite from this source would be on the order to 10 to 20 mg per day. For some individuals, the total intake might be as low as 5 mg per day while, for other individuals who consume large amounts of nitrate-containing vegetables, the amount could be on the order of 100 mg per day.

In that study, saliva was collected in the morning, following breakfast but before the midday meal. In subsequent studies, we have followed the concentrations of nitrite and nitrate in saliva throughout the day for an individual. The results of these studies demonstrate that the concentration of nitrite in saliva is highly variable, ordinarily reaching its peak values sometime in the evening, several hours after the major meal of the day. Since our original data were collected

on morning saliva, and both the average total nitrite intake and its concentration and rate of flow of saliva vary as a function of time, it would be extremely difficult to make an accurate estimate of the total amount of nitrite formed for an individual in a single day. Also, the concentration of nitrite found in saliva may vary by a factor of ten between individuals for reasons which are currently unknown.

3. Intestinal Nitrite and Nitrate

In recent experiments, which have been published in part in Science in June of 1978, we have found that the amount of nitrate excreted in urine is far in excess of the amount of nitrate which is taken in in the diet. These studies were conducted on normal, healthy human volunteers who consumed only special diets, provided by our dieticians, over a period of one to two weeks in time. The quantities of nitrate formed in excess of intake are extremely large and on the average appear to be about 80-90 mg of nitrate per day. We have had individuals with nitrate excesses as low as 50 mg per day and others as high as 750 mg per day. At the present time, we do not understand the cause of the variability, and these studies have now been conducted on diets as diverse as those which contain no source of protein to those which contain either egg or soy or wheat as sources of protein. There do not seem to be any consistent differences as a function of source of protein in the diet.

We have traced this unaccounted nitrate in urine to normal metabolic processes which occur in the human intestine and lead to the formation of nitrite. Based upon studies on fecal samples from healthy individuals and on samples from individuals who had ileostomies, we have discovered that microorganisms in the gut are capable of synthesizing nitrite from compounds like ammonia or other forms of reduced nitrogen, and nitrite is found in most normal human feces. This nitrite may also react in the gut to form N-nitroso compounds; it may be converted by bacteria to nitrate which then appears in feces; or the nitrite may enter the blood via the enterohepatic circulation. Nitrite is very unstable in blood and it rapidly reacts with oxyhemoglobin to form methemoglobin, with the nitrite being converted to nitrate. Thus, most of the nitrite which is synthesized in the intestine ultimately winds up in the blood as nitrate. This nitrate is indistinguishable from nitrate that had been absorbed from food consumed during the day. Experimentally, one could attempt to distinguish between these two sources by the use of nitrogen isotopes, and this research is planned for the near future in our laboratory. The nitrate which is in the plasma is concentrated by the kidney and excreted in the urine, or it is concentrated by the salivary glands and secreted into the saliva where it continues the cycle of reduction to nitrite. Information from other parts of the world on nitrate in urine supports the results of our controlled

metabolic studies and suggest that the phenomenon of gastrointestinal nitrite synthesis is general in the human population.

4. Gastric Nitrite

Nitrite is generally found in the normal human stomach at concentrations of less than 1 ppm, contributed in part by the introduction of saliva into the stomach. There are, however, several conditions in which the human stomach can achieve nitrite concentrations of tens or even hundreds of parts per million. This occurs when the pH of the stomach, which is normally quite acid, rises to a point which will allow the growth of the type of bacteria which can reduce nitrate to nitrite. Under these conditions, the stomach becomes similar to the mouth and even contains similar types of bacteria. Several different conditions which lead to radical alteration of the gastric environment, which allow the growth of these kinds of bacteria, appear to be associated with greater than ordinary risk of gastric cancer. These are all serious pathological conditions and should not be considered in the overall determination of sources of exposure to the normal, healthy individual.

5. Other Sources

There are probably several other sources which should be taken into consideration under specific circumstances. The conversion of nitrate to nitrite may occur whenever there is a simultaneous occurrence of nitrate and bacteria. An important example is in the case of bladder infections, in which urinary nitrite is diagnostic of the infection.

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Smoking of tobacco introduces into the lungs a large amount of nitrogen oxides. These nitrogen oxides are trapped in the lungs and it is highly probable that some are converted to nitrite. There is insufficient information at present to evaluate the contribution of this source. There are also important sources of exposure due to the extensive use of nitrite in the industrial environment as an anti-corrosion agent. Again, although this source of exposure is probably general, it is not possible at the present time to estimate the contribution to the overall case.

B. ESTIMATION OF EXPOSURE

In estimating nitrite exposure, we must deal separately with nitrite which is introduced into or formed in the mouth and then enters the stomach, and with nitrite which is formed directly in the intestine, is converted to nitrate in blood, and which ultimately contributes to the amount of nitrite formed in saliva. In the upper GI compartment, we must balance the preformed nitrite entering the mouth against the nitrite which is formed in saliva as a result of reduction of nitrate. Although the source of nitrate may be either the food itself or a series of reactions which began in the intestine, the overall balance of relative exposure is strongly dependent upon the nature of the individual's diet. Thus, individuals eating largely vegetarian diets would most probably be exposed to large amounts of nitrite

as a result of their elevated nitrate intake. The extreme case of low nitrite exposure in the upper GI compartment involves the individual who eats low amounts of vegetables and uncured meat products. For the individual who eats a relatively balanced diet consuming both vegetables and cured and uncured meat products, the major source of nitrite is that formed in saliva, probably by an order of magnitude over preformed nitrite in food. In addition, we should take into consideration the conditions under which the nitrite reacts in the stomach in determining the overall risk from the different sources. This will be done in a subsequent section.

Let us next consider the nitrite formed in the lower GI compartment. The nitrite formed here is apparently greatly in excess of all other sources of nitrite to which the body is exposed (approximately 25 times greater than that from cured meat products). In addition, studies conducted many years ago demonstrated that nitrite introduced into the intestine is five to ten times more effective in forming methemoglobin than nitrite which is introduced directly into the mouth. Therefore, in estimating the relative significance of this exposure one must again consider the conditions under which it is introduced into the body.

C. CONSIDERATION OF RISK

In considering the relative risk of various sources of nitrite, we should consider the separate risks of conversion of

nitrite to carcinogenic N-nitroso compounds and of interaction of nitrite directly with the various internal organs.

1. Formation of N-nitroso Compounds

It is generally considered that acidic conditions yield the highest quantities of N-nitroso compounds, but this is a simplistic notion based upon studies in well-defined chemical systems. There are many factors which modify rates (e.g. thiocyanate) and yields and even the chemical nature and biological activity of the reaction products. As an example of the lack of necessity of acidic reaction conditions, nitrosamines have been shown to form in human saliva. Furthermore, significant concentrations of N-nitroso compounds are routinely found in human feces as a result of the nitrification process, and it is highly probable that this process is the source of the large flux of nitrosamines which have now been found in human blood. No comparable findings of N-nitroso compounds have been made in normal human gastric contents. If the putative N-nitroso compounds formed in human gastric contents were not detected thus far because they are unstable, or otherwise difficult to detect, an equal hypothetical statement could be made for other compartments such as the intestine. In both cases, the evidence is lacking.

In further considering the relative risk of nitrite from different sources entering the stomach, we should be cognizant of the extent to which dilution and competing reactions

mitigate the quantity of N-nitroso compounds which could be formed. Thus, food is mixed and diluted with saliva in the mouth, and further diluted with gastric juice in the stomach. Therefore, both salivary nitrite and nitrite preformed in food might be at only 25% or less of their original concentration at the time they react in the stomach. In addition, the nitrite entering the stomach from consumption of cured meats would be accompanied by large amounts of proteins, amino acids, and blocking agents such as ascorbic or isoascorbic acid. These blocking agents effectively prevent the formation of N-nitroso compounds in the stomach as they block the same or similar reactions in the stored product.

Although the nitrite which enters the stomach from saliva during the meal would be subject to the same restrictions described above, these considerations would not apply to the condition following extensive stomach emptying. It is an established fact that the highest measurable nitrite concentrations are found in the fasting stomach, when blocking agents may be absent from the reaction environment and there is correspondingly less dilution.

Therefore, the relative risk of gastric nitrosation from nitrite in cured meats containing blocking agents such as ascorbic acid is minimal.

2. Direct Exposure of Blood

In addition to all of the aforementioned factors which mitigate the effects of nitrite in food when it enters the

stomach, there is evidence from animal and human experiments that nitrite introduced orally or intragastrically is rapidly destroyed. Therefore only very large doses can have a significant interaction with the blood. On the other hand, nitrite introduced directly into the intestine moves rapidly into the circulation where it rapidly reacts with oxygenated hemoglobin.

Given the relative degrees of exposure to intestinally-formed nitrite and residual food additive nitrite, and the relative effectiveness for absorption as nitrite from the different routes of exposure, one must conclude that the relative risk of nitrite from cured meats to the blood is orders of magnitude less than the relative risk from endogenous processes.

Mr. TANNENBAUM. Let me point out, first of all, that I have been working on nitrite for about 8 or 9 years. Second, I am the senior author on the scientific papers that have been published which everyone has been using to estimate the amounts of nitrite exposure that occurs in the general population.

I have tried to avoid in the past trying to come to any hard decisions about what my findings mean in terms of total exposure, but I find that I can no longer avoid this responsibility. So what I am going to give you is the hardrock, bottom line, the way I see it. I think that there are certain caveats that have to be taken in coming to these conclusions, and these are spelled out in my paper.

The conclusion that I have come to is that in terms of the total amount of exposure of a person to nitrite in a single day, one winds up with about 3 percent of his exposure coming from food additive nitrite, about 15 percent from salivary nitrite, and about 82 percent from intestinal nitrite.

Contrary to what some people have suggested or believe, it simply is not true that the nitrite which is formed in the intestine somehow has a lower degree of risk than the nitrite which is formed in saliva, which comes from food products. In fact, the results which we have so far are quite to the contrary. I will comment on that in a moment.

Not only do my studies and the studies of other members of the scientific community support the fact that only a small amount of the total exposure of nitrite comes from added nitrite in foods, but I would suggest that the nitrite that comes in foods actually has a smaller degree of risk than the nitrite which comes from our natural exposure. The reason for that is due to a fairly complicated series of considerations that have to be given to reaction rates.

During the course of these proceedings this morning several people have made the statement that of course the reaction proceeds in the stomach more rapidly because it is more acid. I would say that, on the basis of what we know now, that is a rather simplistic notion and is most probably incorrect.

In addition to our exposure to nitrite, it is now well known that we are also exposed to nitrosamines which are being produced by natural processes in the body. In fact, nitrosamines have now been found in both human blood and human feces. Some of this information has already been published: some will be published very shortly.

I have made estimations based on what is known about human exposure which suggest that somewhere between 0.5 miligram and 5 miligrams of dimethynitrosamine per day are being formed and destroyed in the average human body. That would refer to someone who is not eating cured meats.

The reason for this gets down to what is going on in the intestine. What we know now suggests that we are finding nitrosamines in the human intestine and that in fact this is the largest source of nitrosamine formation to which man is exposed. It far exceeds the amount to which he would be exposed by what which would be contributed by nitrite taken in in meat products, that which would be contributed by nitrosamines preformed in meat products, or that which would be contributed by such other sources which are important, such as smoking cigarettes.

That is a brief statement in summary. I will be happy to answer any questions.

Mr. ROSE. Mr. Wampler?

Mr. WAMPLER. Thank you, Mr. Chairman.

Dr. Tannenbaum, I do appreciate very much your coming and sharing your paper with us. I believe the paper will appear in the record in its entirety so that it will be part of our hearing record. It is an extremely well-written paper and one that is important to the subject matter before us.

Dr. Tannenbaum, I hope that nothing that I said earlier will be interpreted as any disrespect for your colleague, Dr. Newberne. I know his credentials are impeccable, but I just feel that in many cases the Government has overreacted.

An interview that you had with WMT stations indicated that perhaps you shared that feeling. I would like to quote your words. I do not mean to be taking this out of context at all. You said:

> But I felt there was a distinct error of overreaction on the part of the Government, given the nature of the conclusions in the report.

Do you recall that particular interview that you had?

Dr. TANNENBAUM. Yes; I have had many interviews over the last few months, including several which disturbed my vacation this year.

I do remember that particular interview. I think I did make that statement. I think I would still stand by it.

Mr. WAMPLER. The point I again want to make, as I tried to elicit from the other two witnesses, is this. In the normal, scientific scheme, when a study of this type—and we are now talking about the Newberne study—is made available and the test data is there, then it is incumbent upon the scientific community to independently evaluate that data to validate it or to point out where it is in error or any conclusions that might be drawn from it. Is that a fair statement?

Dr. TANNENBAUM. Yes; that is a fair statement.

Mr. WAMPLER. Do you have any studies underway yourself now that would tend to validate or to question the validity of the Newberne study?

Dr. TANNENBAUM. I have not, in fact, even examined the results of Dr. Newberne's study. Because I am not a pathologist, I do not think I would like to be involved in the interpretation of those results.

My studies, in fact, augment those findings and should help us in considering whether the results of that study should be taken into consideration in determining legislative action.

For example, if one takes the results of the Newberne study and if one takes the sorts of risk extrapolations that the Food and Drug Administration is proposing, in addition to that if one takes our findings on the amounts of nitrite which is being formed in the intestine, then I would predict that we would probably be dropping like flies of lymphomas if those risk extrapolations were correct.

Mr. WAMPLER. Most of your studies have been done with human beings rather than mice or rats; is that correct?

Dr. TANNENBAUM. Yes, my studies have been done with both human beings and with experimental animals.

Mr. ROSE. We need to recess at this point. We may have a series of two votes on the floor of the House, so it may be 1:30 before we can return.

Dr. Tannenbaum, we may want to talk to you some more when we return.

[Recess taken.]

Mr. ROSE. The subcommittee will be in order.

Dr. Tannenbaum, we appreciate your early return. We want to proceed.

Maybe Mr. Wampler has some more questions and Dr. Martin wanted to ask some questions.

Mr. WAMPLER. I have one brief question, Mr. Chairman.

Dr. Tannenbaum, do you have any reason from a scientific viewpoint to question any of the methodology that was used in the Newberne study? Let me rephrase that. Do you have any difficulty with the way that the Department has interpreted the study?

Dr. TANNENBAUM. The Department?

Mr. WAMPLER. Yes, the Department of Agriculture or the FDA, either or both.

Dr. TANNENBAUM. I would only make a statement as a scientist in response to some of the things which I heard said here earlier today. I think it is unfair to Dr. Newberne to say that the data might be specious. Data are data. There is no way that you can argue about them unless someone would reinterpret the slides.

The key thing is the way the results of those studies are interpreted. The point that Mr. Grassley was coming to and the point that Professor Newberne has made himself, that is the only important thing, to take a set of numbers and interpret them based upon the current kinds of thinking which go in the scientific community relative to this use of statistics and other tools, including mathematical tools.

That is where the need for peer review really needs to come in. I do not think those data have been published and opened up to the entire scientific community so that they might interpret the meaning of those results.

Mr. WAMPLER. Then you would agree with me that peer review is very important when you establish the validity of any study, is it not?

Dr. TANNENBAUM. I think it is extremely important.

Mr. WAMPLER. From your knowledge, do you believe that the Food and Drug Administration has the capability in-house to make that study or should that be a part of the overall review?

Dr. TANNENBAUM. I am not qualified to answer that question.

Mr. ROSE. Congressman Martin?

Mr. MARTIN. Thank you, Mr. Chairman.

Dr. Tannenbaum, I appreciated very much the testimony that you offered earlier in the day.

It would seem to me that the single most important observation that has been made thus far, Mr. Chairman, in these hearings is the report by Dr. Tannenbaum that not only has he found nitrite levels naturally occurring and naturally being formed in the intestine on the order of 40 times the amount to which we would be exposed by consumption of nitrite-preserved products, but with regard to, as far as I know, previously unreported investigations of nitrosamines natur-

ally occurring in the body he has reported to us that he has found, if I understood it correctly, on the order of 1,000 to 10,000 times as much nitrosamine naturally occurring in the body than we would be exposed to from the amount that is allowed under the present food law in pork products.

I would ask Dr. Tannenbaum if he could further elaborate on this relative risk perspective. He did say in his written statement that:

> The risk that could arise from the use of nitrite according to present and proposed USDA regulations would be miniscule compared to those resulting from the body's natural processes.

A little later he says:

> * * * I am mystified by the action of Government officials who call for the ban of a valuable preservative which is a trivial addition to the natural burden.

I understand it there that you are talking about the natural burden of whatever hazard there is or may be associated with nitrites and nitrosamines.

Dr. TANNENBAUM. Yes, that is correct. The significance of the amount of nitrite which comes into the stomach from cured meat products has not been interpreted in light of what we know about the sorts of reactions which nitrite would undergo in that reaction environment.

For example, under the current suggested changes which are going to take place in the way nitrite will be used with cured meats—that is, the 550 p/m ascorbic acid and 120 p/m nitrite regulation—what would come into the stomach at that point—would be a residual nitrite concentration of 10 to 30 p/m and a residual ascorbic acid concentration of at least several hundred parts per million. There would then in the stomach be a dilution. There is actually a study which has shown that the dilution is a factor of an order of 3. So then you would have about 3 to 10 p/m of nitrite and concomitantly also a lower concentration of ascorbic acid.

Given what we know about the formation of nitrosamines in the presence of that ascorbic acid and also in the presence of other constituents which come along with the meat product, I do not see how you are going to form nitroso compounds. In fact, there is no study I know which suggests that nitroso compounds could form under those circumstances.

This is extremely important. If you are going to do a study in which you are going to look at the toxicity of nitrite, then I think you have to look at it within the kind of food environment that acually is going to be used. I do not see the physiological meaning of feeding thousands of parts per million of nitrite in a diet, for example, which is completely lacking in ascorbic acid or other blocking agents which we know are going to be there under the actual circumstance of processing.

Mr. MARTIN. What you are saying then is that not only do we need to be sure that the scientific findings of your research, Dr. Newberne's research, or anyone's research are valid insofar as the evidence is concerned, but we also need to give some attention as to what the meaning of the evidence is once you are assured of the validity of it. Does it

have meaning? What is the relative risk? Is it a real number in terms of the human population of the United States?

Dr. TANNENBAUM. Yes; I think we have to interpret the findings of each study under conditions of intended use.

Mr. MARTIN. Would you agree that, inasmuch as you have found levels of nitrosamine naturally occurring far in excess of the nitrosamine that would be caused by the amount of nitrite added to cured meats, and you have found levels of naturally occurring nitrite far in excess of the amount of nitrite that would be added to the body by eating cured meat, then as a result of that comparison, the studies related to nitrite are, if anything, irrelevant?

Dr. TANNENBAUM. First of all, the studies and findings of nitrosamines are not my studies. They are findings of other individuals, some of which are published and some of which will appear shortly.

As a scientist, I find it difficult to come to the conclusion that anything is irrelevant.

Mr. MARTIN. Irrelevant for purposes of public policy regarding the banning of nitrite.

Dr. TANNENBAUM. I would come back to the use of the words that you quoted earlier, which is that the risk is miniscule.

Mr. MARTIN. Relatively irrelevant.

Mr. Chairman, I have no other questions.

Mr. ROSE. Dr. Tannenbaum, are these conclusions that are in your paper presented to us today the result of research that you personally have conducted?

Dr. TANNENBAUM. The research on nitrites is research that I have personally conducted. The finding of nitrosamines in, for example, blood and in feces in the human intestine is the result of colleagues of mine. Some of it has been published and some of it has not been published.

Mr. ROSE. Could you give us those references. If you don't have them here today, could you supply that in a letter to this committee for the record?

Dr. TANNENBAUM. Yes.

[The information supplied follows:]

MASSACHUSETTS INSTITUTE OF TECHNOLOGY,
DEPARTMENT OF NUTRITION AND FOOD SCIENCE,
Cambridge, Mass., October 4, 1978.

Hon. CHARLES ROSE,
House of Representatives,
Washington, D.C.

DEAR REPRESENTATIVE ROSE: Thank you for the opportunity to provide testimony on the nitrite issue before your Subcommittee. I would like to add some information which you requested at that time on nitrosamines found in samples of human material:

1. The finding of dimethylnitrosamine in human blood (Fine et al., Nature 265:753; 1977), and unpublished research in the Laboratory of the Government Chmist, London, U.K.

2. The finding of volatile nitrosamines in human feces by the research group of Dr. W. R. Bruce in the Ontario Cancer Research Center (Varghese, A.J., et al. Nature in press 1978).

Sincerely yours,

STEVEN R. TANNENBAUM,
Professor of Food Chemistry.

Mr. ROSE. I will go over your first statement and then ask you some questions.

Nitrites are thought to pose a health hazard by virtue of their ability to form nitroso-carcinogens, and the argument has been made that their discontinued use as food preservatives would greatly reduce or eliminate this risk. This is an admirable goal but * * *.

Then you go on to talk about the ballot sheet for total daily exposure of an adult to nitrite.

For food additive nitrite it is 3 percent; salivary nitrite, 15 percent; and intestinal nitrite, 82 percent. You say, "This balance does not take into consideration several other known sources which cannot be quantitatively estimated," which you have listed.

Where does salivary nitrite come from? Is that normally appearing in the saliva or is it somehow encouraged by the ingestion of food additive nitrite?

Dr. TANNENBAUM. No. Salivary nitrite is completely independent of food additive nitrite.

Mr. ROSE. Is intestinal nitrite, likewise, totally independent of food additive nitrite?

Dr. TANNENBAUM. Yes, sir, it is totally independent.

Mr. ROSE. Are these both the same types of nitrites for all purposes? Are they the same chemically? In other words, the intestinal nitrites or the salivary nitrites that you speak of in your paper are in every respect similar chemically to the food additive nitrites that were regarded as carcinogens in the Newberne study?

Dr. TANNENBAUM. Yes. As Representative Martin pointed out earlier, they are chemically identical substances and indistinguishable except, as I point out somewhere in my paper, that one could of course perform an actual experiment in which one labeled one of those sources somehow with nitrogen-15, which would allow you to do that experiment. But they are chemically indistinguishable.

You asked a question about where this salivary nitrite comes from. It is known that in the saliva which comes into the mouth from the salivary glands there is no nitrite; there is only nitrate. The nitrite that is formed is formed by microbial bacteria which normally inhabit the mouth and which convert the nitrate to the nitrite.

I would like to point out that parallel studies to the one that I have conducted and published have now been carried out in many other countries in the world. To my knowledge, no one has ever been found who does not have nitrite in his saliva.

Mr. ROSE. Where does the nitrate come into the human organism?

Dr. TANNENBAUM. Nitrate comes from two sources. It comes, first of all, from the food supply. It is a constituent of almost every living tissue. Even those sources of food which are extremely low in nitrate still contain measurable amounts of nitrate.

Nitrate is the essential nitrogen source for plant growth. It is a form of nitrogen which is taken up by the plant. Therefore, all plant materials contain nitrate and ultimately, therefore, all animal materials contain some nitrate.

Mr. ROSE. Then all vegetables would contain nitrates in some quantities; is that basically correct?

Dr. TANNENBAUM. All vegetable materials contain nitrate in some quantity. Roots and leafy vegetables and such things as celery contain

extremely high concentrations of nitrate. They contain thousands of parts per million.

I would like to point out that that is not the only source of nitrate. Our work has shown that intestinal synthesis also ultimately results in a source of nitrate which appears in saliva. In fact, it would be very difficult to distinguish between the amount of nitrate in your saliva that came from your intestinal processes and that which came from your diet.

Mr. ROSE. When they wind up in the human body, from whatever source they may have gotten there, they are broken down by enzymes into nitrites; is that what you said?

Dr. TANNENBAUM. Yes; that is correct.

Mr. ROSE. Then if we are going to be consistent protectors of the human populace of this country, we should direct our attention to human ingestion of nitrites not only from food additives, but from vegetables and that entire sphere of intake?

Dr. TANNENBAUM. Yes. As I point out in my paper, it is well known, although it is not extensively published, that if you started nitrite analysis on a series of food products, you would find that spinach which has been stored for a day in the refrigerator would have accumulated a fair amount of nitrite. Also, you would find, as we have found in our studies on constitutents of the human dietary materials which we use, that many dried foods, such things as powered egg, have nitrite. Preparations of soybean protein in many instances have nitrite. This comes about as a complicated result of either enzymatic processes or the way drying procedures are carried out.

I think it would be very difficult, if not impossible, to completely ban nitrite that would arise in any form of processing, much less nitrite which appears only as produced by the body's natural processes.

Mr. ROSE. Are there any other questions? Mr. Wampler?

Mr. WAMPLER. How much nitrogen is in the atmosphere that we breathe?

Dr. TANNENBAUM. The atmosphere is approximately 80 percent nitrogen.

Mr. WAMPLER. Is there any way that we in Congress could ban that that you are aware of?

Dr. TANNENBAUM. I don't think so. [Laughter.]

Mr. MARTIN. May I ask one other question, Mr. Chairman?

Dr. Tannenbaum, you have talked about the nitrite that is naturally formed in the body, as to how that greatly exceeds the amount of nitrite to which we would be exposed from cured meats. You have talked about the mechanisms for formation, the enzymatic reduction of nitrate to nitrite in the oral cavity, in the saliva.

Is there any speculation as to whether that naturally formed nitrite might be a part of the body's natural defense mechanism against various food poisoning? For example, don't we know that infants have a rather low amount of nitrite in comparison with adults? Hasn't there been some speculation that at least some part of the otherwise unexplained malady known in an unexplainable way as the infant death syndrome, some part of that might in fact be due to a lack of adequate defense?

Dr. TANNENBAUM. It is interesting that you should ask that question. We have engaged in such speculation that, in fact, some cause

of sudden infant death syndrome, which people are ascribing now to infant botulism, might be due to a lack of formation of nitrite or that the formation of nitrite even in adults may be important in preventing the growth of clostridium botulinum in the human intestine.

In fact, I have discussed this with some friends and colleagues who are much more versed in intestinal and medical microbiology than I am. It is very difficult to know whether the levels of nitrite which are formed in the intestine could in fact function in that manner.

I would say that that is an interesting speculation and perhaps one which we ought to consider, but one that would be difficult to carry further at the present time.

Mr. MARTIN. It would not be that unusual, however, to in a parallel way refer to other substances which are important and essential to the body at certain levels but which at far greater levels of exposure have been found to cause cancer in laboratory test animals.

For example, there is some evidence regarding selenium which is essential in trace amounts. Calcium also would be a very important part of our bodily structure and a certain amount is needed. However, at massive overdoses it forms microcrystals and leads to tumor formation in test animals. Estrogens certainly have their important hormonal effect but overdoses of estrogens cause cancer. I believe the same kind of evidence exists for vitamin D. A recent paper suggests it exists even for massive overdoses of vitamin C, but I am not sure that that is confirmed yet.

There is one other that I would mention. All protein contains tryptophane. Tryptophane has been shown to be at least as potent a carcinogen as saccharine, which the Food and Drug Administration sought to ban. Yet tryptophane is an essential amino acid, in addition to which it is an ubiquitous amino acid.

The point is that, while there are many substances, perhaps including nitrite, which at normal human levels help to sustain life as we have evolved it, yet at much higher doses—and the nitrite tests on the Newberne series of rats were at much higher doses than what you have found in the intestines of humanes—may lead to the disruption of some metabolic functions, thereby preventing the animal's defense mechanism from operating properly.

Dr. TANNENBAUM. What you are saying is certainly conceivable.

I would like to point out in that context that I think that this subcommittee, in considering the nitrite issue, ought to consider that even if here were a risk, it is a preventable risk. The concomitant use of ascorbic acid, for example, in the processing of meats would prevent even the small amount of nitrite that would come from processed meats from doing any physiological damage or reacting to forming nitroso compounds, if there was presence of blocking agents such as ascorbic acid.

Mr. ROSE. Would the gentleman yield at that point?

Mr. MARTIN. Certainly.

Mr. ROSE. Are you saying that if there is any risk from nitrites in meat as a curing agent, that it could be reduced by the addition of ascorbic acid or vitamin C?

Dr. TANNENBAUM. I think that that is correct, either ascorbic acid or other blocking agents which have been proposed.

I think this is the most significant added factor that has to be taken into the interpretation of the Newberne experiment—whether or not there were such blocking agents present in the stomachs of the animals that got the tumors.

Mr. ROSE. Then it would be a valid question to ask whether or not the natural levels of nitrates in rats were determined before the ingestion; is that a good way to put it?

Dr. TANNENBAUM. Not the natural levels of nitrates but whether the diets which were used represent in terms of composition what we would experience in consuming a normal human diet.

Mr. ROSE. Thank you very much. We very much appreciate your waiting for so long, but this has been a very significant part of what we have learned today.

Our next witness is Mr. Joe Czarnecki, vice president for corporate relations, Griffith Laboratory, Alsip, Ill.

Would you come forward, please, sir?

Mr. Czarnecki, I believe you have a statement for the record.

STATEMENT OF JOSEPH CZARNECKI, VICE PRESIDENT OF CORPORATE RELATIONS, GRIFFITH LABORATORIES U.S.A., INC., ALSIP, ILL.

Mr. CZARNECKI. My name is Joseph Czarnecki. I am vice president of corporate relations for the Griffith Laboratories, Inc., with headquarters in Alsip, Ill. I have been employed by this company for 32½ years. For the past 10 years, I have been the principal liaison between our company and the regulatory agencies, including Federal, State, and local.

The Griffith Laboratories has been in existence for almost 60 years, furnishing ingredients such as spices, flavoring materials, curing materials, protein products, and hydrolysates, to name just a few, to the food industry. We manufacture and furnish about 70 percent of the preblended curing materials used in the meat and poultry industry.

I have been asked to confine my remarks to the use of curing materials containing nitrites and/or nitrates in poultry products. This is very difficult to do since the use of these materials is almost identical in red meat and fish as well as in poultry.

Nitrites and/or nitrates in poultry, as well as red meats, are used principally for their preservative effect in controlling the growth of botulism toxin, although they have a great effect also on distinctive flavor development and color retention.

The use of nitrites and nitrates in curing poultry products goes back at least some 40 years, but it is difficult to assemble documented material since the USDA has regularly destroyed vast quantities of its own records regarding product labels and formulae and, in addition, has required processors to destroy their own labels and formulae when the use of a particular label has been discontinued.

In recent years great strides have been made in the poultry industry in making available to more and more people new, economical, and nutritional products utilizing poultry meat. Products such as chicken frankfurters, turkey bologna, turkey salami, to name a few, have gained wide acceptance by a discriminating public, which fact has

helped the producer, manufacturer, and consumer to utilize more nutritious protein with a lower fat content.

Despite erratic methods of distribution and handling in the channels of commerce prior to consumer purchase, products such as I have mentioned above can be safely consumed without fear of food poisoning since they are protected by nitrite.

In recent months, nitrites and/or nitrates have become the favorite whipping boy of many misinformed and misguided professional consumer advocates and members of the media who simply do not understand the economic factors involved but, more importantly, the health factors involved. The difficulty that we all face is to properly educate and inform those in authority that this is not a game to be played. It appears that no one will be satisfied until we have a botulism outbreak that will once and for all prove the safety and necessity for the continued use of nitrites, since there is no proven alternative available at this time.

It is irresponsible to have the FDA and USDA publicize the possible phasing out of nitrite and/or nitrate on the basis of the recent suspect MIT report on the effect of nitrite in the diet of rats. An FDA laboratory survey team showed that the MIT laboratory was suspect. They found, among other things that there was a diet mixup with an animal caretaker feeding the wrong diet to a group of rats. The FDA investigators advised that there was no excuse for this, and stated that feeding these animals the wrong diet was appalling. No quality assurance system was in effect in the laboratory to prevent such mixups. Thus, there is no way to know how often this might have occurred.

The diets were not analyzed for aflatoxins, nitrosamines, or other possible contaminants or carcinogens.

The scales used were not capable of accuracy in weighing the amounts of nitrite mixed into the various diets.

A container of urethane, a known powerful carcinogen, was stored in one of the animal rooms.

The raw data on each rat's death was recorded on paper towels which were later discarded after posting the filecards. Consequently, no check for accuracy was possible under these circumstances.

A chemical pest strip was used in one animal room.

There was no prewashing of the equipment or utensils used in the diet preparation. The investigators noted that there was a possibility of cross-contamination from another animal study diet.

It appears incredible to me that the regulatory agencies would widely publicize a possible phasing out of nitrite based on such a flimsy report.

Thank you, Chairman Rose, for your kindness in inviting me to testify. I appreciate the opportunity of doing so.

Mr. ROSE. Thank you for being here, Mr. Czarnecki.

Congresman Wampler?

Mr. WAMPLER. I want to thank you for your patience in appearing before the committee today.

Let me get your opinion on one proposed alternative.

I believe you introduced a new family of foods that would be nitrite-free, but which would require refrigeration, perhaps at 40° F. or less, from the time they are processed until manufacture, distribution, retail, and ultimate consumption.

This struck me as being rather impractical when you consider the fact that so many people do buy foods which are treated with nitrite as a preservative in order to prevent deadly botulism.

Mr. CZARNECKI. That is true.

Mr. WAMPLER. How practical would this suggestion be? Should we market them in basically the same size, the same shape, with a warning label that this product must be refrigerated at 42° F. or less? How practical is that?

Mr. CZARNECKI. The warning label itself would be no guarantee that the product would not be abused. I am sure you have gone through a supermarket where they are stocking a frozen food case, and for hours those frozen foods will stand on the floor without any refrigeration waiting to be put into that case. It is an up and down deal.

There would be no way that you could guarantee, under the present circumstances, and that you could assure a frozen product from the time that it leaves the plant until it is consumed.

Refrigeration at home is around 50° F., so we are 10° F. above the 40° F. that we want to put on the label right now.

The only safe way is to freeze the product or go to a high salt content, which means you could promote hypertension if you can eat it to begin with.

Mr. WAMPLER. I think I agree with you that that is not a practical approach.

Mr. CZARNECKI. That is right, not to give you food as you know it today. You can make a frankfurter with nitrite. They do it in Rochester, N.Y., and they have done it for years. However, it is in the frozen food case, and sold as a frozen food.

Mr. WAMPLER. We heard testimony from Dr. Tannenbaum and others that you can use sorbic acid on the nitrites and reduce——

Mr. CZARNECKI. That is correct.

The new bacon regulation for pump bacon makes it mandatory that you have 120 p/m nitrite and 550 p/m sodium sorbic.

The rest of the meat regulation, which is still in effect, covering frankfurters, hams, and corned beef, allows you to use 550 parts, but it does not make it mandatory.

Mr. WAMPLER. What has been the practical effect of this in the trade?

Mr. CZARNECKI. The practical effect? It is a food product. It does a fine job for retaining the ability of that nitrite to continue working.

Mr. WAMPLER. Thank you, Mr. Chairman.

Mr. ROSE. We sincerely appreciate your testimony. It has been very helpful to have a person with your experience and background to give us these views, not only to those of us who are here, but to help our record.

We thank you very much for your contribution.

The next witness will be Mr. Frank Koenig, Tuscarora Valley Farm, Chevy Chase, Md.

STATEMENT OF J. FRANK KOENIG, OWNER, TUSCARORA VALLEY FARM, CHEVY CHASE, MD.

Mr. KOENIG. Mr. Chairman and members, I believe there is at this time a method of production which applies to all cured products which solves the nitrite problem for all cured products.

When that method of production is applied to bacon, we obtain this product, which I am holding here in my hand. You may note that it actually looks like bacon, and, in fact, to the best of my knowledge, it represents the first improvement in bacon quality since the original invention centuries ago.

In addition to being nitrite free, it has many other advantages, I think some of which would be very pleasing to the bacon industry, as well as to the entire cured product industry.

Some of the characteristics are shown in exhibit 1 which we have here.

For example, regarding this—since there is no nitrite, there is no nitrosamine formed during cooking. Also, the carcinogens from wood smoking, there are these hydrocarbons in wood smoke which are known to be carcinogens. These have been removed from the liquid smoke in this product. Liquid smoke is derived from natural wood smoking by a condensation process.

Furthermore, in this process all sweeteners have been eliminated. Also, all chemical additives have been eliminated. In addition, the salt content has been reduced by 50 percent.

With regard to the organoleptic characteristics which are those characteristics which can be sensed by the consumer, such as flavor, crispness, aroma, tenderness, juiciness, color, appearance, and so on, these are identical organoleptic characteristics.

At the present time this is being marketed in supermarkets in the freezer section. However, inasmuch as it is seasoned fresh pork, it has microbiological characteristics similar to seasoned fresh pork. Therefore, I have not carried out shelf-life experiments under refrigerated conditions in a supermarket.

But since it is seasoned fresh pork, I would expect, or at least I would predict, it will have a shelf life in the refrigerated section of the supermarket next to the nitrite-cured bacon, similar to fresh pork sausage because it really could be called fresh pork sausage in sliced form rather than ground form.

Also, it is known that solid meat in general lasts longer than ground meat, so inasmuch as this is fresh pork sausage in sliced form, it may actually have preservative quality greater than fresh pork sausage.

With regard to the color, we know in the case of nitrite-cured bacon that one of the principal reasons nitrite is used, is that during the smoking process if you did not use nitrite the meat would turn gray. By using nitrite we have the nitrite combining with the meat chemically to form the artificial color you see in bacon.

In the case of this product, which has an appearance identical to that of bacon, we are really utilizing the natural color of fresh pork.

By the way, what I am saying about this product really applies to all cured products with which I am familiar.

With regard to the protection against botulism, we know that fresh pork sausage does not require nitrite to give us outstanding protection against botulism and all other bacteria.

Therefore, inasmuch as this is seasoned pork, if we temperature abuse this the bacteria will give off gases and tell us the product is rancid.

A further protection against botulism is the fact that there is no need in this product, as in the case of fresh pork sausage, for vacuum packing. Botulism bacteria requires a vacuum in order to produce sausage, so, therefore, I think it is obvious why the U.S. Department of Agriculture found this product was wholesome and they have allowed it to be manufactured since last year.

With regard to cost of production, when this general process of manufacture is applied either to this bacon or any other cured product, the cost of production in this case is actually reduced. It is actually less costly to produce this bacon than nitrite-cured which takes a longer time.

With regard to equipment of manufacture, we utilize the same equipment of the bacon industry. In applying this process to manufacture, no matter which product we are producing, we use exactly the same equipment so there is no need for equipment modification.

With regard to products like hotdogs and various poultry products, the cost of production of nitrite-free products, using this process, is essentially identical. The cost of production of all these products using this process is essentially identical.

Regarding some of these products, there is a need for using freezer trucks for transportation. I would like to point out that in the case of fresh pork sausage, many fresh pork sausages are actually shipped to supermarkets in frozen condition so they will have an additional shelf life.

When they arrive at the supermarket, they then thaw in a refrigerated case, so we see then that in the case of this product we already have the trucks to do it.

In the bacon process, there are two beliefs of the cured-products industry and the industry where they have apparently discovered the beliefs to be false.

The first of these beliefs is that nitrite is a flavoring ingredient.

We just heard from the preceding speaker the belief that nitrite is a flavoring ingredient. I believe my experimentation, and also I have proof of it right here, and also we see proof in the hotdogs being produced, that apparently if nitrite is a flavoring ingredient, it is not apparent in the finished product.

The second discovery that I believe I have made, is that it is believed by the curing-products industry, meat scientists, and in meat science textbooks, that for any cured product that the cured flavor is due to the curing process.

What I have shown is that, in general, cured flavor is not due to the curing process. and cannot be achieved in any uncured product.

These two discoveries really form a basis for the manufacturing product.

To show how easy it is to manufacture these products. the way this bacon was manufactured, was just to take the fresh pork belly and add to it a little salt and a little smoked flavoring in liquid form.

As soon as you allow time for that to permeate through the pork belly, you have bacon. We have been using 8 hours for permeation. We use the regular injection. Instead of injecting a cure, we inject a solution of water and salt in liquid form.

Also, should anyone be interested, you are welcome to try this product. We believe in the present formulation of the product. It has a very delicious bacon flavor and also may be better for you, healthwise.

Thank you.

Mr. ROSE. Thank you, Mr. Koenig. Mr. Wampler?

Mr. WAMPLER. You do not have any cooked sausage, do you?

Mr. KOENIG. I have electric skillets, but something told me to——

Mr. ROSE. Mr. Koenig, we sincerely appreciate your being here and sharing with us your personal experience and your discoveries. We thank you very much.

Without objection, your label will be made part of the official transcript.

[The label follows:]

EXHIBIT #1

Tuscarora Valley Farm

8121 Georgia Ave., World Building, Suite 607
Silver Spring, Md. 20910
588-5220

BACON

SOLUTION TO NITRITE PROBLEM

CURRENT LABEL →

KEEP FROZEN AT ALL TIMES

THIS IS A FRESH PORK PRODUCT -- COOK BEFORE EATING!

No Nitrite Added No Sweeteners Added

FRESH PORK BREAKFAST STRIPS

INJECTED AND MARINATED UP TO 10% WITH A SOLUTION OF WATER, HICKORY SMOKE FLAVORING AND SALT.

U.S. INSPECTED AND PASSED BY DEPARTMENT OF AGRICULTURE EST. 8765

PATENT PENDING

NET WT: 16 OZ. (1 LB.) (454 GRAMS)

Packed For: TUSCARORA VALLEY FARM
Neelyton, Pa. 17239

ADVANTAGES COMPARED TO NITRITE-CURED BACON:

1. No nitrosamines will form during cooking due to added nitrite because no nitrite is added.
2. Carcinogens of wood smoking have been removed from the liquid smoke used in this product.
3. Sweeteners have been eliminated.
4. All chemical additives eliminated.
5. Added salt reduced 50% from 2.5% in nitrite-cured bacon to 1.25% in this product.
6. Identical organoleptic characteristics (flavor, crispness, aroma, tenderness, juiciness, color, appearance, etc.)
7. Shelf life in freezer at 0 degrees F is at least 6 months compared to 2 months for nitrite cured bacon under normal refrigeration.
8. Color is natural color of fresh pork. Color of nitrite-cured bacon is the artificial color resulting from the chemical interaction of nitrite and the meat.
9. If this product is temperature abused the health hazard is the same as for fresh pork sausage, which is no health hazard.
10. Vacuum packaging eliminated because it isn't necessary. Also, botulism bacteria require vacuum for growth.

Mr. ROSE. Next we have Ms. Ellen Haas, director, consumer division, Community Nutrition Institute of Washington, D.C.

She is accompanied by Tom Smith, research director of the Community Nutrition Institute and by Anita Johnson of the Environmental Defense Fund.

I will also ask that Dr. Michael Jacobson, Center for Science in the Public Interest of Washington, D.C., come forward.

Ms. Haas, I believe you are accompanied by Tom Smith and Anita Johnson?

Ms. HAAS. That is correct.

Mr. ROSE. We will listen to what you have to tell us. However, if we can accept your statements for the record and then have you summarize them, we would appreciate it. We might have your reaction to what you have seen or heard this morning.

Please proceed.

Ms. HAAS. In the interest of time, we do have a summary statement.

We are most delighted to have our entire statement inserted in the record.

Mr. ROSE. Without objection, so ordered.

[The prepared statement submitted by Ms. Haas follows:]

Testimony of Ellen Haas
Community Nutrition Institute
Accompanied by Tom Smith, CNI
and Anita Johnson, Environmental Defense Fund
Concerning the Use of Nitrite in Poultry Products

Before the House Agriculture Subcommittee on Dairy and Poultry
September 28, 1978

The Community Nutrition Institute is a non-profit public interest organization that supports the development of a national food and nutrition policy serving consumer needs at the community level. It publishes a weekly newsletter, provides training and technical assistance services and sponsors workshops and conferences on public policy issues in the food and nutrition field.

It is our firm belief that the withdrawal of permission to use nitrite in meat processing is (a) clearly required by the laws designed to protect the public from hazardous foods and food additives, (b) absolutely essential if we are to reduce the burden of elective carcinogens we face unnecessarily and (c) in every respect possible -- even over a relatively short period of time. Consider these facts:

(1) On April 28, 1978, USDA proposed that meat products which are processed without nitrite should not be restricted arbitrarily from being known by their common and usual names -- that "based on agency experience and expertise," these products could be prepared, distributed, and sold in such a manner as to make them completely safe for consumers. Alternatives to the use of nitrite include a rearrangement of processing variables to compensate for the preservative contribution made by nitrite in some products and the addition of labeling provisions explaining proper refrigeration and handling procedures in others. We must remember that we are talking about relative degrees of safety; nothing -- especially nitrite -- is infallible. If we remove nitrite, in many products we can preserve equally well by adjusting

other processing and handling conditions to create a meat environment unsuitable for botulinum outgrowth and toxin production.

(2) At the present time some products might require refrigeration for safety. Meat processors have feared that those persons without refrigerators could be exposed to a hazard, but, as Senator Leahy pointed out in recent Senate hearings, nearly 99% of American households possess refrigerators, according to 1971 Bureau of Labor Statistics figures.

(3) The possibility that Clostridia botulinum will infect meats at all is unlikely. In fact, one USDA researcher called it "very rare" in Congressional hearings in 1971. Data on botulinum incidence is rare but what is available supports this view. Taclindo, et. al. (1967) found type B in one of 73 samples of semipreserved meat products and Insalada et al. (1969) found type B in one sample of frankfurters from among 400 samples of delicatessen-type foods tested. Abrahamson and Riemann (1970) found five samples to contain type A and one sample to contain type B out of 372 samples of semipreserved meat products examined at the retail level.

(4) It is obvious that contamination by Clostridia botulinum, although a rarity, is possible and thus the contingency must be planned for. However, the degree of processing contamination and subsequent handling abuse necessary for a significant amount of toxin to form is tremendous. In a recent Virginia Polytechnic Institute study, samples of bacon that were contaminated with 300-500 spores per gram of bacon, processed normally, and then held at a temperature of 81°F. It did not become toxic until after 10 days. Researchers today estimate that a more realistic spore load level might be one spore per seven pounds of meat. Thus

the amounts used constitute an exaggeration factor of a million to a million and a half times that considered "average." The possibility that any meat, processed or otherwise, would be treated to 81° temperatures for ten days is probably equally rare.

(5) At least one chemical preservative seems promising for development as a replacement for at least the greater portion of nitrite additives currently used. Studies have shown that .26% potassium sorbate in conjunction with 40 ppm sodium nitrite is at least as effective in preservation as 120 ppm sodium nitrite in bacon. More importantly, it appears as if sorbate may be completely adequate on its own. In the studies at VPI mentioned earlier, bacon with spore loads of 300-500 per gram which was handled at 81°F became toxic after 10 days when it contained neither nitrite nor sorbate and after 35 days when it contained 120 ppm nitrite or 40 ppm nitrite and .26% sorbate. This same bacon, when containing .26% sorbate alone did not become toxic until after 25 days at the extreme temperature used. Again, we must remember the nitrite standard is not an absolute; from the evidence presented it seems clear that a considerable margin of safety is easily obtainable.

(6) In this regard it must also be pointed out that (a) sorbate functions as a preservative only, it does not affect color or taste and (b) tests are currently underway to determine the efficacy of sorbate at concentrations of .39% which, if the progression in efficacy from .13% to .26% is any indication, is extremely promising. However, it is important that the FDA undertake a simultaneous investigation of the safety of this chemical at these concentrations -- considering the potential level of human exposure from use in processed meats.

(7) The use of sorbic acid in poultry products is of particular interest. In work done at the University of

Minnesota, it was found that combinations of sorbic acid and nitrite dramatically increased the time necessary for meat toxicity from Clostridia botulinum, but also that sorbic acid in concentrations of .2% were equally effective in preventing toxin formation (albeit through a germination mechanism instead of an outgrowth mechanism) as was 156 ppm nitrite, the concentration currently used by the poultry industry in cured products. This finding was probably influenced at least in part by the fact that nitrite has been shown to be less effective as a preservative in poultry products than in red meats. For both 156 ppm nitrite and .2% sorbic acid, the toxicity time periods were approximately double those found for untreated meats. This, then, has been the margin for abuse lent by nitrite in cured poultry products. As with red meats, it is fully possible that safety margins even greater than we have known in the past will be possible with greater concentrations of sorbic acid.

Officials at the National Broiler Council estimate that approximately one percent of the aggregate young chicken slaughter, in terms of weight, is represented by processed and cured products such as chicken bologna and chicken frankfurters. The figure is misleading, however, as over 52% of that carcass weight is discarded as refuse during product formulation. The bulk of these products comes from the left over chicken necks and backs which have been growing in volume in recent years as consumers have been turning increasingly toward the convenience of cut up chicken, both fresh and also breaded and precooked. The latter market is reported to be one of the fastest growing in the industry. Perhaps understandably, some of the firms marketing these products are the same ones which have been instrumental in developing the comminuted poultry products in recent years.

Today's chicken hot dogs and luncheon meats are made possible through the technology of mechanical deboning. In a

nutshell, this technology allows the conversion of what was once unusable scrap into a very profitable product. If these products could not be manufactured then the companies might take a loss on the wasted parts, so the argument goes.

The validity of this claim is highly specious. First of all, and most importantly, nothing on the horizon would indicate that the products will cease to be produced -- we feel the effects of a nitrite withdrawal will be virtually unnoticeable. Second, when one compares the price retailers are getting for whole chickens to that for the cut up parts, it is clear that the missing backs and necks represent nothing in the total revenue picture. A spot check run at the beginning of this week at a neighborhood Safeway revealed these prices:

whole chickens	59¢/lb.
wings	89¢/lb.
thighs	$1.09/lb.
breasts	$1.19/lb.

It is clear that in this situation the sum of the parts is greater than the whole. Of course some of this cost increase is attributable to increased labor and packaging costs associated with further processing, but it is generally agreed that both processor and retailer margins are greater with parts than with whole birds. How much is unsure, but certainly more than enough to compensate for the necks and backs which are not sold at retail.

The firms that are producing the comminuted poultry products are by and large those which deal in the volumes necessary to (a) generate enough leftover necks and backs as to make production worthwhile and (b) acquire the capital necessary for the equipment, packaging, distribution, and promotion investments. Accordingly, the bulk of these products are marketed by firms such as Holly Farms, Tyson Foods, and Weaver Company.

Even if there were an adjustment period during which consumers were being introduced to nitrite free products, these firms would certainly be able to cope. Holly Farms, a subsidiary

of Federal Company, contributes over 58% of the revenues and near 27% of the profits of Federal Company, which last year ranged to $589 million and $9 million respectively. The firm is highly integrated vertically, operating many feed facilities, poultry processing plants, hatcheries, and offal rendering plants. Federal Company also deals in bakery supplies and pet food.

Tyson Company, with sales of $215 million in 1977 and net income of $2.3 million, is vertically integrated to a comparable degree. Tyson owns five separate poultry concerns dealing with every aspect of the business. Victor F. Weaver and Company has been a leader in developing the retail precooked chicken parts which have grown so popular over the last several years and the production of hot dogs and luncheon meats has been a logical outgrowth of this processing role.

Despite the fact that this industry would be fully capable of weathering whatever minimal market adjustments that might be produced by a discontinuation of nitrite use, we feel very strongly that such a process will not be necessary.

In support of this position, we point to several established facts. First. The need for nitrite as a preservative in frankfurters and luncheon meats which receive a "full cook" has been shown to be very questionable. Studies discussed earlier showed that even with no preservative precautions, grossly contaminated meats held at excessive temperatures -- conditions almost unreasonably rare -- did not become toxic for nearly a week and a half. Even further, it has been demonstrated that a tested concentration of sorbic acid, a colorless and tasteless preservative that is currently GRAS, is the equal to nitrite for preservation purposes, at the maximum nitrite level allowable.

In addition, the market currently sports a variety of the chicken luncheon meat that contains no nitrite, the sliced chicken loaf. This product, made mostly from the white breast meat of the bird, consists of small chunks of meat suspended in an emulsion. According to researchers, it is processed under conditions very similar to the nitrite cured luncheon meats and

franks and is subject to no less of a potential hazard from botulinum contamination. It is sold right next to the pork, beef and poultry luncheon meats that do contain nitrite and bears no additional handling precautions on the label.

More than one person has said that consumers would naturally know that these meats needed special care because of their different color or because of the unfamiliarity with processed poultry meats, as compared to pork or beef. We feel this argument is faulty, however, because (1) if color were the indicator to consumers then we could easily withdraw the use of nitrite and not allow any other colorants to be used thereby signalling consumers that special care was needed for all processed meats and (2) if a lack of familiarity with processed poultry products encourages the consumer to treat slices of chicken loaf in a special manner, then it would be equally educational in dealings with lunch meats, hot dogs, and turkey hams. We think the argument is most specious, however, because through our work with different groups of people at the community level we have come to realize that consumers feel all foods that the government allows to be marketed without precautionary or warning labels is of equal safety -- especially among foods of a specific class, say, processed meats. Thus, without special instructions the poultry variety will be treated in virtually the indentical manner as those made from pork or beef.

There is one difference between the chicken rolls and the lunch meats with nitrite, however. The former are almost always made from white meat whereas the latter come from left-over neck and back dark meat. Processors are eager to promote the fact that chicken rolls are all or mostly breast meat (especially since using white meat specifically for this purpose causes the products to offer no cost savings over the beef or pork analogs) and the use of nitrite might darken the meat to an undesirable shade of pinkish-brown. Neck and back derived franks, however, become greyish brown during processing and the use of nitrite allows for the familiar red-cure color to come through.

Some processors feel the similarity between processed poultry and processed red meats, as a result of nitrite use, is important to sales of the products as the poultry offer the same taste and color but at less cost. If this rationale is valid and if the need to ride on the coattails of the processed pork industry is perceived to be a real one then a complete discontinuation of nitrite use in all franks, luncheon meats and hams would have no special effect on the poultry industry. Neither the poultry industry nor the red meat industry would be able to use nitrite; when the new nitrite free red meats were marketed, the poultry industry could duplicate their spice mixtures.

This discussion leads us to an interesting question -- especially considering the rather limited efficacy of nitrite in poultry under the extreme test conditions the red meat industry is fond of using, are poultry processors using nitrite solely because the red meat industry is? Because without it the chicken hot dogs and lunch meats would not be similar to the pork or beef variety?

Even if this is the case now, it does not have to be in the future. In fact, we feel the processed poultry industry would do much better if it stopped emulating the red meat industry and began to develop its own variety of "pure poultry" processed meats. The sliced chicken roll is one example, pressed poultry deli meats are another. Neither contain nitrite, both are very clearly poultry and my guess is that they will only become more popular with consumers in coming years. The industry has already begun to promote three of the advantages that the poultry meats possess over the pork and beef variety -- that they are lower in fat, higher in protein and cheaper to buy. There is no reason why new or natural non-imitation flavors and colors should not also be developed for these meats.

For cured turkey products, which make up nearly 10% of the turkey market, these arguments are only more true. And with the

solid-meat turkey products, there is almost even more of an incentive to carve out a separate market, distinct from that of beef or pork. These products possess perhaps the highest protein to fat ratios of any meats consumed by Americans today. Furthermore, they possess a subtle but very pleasing taste and routinely cost 20% less than the pork variety. In an interview with Food Engineering magazine, Dr. Julius Bowerman of Longacre, a concern that manufactures turkey hams, said that "with turkey there's no over-powering taste to remove or cover up. By adding seasonings and spices to turkey meat and baking it in a smoke atmosphere, we duplicate the ham taste exactly." The fact that this process is possible is of note, that it is necessary is in doubt. The article also states that Longacre markets turkey salami and turkey pastrami which were "purposely made to taste different than beef pastrami and salami. The taste could have been duplicated exactly, but there wasn't much difference in price between [the poultry and red meat products] so Longacre gave the products a flavor characteristic of their own."

In sum we would like to reiterate that the processed poultry industry stands only to gain from an across-the-board elimination of nitrite use. The chemical is not necessary for preservation purposes, nor is it essential in the imitation of pork flavor and color in meats which are fairly well endowed with desirable characteristics of taste and color in their own right.

Ms. HAAS. I have tasted Mr. Koenig's bacon. It was displayed at the Consumer Federation of America. I thought it was delicious.

Anyway, I am still living. I did not get botulism. I think it is safe and healthy and I am most encouraged about the progress made in alternatives.

Let me also say it is our organization's firm belief that the withdrawal of permission to use nitrite in poultry and red meat processing is, (*a*) clearly required by laws designed to protect the public from hazardous foods and food additives; (*b*) absolutely essential if we are to reduce the burden of elective carcinogens we face unnecessarily, and (*c*) in every respect possible—even over a relatively short period of time.

We have done a tremendous amount of research in the area of poultry over the last several years and would like to share that information with you.

Consider these facts:

One: On April 28, 1978, USDA proposed that meat products which are processed without nitrite should not be restricted arbitrarily from being known by their common and usual names—that "based on agency experience and expertise," these products could be prepared, distributed, and sold in such a manner as to make them completely safe for consumers.

Alternatives to the use of nitrite include a rearrangement of processing variables to compensate for the preservative contribution made by nitrite in some products and the addition of labeling provisions explaining proper refrigeration and handling procedures in others.

We must remember that we are talking about relative degrees of safety; nothing—including nitrite—is infallible.

If we remove nitrite in many products we can preserve equally well by adjusting other processing and handling conditions to create a meat environment unsuitable for botulinum outgrowth and toxin production.

Two: At the present time some products might require refrigeration for safety. Meat processors have feared that those persons without refrigerators could be exposed to a hazard, but, as Senator Leahy pointed out in recent Senate hearings, nearly 99 percent of American households possess refrigerators, according to 1971 Bureau of Labor Statistics figures.

Three: The possibility that Clostridia botulinum will infect meats at all is very unlikely. In fact, one USDA researcher called it "very rare" in congressional hearings in 1971. Data on botulinum incidence is rare but what is available supports this view.

Mr. ROSE. Just go over these things you have said to this point. There may be a little risk of botulism. Everybody has a refrigerator. Are you saying that you are convinced that we should cease the use of nitrites in meat products?

Ms. HAAS. Our testimony goes on to show, Congressman Rose, that alternatives exist today——

Mr. ROSE. Why should we be forced to the alternatives? Let us zero in for a moment—and I appreciate your sincerity and everyone's sincerity who has a position on this.

As chairman of a subcommittee, I am trying to keep an open mind and look objectively at all of the facts and all of the evidence. However,

it appears to me that that objective had not existed. We are dealing in a field of knowledge that is very incomplete.

We have just heard a professor of food chemistry from the Massachusetts Institute of Technology testify about intestinal nitrite levels, salivary nitrite levels, and food additive nitrite levels. He indicated that only 3 percent of the total daily injection of nitrites or presence could be attributed in this way, and that the blockage factors are present in the human body. They could be encouraged if nitrites were accompanied by sorbic acid in a curing mechanism.

Therefore, forget about the alternatives for a moment.

Why are you convinced that we need to——

Ms. HAAS. I think we have to consider the alternatives. I think we have to go back to the first three statements I made.

First of all, it is the law. That was clearly stated today by Mrs. Foreman and Dr. Kennedy. It has been stated before because of the Food, Drug, and Cosmetic Act.

Mr. ROSE. Do you think that law is right?

Ms. HAAS. Yes.

Mr. ROSE. Would you oppose any attempt to change the Delaney amendment in such a way that it would allow us to take into consideration the risk of nitrites from salivary sources and intestinal sources as well as food additive sources?

Ms. HAAS. That is a very important question. I think this is what our second point was—that food additives are elective. They are deliberate additions into the food which can be controlled.

Saliva is in our body. If you talk about spinach, spinach is different. You can choose to buy it or not. However, nitrites in foods are often hidden ingredients that are contained in the food. Consumers do not have a choice in the market because these alternatives have been restricted in the proposed regulation, so consumers do not choose between cancer-free and cancer-inducing foods.

For that reason, we feel that Congress, in its wisdom, in 1958 and in 1960 decided that consumers should not have to bear the burden of unnecessary risk, particularly when—and I am adding today, 1978—when alternatives do exist which will not harm the industry, which have been shown to be valid, and in the end will give consumers healthful foods.

Therefore, what we have tried to do, and what I would like to continue to do, is to explain to you how, particularly in poultry, alternatives are very viable alternatives for nitrite.

Mr. ROSE. Would you consider the addition of sorbic acid as an alternative that would be viable?

Ms. HAAS. We address that method, yes.

Mr. ROSE. All right.

Ms. HAAS. Four: It is obvious that contamination by Clostridia botulinum, although a rarity, is possible and thus the contingency must be planned for.

However, the degree of processing contamination and subsequent handling abuse necessary for a significant amount of toxin to form is tremendous.

In a recent Virginia Polytechnic Institute study, samples of bacon that were contaminated with 300–500 spores per gram of bacon,

processed normally, and then held at a temperature of 811° F. It did not become toxic until after 10 days.

Researchers today estimate that a more realistic spore load level might be 1 spore per 7 pounds of meat. Thus, the amounts used constitute an exaggeration factor of 1 million to 1½ million times that considered average. The possibility that any meat, processed or otherwise, would be treated to 81° F. temperatures for 10 days is probable equally rare.

Five: At least one chemical preservative seems promising for development as a replacement for at least the greater portion of nitrite additives currently used. Studies have shown that 0.26-percent potassium sorbate in conjunction with 40 p/m sodium nitrite is at least as effective in preservation as 120 p/m sodium nitrite in bacon.

More importantly, it appears as if sorbate may be completely adequate on its own.

In the studies at VPI mentioned earlier, bacon with spore loads of 300–500 per gram which was handled at 81° F. became toxic after 10 days when it contained neither nitrite nor sorbate and after 35 days when it contained 120 p/m nitrite or 40 p/m nitrite and 0.26-percent sorbate.

This same bacon, when containing 0.26-percent sorbate alone did not become toxic until after 25 days at the extreme temperature used.

Again, we must remember that the nitrite standard is not an absolute; from the evidence presented it seems clear that a considerable margin of safety is easily obtainable.

And, last, the use of sorbic acid in poultry products is of particular interest. In work done at the University of Minnesota, it was found that combinations of sorbic acid and nitrite dramatically increased the time necessary for meat toxicity from Clostridia botulinum, but also that sorbic acid in concentrations of 0.2 percent were equally effective in preventing toxin formation—albeit through a germination mechanism instead of an outgrowth mechanism—as was 156 p/m nitrite, the concentration currently used by the poultry industry in cured products.

This finding was probably influenced at least in part by the fact that nitrite has been shown to be less effective as a preservative in poultry products than in red meats. For both 156 p/m nitrite and 0.2 percent sorbic acid, the toxicity time periods were approximately double those found for untreated meats. This, then, has been the margin for abuse lent by nitrite in cured poultry products.

Officials at the National Broiler Council estimate that approximately 1 percent of the aggregate young chicken slaughter, in terms of weight, is represented by processed and cured products such as chicken bologna and chicken frankfurters. The figure is misleading, however, as over 52 percent of that carcass weight is discarded as refuse during product formulation.

The bulk of these products comes from the leftover chicken necks and backs which have been growing in volume in recent years as consumers have been turning increasingly toward the convenience of cut-up chicken, both fresh and also breaded and precooked.

Today's chicken hotdogs and luncheon meats are made possible through the technology of mechanical deboning. In a nutshell, this technology allows the conversion of what was once unusable scrap

into a very profitable product. If these products could not be manufactured, then the companies might take a loss on the wasted parts, so the argument goes.

The validity of this claim is highly specious. First of all, and most importantly, nothing on the horizon would indicate that the products will cease to be produced—we feel the effects of a nitrite withdrawal will be virtually unnoticeable.

Second, when one compares the price retailers are getting for whole chickens to that for the cut-up parts, it is clear that the missing backs and necks represent nothing in the total revenue picture.

A spot check run at the beginning of this week at a neighborhood Safeway revealed these prices: Whole chickens, 59 cents a pound; wings, 89 cents a pound; thighs, $1.09 a pound; and breasts, $1.19 a pound.

It is clear that in this situation the sum of the parts is greater than the whole. Of course, some of this cost increase is attributable to increased labor and packaging costs associated with further processing, but it is generally agreed that both processor and retailer margins are greater with parts than with whole birds. How much this is, is unsure, but certainly more than enough to compensate for the necks and backs which are not sold at retail.

The firms that are producing the comminuted poultry products are by and large those which deal in the volumes necessary to (*a*) generate enough leftover necks and backs as to make production worthwhile, and (*b*) acquire the capital necessary for the equipment, packaging, distribution, and promotion investments.

Accordingly, the bulk of these products are marked by firms such as Holly Farms, Tyson Foods, and Weaver Co.

Even if there were an adjustment period during which consumers were being introduced to nitrite-free products, these firms would certainly be able to cope. Holly Farms, a subsidiary of Federal Co., contributes over 58 percent of the revenues and near 27 percent of the profits of Federal Co., which last year ranged to $589 million and $9 million, respectively. The firm is highly integrated vertically, operating many feed facilities, poultry processing plants, hatcheries, and offal rendering plants. Federal Co. also deals in baker supplies and pet food.

Tyson Co., with sales of $215 million in 1977 and net income of $2.3 million, is vertically integrated to a comparable degree. Tyson owns five separate poultry concerns dealing with every aspect of the business. Victor F. Weaver & Co., has been a dealer in developing the retail precooked chicken parts which have grown so popular over the last several years and the production of hotdogs and luncheon meats has been a logical outgrowth of this processing role.

Despite the fact that this industry would be fully capable of weathering whatever minimal market adjustments that might be produced by a discontinuation of nitrite use, we feel very strongly that such a process will not be necessary.

In support of this position, we point to several established facts.

First, the need for nitrite as a preservative in frankfurters and luncheon meats which receive a "food cook" has been shown to be very questionable. Studies discussed earlier showed that even with no preservative precautions, grossly contaminated meats held at excessive

temperatures—conditions almost unreasonably rare—did not become toxic for nearly a week and a half.

Even further, it has been demonstrated that a tested concentration of sorbic acid, a colorless and tasteless preservative that is currently GRAS, is the equal to nitrite for preservation purposes, at the maximum nitrite level allowable.

Mr. ROSE. You are saying there should be no problem in making chicken frankfurters and chicken bologna nitrite free?

Ms. HAAS. That is right.

Mr. ROSE. So you are not questioning the product or the economics?

Ms. HAAS. You will hear at the conclusion that we are not questioning those products at all. We think they have great nutritional benefits.

Mr. ROSE. All right.

Ms. HAAS. We are saying they can be reduced without nitrite and at the same time consumers would not be at a significant risk concerning botulism.

In addition, the market currently sports a variety of the chicken luncheon meat that contains no nitrite, the sliced chicken loaf. This product, made mostly from the white breast meat of the bird, consists of small chunks of meat suspended in an emulsion.

According to researchers, it is processed under conditions very similar to the nitrite-cured luncheon meats and franks and is subject to no less of a potential hazard from botulism contamination. It is sold right next to the pork, beef, and poultry luncheon meats that do contain nitrite and bears no additional handling precautions on the label.

More than one person has said that consumers would naturally know that these meats needed special care because of their different color or because of the unfamiliarity with processed poultry meats, as compared to pork or beef.

We feel this argument is faulty, however, because:

One: If color were the indicator to consumers then we could easily withdraw the use of nitrite and now allow any other colorants to be used, thereby signaling consumers that special care was needed for all processed meats, and,

Two: If a lack of familiarity with processed chicken loaf in a special manner, then it would be equally educational in dealings with lunch meats, hotdogs, and turkey hams.

We think the argument is most specious, however, because through our work with different groups of people at the community level we have come to realize that consumers feel all foods that the Government allows to be marketed without precautionary or warning labels is of equal safety—especially among foods of a specific class, say, processed meats.

Thus, without special instructions the poultry variety will be treated in virtually the identical manner as those made from pork or beef.

There is one difference between the chicken rolls and the lunch meats with nitrite, however. The former are almost always made from white meat whereas the latter come from leftover neck and back dark meat.

Processors are eager to promote the fact that chicken rolls are all or mostly breast meat—especially since using white meat specifically for this purpose causes the products to offer no cost savings over the

beef or pork analogs and the use of nitrite might darken the meat to an undesirable shade of pinkish-brown. Neck and back derived franks, however, become grayish-brown during processing and the use of nitrite allows for the familiar red-cure color to come through.

Some processors feel the similarity between processed poultry and processed red meats, as a result of nitrite use, is important to sales of the products as the poultry offer the same taste and color but at less cost.

If this rationale is valid and if the need to ride on the coattails of the processed pork industry is perceived to be a real one, then a complete discontinuation of nitrite use in all franks, luncheon meats and hams would have no special effect on the poultry industry.

Neither the poultry industry nor the red meat industry would be able to use nitrite; when the new nitrite-free red meats were marketed, the poultry industry could duplicate their spice mixtures.

This discussion leads us to an interesting question—especially considering the rather limited efficacy of nitrite in poultry under the extreme test conditions the red meat industry is fond of using: Are poultry processors using nitrite solely because the red meat industry is? Because without it the chicken hot dogs and lunch meat would not be similar to the pork or beef variety.

Even if this if the case now, it does not have to be in the future. In fact, we feel the processed poultry industry would do much better if it stopped emulating the red meat industry and began to develop its own variety of "pure poultry" processed meats.

The sliced chicken roll is one example; pressed poultry deli meats are another. Neither contain nitrite, both are very clearly poultry and my guess is that they will only become more popular with consumers in coming years.

The industry has already begun to promote three of the advantages that the poultry meats possess over the pork and beef variety—that they are lower in fat, higher in protein, and cheaper to buy. There is no reason why new or natural nonimitation flavors and colors should not also be developed for these meats.

In sum we would like to reiterate that the processed poultry industry stands only to gain from an across-the-board elimination of nitrite use. The chemical is not necessary for preservation purposes, nor is it essential in the imitation of pork flavor and color in meats which are fairly well endowed with desirable characteristics of taste and color in their own right.

Mr. ROSE. Thank you very much. I go back to what I asked before. All you are talking about is alternatives.

Ms. HAAS. We feel there is a clear need, both legally and healthwise, for the poultry industry to embark upon a program and for Government to sanction nitrite-free poultry products. We think evidence and research has been clear.

Mr. ROSE. It looks as though Mr. Wampler will get his nitrite-free bacon in a moment.

Mr. WAMPLER. At this moment I will take it with or without.

Mr. ROSE. Mr. Wampler, do you have any questions?

Mr. WAMPLER. I want to thank you for your testimony.

You heard the earlier colloquy I had about my concern regarding nitrite-free products which have to be refrigerated at a rather low level in order to reduce the possibility of botulism.

A study made in VPI, one commissioned by Monsanto in the private sector, I have not yet had a chance to study it as I planned to, but the point is that it seems to me there is an alternative.

Rather than having nitrite-free products, we establish a level, perhaps, at 40 parts per million and then use a sorbic acid which tends to reduce the possible exposure on the one hand, but yet I think you are underplaying the danger of botulism which we know is deadly. We know that beyond a shadow of a doubt.

You mentioned a statistic—98 percent of the homes have refrigerators. What happens if a schoolchild in the mountainous section of my district goes to a school which does not have a school lunch program, or a child chooses not to participate in it, he takes a product that is nitrite-free, sandwich meat an as example, puts it in a brown lunch bag, and takes it to school?

In many cases he leaves home at 6 or 7 in the morning. He goes to school, puts his container on a shelf, does not put it in a refrigerator. Perhaps he does not eat until 6 or 7 hours later. What happens?

Ms. HAAS. I will ask Mr. Smith, our research director, to answer that. I believe that risk in 6 to 8 hours would not be significant.

I am concerned, too. I have two school-aged children who take processed meats in their sandwiches and take brown bags. I would not advocate my children having an increase in risk.

This is one of the questions I have asked and Tom Smith has undertaken very close monitoring of all that. I would like him to answer that.

Mr. WAMPLER. As he answers it, I would like him to relate what happens as the temperature rises.

Mr. ROSE. We are in a much more affluent part of America where you are lucky enough to raise your children. In my district, and in Mr. Wampler's district, we might have poorer constituents who might have had this meat we are talking about, perhaps in not the finest quality refrigerator.

They might even have gotten it at a grocery store after it had been handled for some time. It is not something that came off a grocery shelf that afternoon.

Here again, we are looking at alternatives without facing the first question—what do you do with this evidence of all the nitrites around?

Mr. SMITH. That is a tall order. First, let me handle Mr. Wampler's question.

As pointed out in the testimony, the amount of contamination and subsequent handling abuse needed for signicant toxic information is very substantial.

Again, the data we quoted was the Monsanto study, part of the Senate hearing. Basically it showed that bacon, which was contaminated at a level of 300 to 500 spores per gram, then processed normally, and then held at 81° F. for a period of 10 days, that spore load level of 300 to 500 spores per gram is in contrast to what researchers estimate to be a normal or supposed load of 1 spore per 7 pounds of meat. That is 1 million to 1½ million.

The possibility that these meats would be held at 81° F. for a continuous 10 days is probably equally rare and as Dr. Angelotti pointed out at earlier hearings, anyone who takes sandwich meats to school and leaves them in a locker room over a weekend, runs no risk—assuming that the processing additions at the plant, handling facilities, the manner in which these meats are handled at the stores, as well as at the processor level, was according to good and standard manufacturing levels.

Mr. WAMPLER. Let me make this comment.

In addition to the health aspects and the danger of botulism, what you propose, I think, raises a very serious question of product reliability. If you require this product to be refrigerated at 40° F. or 42° F. from the time of production, distribution, marketing to consumption, do you not raise an almost impossible question of product liability? Would you not have an unlimited number of lawsuits raised on implied liability, which long have been established under the law?

A lawyer friend of mine made a comparison. He basically represents plaintiffs in court claims. If you loved the swine flu situation, you would certainly love this because you will have an unlimited number of lawsuits due to conditions created here.

Ms. HAAS. Ms. Johnson is an attorney who can perhaps answer that question.

Mr. SMITH. Let me add one thing, first.

For meats contaminated with botulinum, to rule out that possibility through refrigeration, a 40° F. temperature is necessary. As you increase the temperature to 50° F., there are incremental increases. It is not as if you raise it above 42° F. and immediately toxin forms.

Even if it is kept at 50° F., there is a reasonable degree of safety.

Also, there are meats currently marketed nationwide in substantial volumes which contain no nitrites. For example, we mentioned processed chicken rolls. We also pointed out in our testimony there is no additional labeling precaution, not handled in a different manner, stored in retail display cases next to the pork and beef products, consumers treat them no differently.

There is no caution on the label. They are equal risks and consumers treat them in the same way. These are products currently allowable.

Mr. WAMPLER. Keep it in a frozen food section rather than an open display counter. You have to recognize that not every consumer in America would be as sophisticated as those of you appearing here today. Reading labels is not as meaningful to them.

If you are going to bring out, for example, a new family of food products, such as frankfurters, salami, bologna of the same shape, same size, basically packaged the same way which is nitrite free, you can put a label as big as the Capitol dome on it, but that will not protect them. This is what concerns me.

Rather than a nitrite-free product, you should find a way to reduce nitrite to the lowest possible level that will allow protection against botulism. Having sorbic acid seems the most viable alternative I have heard.

Ms. JOHNSON. Product liability lawsuits arise only after injuries. What we have been saying is that these cured meat products have a very wide margin of safety from botulism without nitrites.

The consumers you are talking about, those whose iceboxes are slightly warmer than average, they still have a very wide margin of safety.

Not only do they have this wide margin of safety from refrigeration in transit, but many cured meat products are high in salt, have always been high in salt. Many cured meat products are high acid products, such as salami, pepperoni, where the atmosphere will not permit botulism to occur.

In short, we do not believe there will be botulism injuries from nitrite-free food and, therefore, do not believe there will be product liability problems.

Mr. WAMPLER. That is debatable. There are those who believe there are.

The threat is there. You cannot deny that possibility.

Ms. JOHNSON. The force of our testimony is that there is an enormous margin of safety already built in, a 10-day margin of safety on many products.

Mr. WAMPLER. Why are you trying to limit it to something which, relatively speaking, is not a threat and substituting a system which is a threat?

Ms. HAAS. We see nitrite in meat as a threat to consumer health. If you go to trying to define a new policy, trying to define it as disease prevention, then regulations to insure disease prevention, which this would be, is something which would be in the consumer interest—whether it be affluent or whether it is low income.

Yes, I am middle class, but we work very much with low-income consumers and have a head start program. We know the needs of these people and we know, also, the tremendous amount of health care costs where USDA has estimated several years ago that $30 billion can be saved with improved diet. Improved diet in foods improves safety.

The question was asked earlier about costs; the costs to consumers to improve health care are very real. The threat of cancer is very real. That is why we have taken the approach of saying—what are the alternatives and can the industry produce a product that is available to consumers at a reasonable price and is still safe?

We go to our supermarket and see chicken loaf. We see nitrite-free bacon occasionally—rarely, but occasionally. We see it can de done. I think that is a possibility that Congress should support and a responsibility which would be responsive to the food industry.

Mr. ROSE. A responsibility that Congress should encourage?

Ms. HAAS. You have a situation here where, as Commissioner Kennedy said this morning, the question was asked of him whether he believes that nitrite causes cancer. The question was yes or no. He said: "Probably."

From all he could see, and FDA and all they could evaluate, it was a fine study. It is being sent out for evaluation.

However, it is clear there are linkages. We have been discussing this issue for at least 10 years. There are linkages between nitrites and cancer.

What I believe Congress should be encouraging on the part of the industry is to develop those alternatives, not even to have the question hanging through the air.

Mr. ROSE. Why do you not call your organization "Organization to Encourage the Development of Alternative to the Current Food Industry?" That sounds to me as though really what keeps you going. Let us call it an alternative rather than umbrella of protecting the consumer. God bless the consumer.

What they are saying to Bill Wampler and to Charlie Rose is: "God help us from all this protection." We are up to our necks in protection. Our tax dollars are going out the window paying for it.

Ms. HAAS. Overregulation is a good point, but not when it comes to safety and health. Survey after survey that I see and conversation after conversation that I have show that consumers want necessary regulation, not unnecessary regulation. The area of safety and health, is an area where they feel their Government has a responsibility to uphold public health standards that are at the highest and not sacrifice that for economic interests.

Ms. JOHNSON. Nitrosamines, as described by Dr. Kennedy, as being among the most potent carcinogens known—they present exposures elsewhere in the environment besides in cured meat. Nitrosamines have been found in cosmetics such as Max Factor products, Revlon, and Coty. They have been found in tobacco smoke and drinking water. They have been found in high work place exposures and they have been found in the air in such cities as Baltimore, Md., and in certain areas of Virginia.

We have to attack the environmental exposure of nitrosamines. We are lucky with food exposure because we know where the nitrosamines are coming from. It is easy to prevent that. You go to alternative curing methods.

These other environmental exposures will be costly. It will not be cured meat, and it will be extremely difficult technically.

Getting nitrosamines out of the air will be difficult. Getting them out of our food is not difficult. We are lucky there is an easy way to prevent nitrosamine exposure in food.

Mr. ROSE Thank you very much Dr. Jacobson, do you have a statement?

Mr. JACOBSON. I have a prepared statement which I shall not read.

Mr. ROSE. Would it be agreeable to you if we inserted it?

Mr. JACOBSON. Yes; I would appreciate it.

Mr. ROSE. Without objection, so ordered.

[The prepared statement submitted by Mr. Jacobson follows:]

STATEMENT OF MICHAEL F. JACOBSON, PH.D., EXECUTIVE DIRECTOR,
CENTER FOR SCIENCE IN THE PUBLIC INTEREST, WASHINGTON, D.C.

The Use of Nitrite in Food

Thank you for this opportunity to present my views on problems related to sodium nitrite. I am Michael Jacobson, executive director of the non-profit Center for Science in the Public Interest. I first studied the uses and safety of sodium nitrite in 1970 when I was writing a book (Eater's Digest; Doubleday & Co.) about food additives. In 1973 I wrote a 60-page booklet--"How Sodium Nitrite Can Affect Your Health"--about nitrite that described in some detail its use in food and its hazards to humans. In 1977 I was named to the U.S. Department of Agriculture's Expert Panel on Nitrite and Nitrosamines.

Scientists have known for decades that nitrite is harmful--it can prevent red blood cells from carrying oxygen--and there has long been a concern about limiting human exposure to this chemical. A second kind of hazard was identified in the 1960s. Nitrite, it was found, could under appropriate conditions react with other chemicals (secondary amines) to form nitrosamines, tiny amounts of which have caused cancer in several species of animals. Scientists presume that humans would react to nitrosamines the same as do our distant animal relatives. In the past few years and even months, FDA-sponsored studies at MIT have shown that nitrite itself--without forming nitrosamines--might cause cancer.

The response of the federal government and private industry to the acknowledged hazards of nitrite has been discouraging. For seven years, the Department of Agriculture has acknowledged that bacon frequently--and other foods occasionally--contains small amounts of nitrosamines, but until 1977 there was no real effort to reduce the hazard. I think the real question this Committee should be investigating is why FDA and USDA have been so negligent over the years. This negligence is most apparent when you look at the regulatory history of foods in which nitrite has been completely unnecessary or from which it may be rather easily eliminated.

Baby food companies have admitted since the beginning of the controversy that their canned products are sterilized and that the nitrite served only a cosmetic and flavoring purpose. Despite this admission, the government did nothing to stop the addition of nitrite. Instead, it was pressure from public interest groups that induced the baby food industry to stop using nitrite. Deviled ham, Vienna sausage, and potted meat food products are other sterilized cured meats that contain added nitrite.

At the 1971 nitrite hearings held by the House Inter-governmental Operations Subcommittee, it was revealed that nitrite would not be necessary in certain cured fish if the fish were heated to a slightly higher temperature during processing. Again, the federal government did not follow up by requiring the industry to modify its processing method. Canadian regulations do not permit the use of nitrite in fish.

When discussing with industry or government officials the possibility that nitrite could be replaced by safer chemicals or physical processes, or left out entirely, they staunchly defended nitrite and generally contended that it was irreplaceable. Consequently, to my knowledge, there has never been a serious, systematic, earnest effort to reduce substantially or eliminate the addition of this noxious chemical to food. If I may hazard a guess as to why the meat industry has for the past 15 years made unthinkable the possibility that nitrite promotes cancer and might be banned, I think that the industry desires nitrite not so much for its preservative effects, but for its effects on color and flavor. If a chemical, such as sorbic acid, or processes such as sterilization, partial pre-cooking or freezing, were used as a preservative instead of nitrite, some cured meats might look or taste slightly different... and sales might drop. This, I think, is what the industry fears, and is at the heart of its resistance to regulatory measures that would further protect the public's health.

Throughout the controversy about nitrite, the meat industry has maintained that botulism will be breaking out all over, if nitrite is banned. However, there is little information that would enable one to determine the risk of botulism. I think that botulism is much less of a threat than the meat industry would lead one to believe. For instance, chicken roll is sometimes produced without nitrite, but is quite similar to bologna or hot dog; it is vacuum-packed, creating conditions in which Clostridium botulinum might grow.

However, botulism has never been caused by this product, and USDA continues to allow its production. Similarly, bratwurst is a frankfurter-like product made without nitrite. Botulism has never been caused by it, either. Furthermore, more and more companies have been producing nitrite-free bacon and hot dogs, again with no apparent problem.

Part of the recent controversy about nitrite concerns the finding that bacteria within the human body can convert nitrate and other nitrogen-containing compounds to nitrite. The exact extent to which this occurs is not known (and varies from person to person). It is conceivable that humans are exposed to as much or more nitrite through this route as by nitrite added to food, but several considerations indicate that the nitrite added to meat remains a significant threat to consumers:

* Nitrite in food is much likelier than nitrite secreted at 3:00 in the morning by the salivary glands to react with amines in the stomach to form nitrosamines; in other words, not all nitrite poses the same risk.

* Nitrite seems to "disappear" after it is added to meat; it is quite possible that it is bound in some form that can later produce nitrosamines.

* The high temperatures of cooking promote the formation of nitrosamines from the nitrite in food.

* Finally, our goal should be to minimize risks wherever possible; the finding of an additional risk should not excuse the presence of a risk discovered earlier.

In the past six or seven years countless newspaper and magazine articles and radio and TV stories have informed the public about problems related to sodium nitrite. Partly because nitrite promotes cancer (and partly because most nitrite-containing products are extremely high in fat, and thus promote heart disease), millions of people have begun eating less cured meats. One major commodity speculator has told me that he estimates that the "nitrite scare" has reduced the price of hog bellies by about 10 cents a pound, or fifteen percent. This translates into a loss to farmers of $200 million a year. This loss should have, but has not, been an incentive to make bacon a safer product. The meat industry has only itself to blame for these lost sales and, if nitrite is not phased out in the near future, will subject itself and its products to continued criticism, controversy, and lost sales in the future.

I strongly urge this Committee to learn about the various practical alternatives to nitrite that are currently or shortly will be available. The Department of Agriculture recently sent me a list of 17 federally-inspected meatpackers that produce one form or another of nitrite-free meat. Additional plants may be under state inspection. Furthermore, some companies may be using processes that would produce safe meat without nitrite. For instance, some bacon is partially pre-cooked at a manufacturing facility and then shipped to cafeterias. In fact, perhaps this Committee could persuade USDA to test alternative processes and chemicals that might replace nitrite. Having proof that sterilization or some other process provides protection against botulism in the various kinds of cured meat would smooth the way to phasing out nitrite.

I believe that nitrite could be eliminated from cured meat and fish products over the next 18-24 months without risking the public's health and without significantly increasing the cost of food. The alternative to making these changes is to continue to expose the public to the risk of cancer, a risk which the FDA estimates to be thousands of lives.

Thank you very much.

Mr. JACOBSON. One thing I would like to say is that I do not think any of us, and I, certainly, have it in for sodium nitrite. I frankly do not care one way or another about sodium nitrite. I never had any prejudice about it.

There have been a number of questions which have risen about sodium nitrite over the last 10 or 15 years regarding the formulation of nitrosamines and more recently whether nitrite itself promotes cancer.

If somehow the nitrite could be neutralized so that it does not pose a risk of forming nitrosamines or causing cancer, then it may be perfectly appropriate to leave it in food and the public could be reassured that even though the product does contain nitrite that somehow it has been captured or neutralized so that the product is safe. Then people would understand that these meats are safe.

We have not gotten to that point. I do not think scientists have found ways to completely neutralize detrimental and questionable steps of sodium nitrite.

Mr. ROSE. But we have gotten to the point of people not injecting nitrite in cured meats, do you think?

Mr. JACOBSON. If somehow this nitrite could be neutralized or captured in some way in the meat, then maybe it would be OK to consume the nitrite. As it is now, though, I think nitrite does pose a problem.

In the range of problems in society, it is a moderate problem. I think there are bigger problems. A lot of people die in automobile crashes. People die of heart disease and from smoking too many cigarettes. These are far bigger problems.

However, I think nitrite added to meat and poultry products does pose a small risk. I think people out there have perceived there is a risk.

There have been congressional hearings dating back to 1971. The Food and Drug Administration argued there is a risk. Various scientists argued there is a risk. People are eating less cured meat.

If you do not want to think about the health problems to the general public, it is worth considering the economic impact on hog producers, in particular. Hog farmers are getting less money for their hogs than they would if there were no problem with nitrite.

A Chicago commodity speculator estimated what hog bellies would be selling for. When you add up the decreased income to producers, it comes to about $200 million a year. Did you hear that? It comes to about $200 million a year that hog producers are not getting because, partly, anyway, of this perceived threat by the public. There is certainly another reason to eliminate the use of nitrite as much as possible.

Ms. Haas talked about alternatives to nitrite. It seems sometimes you can leave it out.

I would like to supply the subcommittee with some chicken roll.

Mr. ROSE. I appreciate that, but for the last 3 months I have not eaten any meat at all.

Mr. JACOBSON. I am not offering it to you to eat.

Mr. ROSE. I have been on a diet which caused me to lose 50 pounds. We will report this in our transcript.

Mr. JACOBSON. These products do not contain sodium nitrite. I purchased this at a supermarket in Washington. I asked specifically

whether I should handle this differently from normal bologna. They said: "No, handle it the same way."

There have been no problems of botulism from this kind of product. If Members of Congress believe there is a problem, it might be worth urging the Department of Agriculture to require the addition of nitrite to this product as well, but this and many other products can be made quite easily without nitrite at all.

Mr. ROSE. Then you would stand for the proposition that the poultry industry is alive and well and has nothing to fear?

Mr. JACOBSON. It seems the poultry industry is better off than the cured pork and beef industry.

Mr. ROSE. That would seem to be the conclusion I have reached also. This was to be a poultry hearing, but all we have heard about is red meat. My poultry industry friends should be smiling a little bit at this point.

Mr. JACOBSON. There have been a few other questions I would like to address briefly. One is the question of nitrite in vegetables. This is certainly a problem if some of the nitrate is converted to nitrite and posing a threat to people.

I suggested in the past that the Department of Agriculture investigate to determine whether there are ways to reduce the nitrate levels in these extremely nutritious vegetables, the kinds of foods people should eat more of.

Mr. ROSE. Did you question Dr. Tannenbaum's statement earlier today that nitrite from vegetables is of the same chemical composition as nitrites from food additives?

Mr. JACOBSON. The nitrate in vegetables is different from the nitrite in cured meats.

Mr. ROSE. In the body it breaks down to form——

Mr. JACOBSON. Some will be converted to nitrite. That nitrite is essentially the same as the nitrite added to cured meat.

Mr. ROSE. But it is not the same?

Mr. JACOBSON. Consider that the bacon, for instance, is fried at a high temperature. There is an opportunity for the nitrite to form nitrosamines, whereas celery is not normally fried.

Mr. ROSE. So the culprit is nitrosamine and not the nitrites?

Mr. JACOBSON. They are both culprits. As a couple of people here suggested, it is easier to take care of the nitrite added to certain cured meats, whereas it is difficult to take care of the nitrite that is naturally present or that is converted from something that occurs naturally. What we should be trying to do is minimizing these risks.

Mr. ROSE. Then mothers who have telling their children to eat their spinach have been exposing them to an unnecessarily high quantity of nitrite? That is the only logical conclusion I am drawing.

Mr. JACOBSON. They would be consuming less nitrate and nitrite if they ate apples instead of spinach. It is possible that if less nitrite fertilizer were used and these vegetables grown in different regions of the country, the nitrite levels would be less.

Mr. ROSE. I tell you what I think we are upset about, and you have heard this over and over again. I went to school and studied a great deal of chemistry, and Dr. Martin has his Ph. D. in organic chemistry.

We do not want to expose people in any unnecessary risks, but we resent any effort that negates—from an intellectual standpoint—the

right that you can pursue whatever course of action you wish, because this is a free country. I will be sure that as long as I am here it stays that way so that you may say whatever you wish to say about food and consumer interest.

However, to go down the road of regulation and this discussion of alternatives to nitrites before the jury is adequately in, this does not hit me as being in the best interest of all of us. I am sorry. I am stuck at that place in this discussion.

We do not know all we need to know about nitrite levels.

If what Dr. Tannenbaum says is correct, and I have no reason to believe that he is not very sincere in what he has presented to us here today, we do not know all we need to know about nitrosamine levels in the body.

Mr. JACOBSON. I agree a tremendous amount of research should be done, but we will never know all the facts. Some of these questions are quite easy——

Mr. ROSE. While we are working through that, we are tearing up certain industries in the minds of the American public. I just do not think that is fair.

Mr. JACOBSON. There is certainly a reasonable doubt as to the safety of nitrite. People have perceived that doubt and are buying fewer products.

I think it is incumbent on the meat industry to provide safer products. It would certainly be beneficial to producers.

Mr. ROSE. Doubts have been placed there carefully by people reacting. You are shaking your head, Ms. Haas.

Ms. HAAS. I think the dilemma is a question of how proceedings of the FDA and the USDA take place.

Here you have a 3-year study, a major investment of the Food and Drug Administration, to get the best quality of scientific research on a controversial issue. It was done and brought in.

Are they supposed to keep that a secret from the public?

Mr. ROSE. No.

Ms. HAAS. You cannot expect them to.

Now they say they will not take any final action for 15 months, even if they decide to take an action. The process will be open. Everybody will have a chance to comment. Everybody will have an opportunity to get their positions heard.

Do you choose to have that in a closed-door session as well?

Mr. ROSE. No.

Ms. HAAS. In order to have open Government we have to realize that there will be some anxiety. That is what I think Dr. Jacobson was relating to. It is better for us to resolve this nitrite issue in this 15 months interim time than to let it fester, because it is festering and it is affecting the industry as much as it is affecting consumer anxiety.

It is there, and it is there as much because of the emotional reaction on the part of all those affected by them rather than trying to come forth and facing the issue and trying to face what we believe should be research and alternative developments.

Mr. ROSE. What would you say if it became evident in the months ahead that the nitrite level in human beings that are caused by food

additives are so insignificant so that when compared to salivary nitrite and intestinal nitrite it would not warrant our concern?

Is not that a possible conclusion?

Ms. HAAS. From what I have seen now, of course it is possible. At the same time, from what I have seen, and because of the arguments we have given, that is not the case.

We cannot control everything in this world. However, we do have the ability to control deliberate additions to our foods. That is the case here. This is something that can be done. We can act about what is put into our food.

Mr. ROSE. Do you not understand and agree that dehydrated foods place nitrite levels into our system, dehydrated foods are an additional source of nitrites?

Ms. HAAS. I think that is what you would call a beside-the-point thing.

Mr. ROSE. Refrigerated fresh vegetables add to the nitrites in vegetables. Is that not correct?

Ms. HAAS. Yes. Dr. Jacobson addressed himself to that. If there could be a way to address that problem, we should address that problem.

Mr. ROSE. Has your organization warned people about the dangers of refrigerated fresh vegetables to the extent that you have attempted to warn people about nitrites?

Ms. HAAS. We are not a warning organization. Our responsibilties do not follow that line.

Mr. ROSE. Has the Community Nutrition Institute placed the same emphasis on the nitrite problems of food additives that exists from nitrite ingestion which comes from refrigerated fresh vegetables?

Ms. HAAS. I think in any discussion of food safety we would have. Yes, we would present that as a statement of fact because we believe in giving all sides of the issue and all the information available.

At the time we still feel that because nitrites in food, bacon, what have you, is a deliberate addition, the Government has a responsibility in that area.

We would tell people, particularly if they ask, because certainly it has been in the media. We would say: "Yes, there is nitrate in spinach."

Mr. ROSE. Either you should emphasize those points equally well or change the name of your organization.

Let us hold up right here and continue with this when we come back from voting on the floor.

[Recess taken.]

Mr. ROSE. The subcommittee will be in order.

I thank our witnesses for waiting. Mr. Wampler.

Mr. WAMPLER. Ms. Haas, I have one brief statement I wanted to make by way of summary. We thank you and your associates for coming. I suppose where we differ, as I understand your position, is this.

I have yet to hear a witness today say that nitrites cause cancer. We have heard "perhaps," "evidence points that way," and so on.

As I understood your statement, you said on the basis of the MIT study, you thought that nitrites should be banned.

I happen to hold a different view. I think that is an inconclusive study. I certainly agree with you that it ought to be out in the public domain and debated. It should have peer review.

As far as I am concerned, and I recognize there are statutory laws that the regulatory agencies have to work within, but what we want is positive and conclusive proof before we take precipitous action that would substitute what we now have, nitrite-treated foods, which we know are safe from botulism, and something we have not mentioned in the line of food products that you are suggesting is the high rate of spoilage and deterioration, which would make them unfit for human consumption.

These are things I want to be convinced of.

I have not heard any evidence here today which suggests this study is conclusive. Until such time, as far as I am personally concerned, I think we should continue research and development and possibly lowering the levels of nitrites used, but to ban them, I think, would be the height of folly at this time and inviting disaster.

Ms. HAAS. I will allow Mr. Smith to address one point first.

Mr. SMITH. In your consideration, you should realize that the fatality rate for botulism cases is only around 10 percent. That is certainly a high rate. We should also consider the number of botulism cases annually. I am not sure of the exact figure.

Mr. WAMPLER. We have a study which suggests from time to time the mortality rate has been rather extensive.

Mr. SMITH. We will never ever be able to walk through the cancer ward and pinpoint those people who have eaten too many hotdogs, but when a test and a review is made by the FDA, valid and creditable, one which shows nitrite additives posed as great a threat as they do, action must be taken. We are not asking for precipitous action, but action taken because of the hazards shown.

Mr. WAMPLER. I do not think it has been demonstrated, not to my satisfaction, at least. The study itself, from a scientific viewpoint, is not valid and conclusive. Therefore, until such time as it has a peer review and its credibility is established beyond any reasonable doubt, it is not the basis for action.

Ms. HAAS. That is exactly where the policy debate will center. I think at the same time—well, you understand our position.

Mr. WAMPLER. Yes.

Ms. HAAS. I want to underscore the position that we feel a phasing ban is possible. We do not want to see any economic dislocations for producers or processors. We want this to be done in as reasonable a manner as possible with as much possible chance for lack of disruption and lack of increased consumer cost as possible.

As Dr. Kennedy so well stated today, he even felt a ban was called for. His letter of explanation was quite clear.

I think the peer review—and this is important because we share the view that peer review is important—peer review will come during the regulatory process. No action will be taken prior to the time that scientists, both in Government and in academia, can look at that study and decide on the validity of that study.

However, I do believe, because policy is often that, two different views, there will be differences that will never be resolved.

If that is the case, we can err on the side of consumer risk.

Mr. WAMPLER. Again, this brings on a much greater question that will have to be resolved sooner or later by Congress, the question of whether we are going to weigh risk versus benefit or going back to the rigid language that there can be no risk at all.

Mr. HAAS. A most difficult point, and we are already in that policy discussion. It has been going on since saccharin and before that, the most difficult thing to assess is the health implications for consumers and the health care costs, not only in dollars, but in lives.

Even if we can save people the horrible chance of being in that cancer ward, we have done something good.

If we can provide ample opportunity to protect against botulism by alternatives, information, and education, we have helped society as well.

Mr. ROSE. I genuinely appreciate the expression of love that you have made in your statement there. I think that is truly what it is: A concern and a care about people. I appreciate that very sincerely.

However, I like to think that I am capable of the same consideration, care, and concern, for my brothers and sisters in this world.

Just as you will never know by walking through the cancer ward who, ate too many hotdogs, neither will you know who ate too much spinach or lettuce or whatever, or who hated themselves too much and gave themselves cancer, if you want to get into that area of stress.

Let me quote to you in closing the GLP Review Committee. This is an actual Department of Health, Education, and Welfare committee report which reviewed the Newberne data. I have a copy of that, also:

> Because of the above, coupled with the observation of rampant lack of adequate control on the studies, we conclude that the studies observed are of questionable integrity.

Those are not my words, but HEW's words.

Ms. HAAS. That is also standardized procedure, to say there are questions. There are always questions which remain.

In other periodicals I may have reviewed, I have seen that absolutes do not always exist.

Mr. ROSE. What do you think of Paul Newberne's own statement in his final report on contract FDA 74,7181, "Nitrite in the Rat," made in 1978, page 13:

> While the results do not permit assigning nitrite, approximate carcinogenic role in the induction of lymph node reticular tumors, an enhancing effect is evident. Thus, nitrite appears more a promoter of the neoplastic process than an inhibitor.

Any reaction?

Ms. HAAS. I will let Tom Smith answer that.

Mr. SMITH. The only thing I would say is that Dr. Newberne in his testimony to the Senate Committee on Agriculture cleared up some of the possible misconceptions which may have arisen from that statement and from others, where he was quoted in various press comments.

He said:

> The study fully justified a phased-out usage of nitrite, phased-in ban. The study was creditable and the studies did not take away from that creditability.

Dr. Kennedy has been of the same view.

Mr. WAMPLER. Did not Dr. Newberne say he did not favor phasing out until there was a suitable substitute?

Mr. SMITH. He said the nitrite should not be used in any products where its purposes were only for color and taste. Beyond that, I believe he said a phasing out of the use of nitrite.

Mr. ROSE. Should not be phased out until there is a suitable substitute. Let us not get off that so quickly.

Are you sure he did not say that?

Mr. SMITH. I am willing to look at any statement he made.

Mr. ROSE. That is what he said.

Ms. HAAS. This morning Dr. Kennedy read his letter, Dr. Newberne's letter, to the FDA, which did clarify that position. He talked of support for a phased-in ban. I did not recall the additional words "until there is a substitute."

We will have to check this morning's record. It has been a long day.

Mr. ROSE. I will be guilty of what I am accusing everybody else of, and that is talking without having data before me.

Folks, thank you very much. I hope we have shed some light and not just heat.

In the interest of time, I want to ask whether we can move along more rapidly here.

We have Dr. Julius Bauermann. Dr. Bauermann represents the Special Poultry Research Committee.

Do you have a statement for the record?

Dr. BAUERMANN. I have a prepared statement, Mr. Chairman. When I arrived here this morning, the sign on the door said this was the Dairy and Poultry Subcommittee.

Mr. ROSE. You can turn it into that quickly by your presentation. We have not heard much about that.

Dr. BAUERMANN. My concern was that I listened to a lot about red meat and bacon. I would like for a moment to have a squawk or a gobble in behalf of the poultry industry.

Mr. ROSE. Without objection, your written statement, in its entirety, will be placed in the record at this point.

[The prepared statement submitted by Dr. Bauermann follows:]

STATEMENT OF JULIUS F. BAUERMANN, CHAIRMAN OF THE TECHNICAL COMMITTEE OF THE SPECIAL POULTRY RESEARCH COMMITTEE

TESTIMONY OF THE

SPECIAL POULTRY RESEARCH COMMITTEE

BEFORE THE

SUBCOMMITTEE ON DAIRY AND POULTRY

OF THE

HOUSE COMMITTEE ON AGRICULTURE

SEPTEMBER 28, 1978

Mr. Chairman, my name is Dr. Julius F. Bauermann and I am Chairman of the Technical Committee of the Special Poultry Research Committee and Director of Food Technology for Horace W. Longacre, Inc., of Franconia, Pennsylvania. Appearing with me today are George B. Watts, President of the National Broiler Council, Lew Walts, Executive Vice President of the National Turkey Federation, Lee Campbell, Vice President of the Poultry and Egg Institute of America and Philip Olsson of Collier, Shannon, Rill, Edwards & Scott, counsel to the Special Poultry Research Committee.

The Special Poultry Research Committee is an ad hoc organization formed last year to respond to questions raised by the United States Department of Agriculture and the Food and Drug Administration concerning the status and safety of nitrite use in poultry products. The principal activities of the Committee have been the submission and support of a food additive petition filed with the Food and Drug Administration and initiation and maintenance of a lawsuit in the Federal District Court in Arkansas challenging the United States Department

of Agriculture's determination that "prior sanction" does not exist for the use of nitrites[1/] in poultry.

Nitrite Use in Poultry

Nitrite has been used for many years as a curing agent in a wide variety of poultry products. Poultry products which contain nitrite include smoked turkey, smoked chicken, chicken franks, turkey franks, chicken bologna, turkey bologna, turkey ham, turkey salami and smoked turkey parts. USDA has approved more than 3,000 labels for poultry products cured with nitrites.

Nitrite is used in these poultry products, just as it is in red meat products, for its preservative properties, particularly because nitrite use inhibits the growth of botulinum organisms and other food pathogens. Nitrite also provides the distinctive flavor and color of these cured products. Although alternatives have been suggested for preserving poultry and red meat, they are not effective or practical, on the basis of present knowledge, to inhibit the growth of botulinum organisms. Any action taken at this time to prevent the use of nitrite as a preservatiive of poultry or red meat would be based on inadequate knowledge, and would have a severe adverse economic effect on industry. Such action would eliminate effective means of preventing botulinal poisoning.

Economic Impact.

To date, the U.S. Department of Agriculture has not developed an economic impact analysis regarding a phasing out of nitrite use in poultry. Our committee, however, believes the economic impact of such a phase out would be severe. Approximately 500 poultry plants will process nearly 10 billion pounds of chicken and 2.1 billion pounds of turkeys under federal inspection

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1/ Sodium nitrite and/or potassium nitrite.

this year. Based on U.S. Department of Agriculture data, it is estimated that an additional 1,100 plants cut up and/or further process chicken and that an additional 400 plants cut up and/or further process turkeys.

Less preferred broiler parts, such as necks and backs are obviously more difficult to market than drumsticks, wings, thighs, and breasts. These less preferred parts are further processed into chicken hot dogs, chicken bologna, and similar products, or used as up to 15 percent of the ingredients with red meat in hot dogs or bologna. These further processing uses enable broiler firms to spread production and processing costs over a larger volume of product, thus, reducing overall costs and assuring more economical prices to consumers.

Further processing of turkey parts also permits consumers to purchase conveniently prepared and sized turkey products. Cutting up turkey carcasses at plant level enables consumers to economically purchase portions of the turkeys in convenient sizes. Less preferred parts and larger-size turkeys can be further processed into economical, nutritious, wholesome products for consumers.

Combined per capita consumer expenditures for chicken and turkey together were $39 last year. For this $39 consumers were able to purchase an average of 43.3 pounds of chicken and 9.2 pounds of turkey. About 3 pounds per person of young chicken and about 5 pounds per person of young turkey consumption were purchased in a further processed form. These facts clearly point out that utilization of less preferred poultry parts by preparation of cured poultry products has helped to make poultry the best meat value to consumers.

According to USDA calculations, aggregate net returns for broilers, during the five-year period 1972-1976, were $506.8 million, an average net margin of 1.2 cents per pound. For turkeys during the same five-year period, aggregate returns were $329.3 milion or 3.4 cents per pound.

In a recent review of earnings in the broiler industry, Dr. Ray A. Goldberg, Moffett Professor of Agriculture and Business, Harvard University, described the breakeven costs on broilers as "so close to the sales price that minor changes in average prices could be the difference of (sic) major profit or loss operations. These thin margins mean that efficiency of fractions of a cent per pound are critical competitive tools as are marketing savings or product differentiations"[2/].

A survey of 27 poultry firms conducted by the Special Poultry Research Committee for 1977 produced the following data concerning the quantity and dollar value of cured poultry products.[3/]

	Pounds Marketed -pounds-	Processor Sales Value - dollars-	Estimated Retail Value -dollars-
		Million	
Cured and/or Smoked Turkey Products	93.7	92.9	128.3
Cured Chicken Products	32.7	18.1	25.9
	126.4	111.0	154.2

2/ "New Cycles in the Broiler Industry", paper presented to National Broiler Council Annual Conference, Washington, D.C., October 14, 1976.

3/ The survey included 27 poultry firms known to be producing and/or marketing significant quantities of cured poultry products.

Thousands of employees are involved in production and processing of these products at the 27 poultry firms surveyed. If the marketing of cured poultry products were halted, these employees would lose their jobs. These 27 firms surveyed have a total of 30 plants processing cured poultry products, with with an estimated aggregate investment of $15.3 million in production and processing equipment. This figure does not include buildings. If the use of nitrite in poultry products is prohibited, the impact on the poultry industry would be severe. In the turkey industry, the alternate use of parts now being cured would be as fresh and frozen non-cured parts. There is no indication that this market could absorb even a small fraction of the volume of turkey meat now being marketed as cured products. Necks and backs would be diverted into animal feed at a value of less than 5 cents per pound. Substantial producer and processor losses would result. These losses would force a substantial reduction in turkey production , cause many growers to go out of business, thereby, creating significant increases in the cost of turkey and turkey products to consumers. Obviously such a circumstance would add to the inflation factor in the food sector. There would be an equally severe impact on corn and soybean markets if nitrite use in meat and poultry were banned.

Assuming a price-flexibility for turkeys at the processor level of 2.0[4/], that is, the percentage change in the price of turkeys which accompanies a one percent change in turkey supplies, the loss to all turkey industry processors attributable to nitrite ban would be $218 million at the 1977 output level, and substantially more at the 1978 level.

4/ See price-production relation discussions in The Turkey Industry Structure, Practice, and Costs, Marketing Research Report No. 1000, Econ, Res. Serv., USDA June, 1973; "An Economic Analysis of the U.S. Poultry Sector, "Dale Heien, American Journal of Agricultural Economics, May 1976.

Concerning the impact on the broiler industry, it is estimated that 82 million pounds of the 1977 young chicken production was used for cured products. The primary ingredient being used in cured chicken products, such as chicken hot dogs and chicken bologna is meat from chicken necks and backs. Currently, the USDA reported market price for chicken necks and backs is about 10 cents a pound. However, when the necks and backs are diverted into rendering their value decreases to about 4 cents a pound. Thus, if the 82 million pounds of chicken necks and backs had been diverted to rendering rather than valued at the fresh market price equivalent, the loss to the chicken industry would have been about $4.9 million in 1977. These data do not, however, take into account the adverse price impact on the rendering market which would be caused by the greater supply of necks, backs and frames.

The aggregate impact of a nitrite phase-out on the turkey and young chicken industry would be approximately $223 million. This calculated economic cost does not include the disruptive effects on supply industries, such as corn and soybean producers, packaging suppliers, drug companies, building contractors, transportation firms, and others. While the primary and severest impact would fall upon poultry production and processing, the impact on supplier industries would also be significant. Eventually the most important impact would be on consumers through higher retail costs.

SPRC Activities

On November 1, 1977, the Special Poultry Research Committee (SPRC) filed with the FDA a "Request for an Interim Food Additive Regulation for the Use of Sodium Nitrite in Poultry Products." The petition was filed in response to an FDA notice published in the September 2, 1977 Federal Register (42 Fed. Reg. 44376) requesting information and data concerning the use of sodium nitrite in poultry.

Included as part of the SPRC petition were results from scientific studies conducted for SPRC demonstrating the need for and safety of nitrite use in processed poultry products. Research conducted by the Swift Research and Development Center establishes the effectiveness of nitrite in inhibiting the growth of botulinum organisms in poultry. Research conducted by the Technical Services Corporation demonstrates the absence of nitrosamine formation in poultry products cured with nitrite.[5/] These submissions are currently being studied by the Food and Drug Administration.

On November 2, 1977, SPRC filed suit against USDA and FDA in Federal District Court in Arkansas seeking declaratory and injunctive relief. The lawsuit challenges USDA's determination that the use of sodium nitrite in poultry is not covered by a "prior sanction" within the meaning of the Food, Drug and Cosmetic Act.

Further comments on either the Special Poultry Research Committee petition or the lawsuit would be inappropriate at this time since both actions are still pending.

In conclusion, the Special Poultry Research Committee urges the Subcommittee to carefully monitor the activities of the FDA and USDA concerning nitrite use in cured poultry, in poultry products and meat products. A total ban or gradual phase-out of nitrite use would clearly cause severe economic hardship to the poultry industries and to consumers. The risk of botulinal poisoning is substantial and has long been accepted by the scientific community while the hazards of nitrite use are speculative at best. In the absence of more accurate information and the development of an effective and suitable substitute, nitrite use should not be prevented.

The Special Poultry Research Committee appreciates this opportunity to present its views before the Subcommittee.

5/ FDA data also demonstrate the absence of nitrosamine formulation in poultry products cured with nitrite.

Mr. ROSE. Thank you, Dr. Bauermann. Mr. Wampler?

Mr. WAMPLER. Thank you for your very comprehensive statement.

On page 2 of your statement you said:

> Although alternatives have been suggested for preserving poultry and red meat, they are not effective or practical on the basis of present knowledge to inhibit the growth of botulism organisms.

You heard the earlier testimony about the use, and this applies basically to the red meat industry, the use of sorbic acids.

Is there any reason you could not use this as a preservative in poultry or turkey products?

Dr. BAUERMANN. Those poultry products that have sodium nitrite in them now have ascorbic acid or sodium ascorbate, one of those derivatives.

The sorbic acid tests, which have been alluded to before, which were run at the University of Minnesota, show promise.

However, this food additive is not approved for use in poultry products or any but a few foods at the present time and certainly not at the levels that seem to be developing to be effective.

Mr. WAMPLER. The figure I recall was 40 parts per million of nitrites.

As I understand it, is that level too low for preservatives in poultry products?

Dr. BAUERMANN. Yes. The tests we ran with the food additives showed we need something in the neighborhood of 120 parts per million in nitrite in order to get an effect against botulism or toxin production.

Mr. WAMPLER. I believe you mentioned the fact that the U.S. Department of Agriculture has not yet developed an economic impact statement, what the proposed action would take.

Dr. BAUERMANN. That is right.

Mr. WAMPLER. This subcommittee is concerned about that. We are anxiously awaiting that study.

Dr. BAUERMANN. That is correct. I do not believe such a study is contemplated at this time, Mr. Wampler.

Mr. WAMPLER. To the extent we can. we will insist that be part of the regulatory proceeding. I believe Mrs. Foreman indicated it might be forthcoming along with all other types of impact statements.

Dr. BAUERMANN. There is a statement in draft form being circulated concerning pork, but one has not even been begun on poultry. I have that on excellent information.

Mr. WAMPLER. You are perhaps right. I was referring more to pork, perhaps, and perhaps she was.

Dr. BAUERMANN. I think so. There has been a tendency today to use pork as an example for poultry. This is not really true in every instance.

Mr. WAMPLER. Obviously your position is, then, that the Department of Agriculture should develop an economic impact statement and analysis regarding phasing out use of nitrite in poultry?

Dr. BAUERMANN. Yes, sir.

Mr. WAMPLER. Thank you.

Mr. ROSE. Let the record show that Mr. Wampler has eaten some bacon and he is still alive.

I would like to thank our witnesses for being here. We will excuse you at this time.

Dr. BAUERMANN. One more comment.

Dr. Jacobson showed you two poultry rolls. My company happens to manufacture one of those products.

I would like to correct some erroneous assumptions made by Ms. Haas' testimony.

Both of those products are made in identical fashion by two companies, one being the one for which I work.

The products are fully cooked to 180° F. before sliced and vacuum packed. They are not vacuum packed prior to being put into that sliced form, but they would be fully cooked.

The problem is that when those products are reheated, they fall apart because they are made in a thermal plastic process. It would melt. You would have what looks like a gravy and piece of meat. Obviously, if you tried to make a frankfurter out of the same type of material and put it in a pan to fry, it would flatten out in the pan.

I think the example should not be construed to be typical of nitrite, as nitrite-added products are.

Mr. ROSE. Next we have Mr. Ray Kennedy, president, Floyd Valley Packing Co., Sioux City, Iowa.

STATEMENT OF RAY KENNEDY, PRESIDENT, FLOYD VALLEY PACKING CO., SIOUX CITY, IOWA

Mr. KENNEDY. Thank you, Mr. Chairman.

Mr. ROSE. I believe you have a statement for the record. Please proceed.

Mr. KENNEDY. Thank you, honorable chairman and members of this subcommittee.

I am the president of a pork packing plant and a nitrite-free processing company. I am also the president of a research and development company which has been working on nitrite-free products for the last 12 years.

All of these companies are located in Sioux City, Iowa, the No. 1 hog market of the United States.

I have been concerned about the long-range effects caused by needless delays in recognizing the correction of an obvious problem. This is not only damaging our industry's image; but the hog producer, who has become the pawn of our industry, through price manipulation of live hogs in the nitrite controversy.

The one exception to this is the cooperatives who kill off on a yield basis and share their profits with their producers. However, like most independent processors, we have a lot at stake.

We kill from 3,000 to 5,000 head of hogs in our plant and we are the inventors of a broad range of creative, no nitrite alternatives for cured meat items. We do duplicate the flavor of nitrite with safe spices.

These products, by comparison, have equal or longer shelf life than the traditional types, but shelf life is not nearly as important as superior quality with profitable sales that brings peace of mind for the consumer who will know that our industry has finally done something to allay their well-founded fears of nitrites.

Today we are successfully marketing a variety of no-nitrite bacon alternatives. We are not challenging the debatable theory of nitrite versus botulism, but choose to eliminate both botulism and nitrites in favor of modern processing methods and careful handling to the customer. We have the ability to extend the shelf life of our products to over 1 year without any refrigeration—using no nitrites and no fear of botulism.

It took a new administration under Ms. Foreman's direction to investigate our claims. The previous administration approved our bacon 7 years ago. We successfully challenged the sliced bacon market for 1 year, then were removed from the market by the USDA, and kept off the market for 6 long years.

The present administration approved our bacon as Bakon from December 1977 to July 1 of this year. It is now know as Por-Kee Bacon Alternatives and other products.

We have broadened our R. & D. into all traditional types of cured meat items, including beef and poultry items.

The unity or common front posture of those who oppose the ban on nitrites has backfired causing them to lose credibility among their own membership as they failed to support their long drawn out claims for eliminating nitrosamines in nitrite-colored fried bacon using 120 p/m of nitrite coloring.

Since the establishment of the Por-Kee name on August 1 of this year for all types of nitrite-free products, we are licensing small, medium-sized and large processors who come to us. These formerly deluded processors now have the vision to see our process as a new wave of the future, and the salvation of their business.

Our survey of locker plant owners indicate 30 percent to 50 percent of hog producers themselves are requesting locker plants that kill hogs for their own family use to process their bacon without nitrite.

Hog producer groups are now financing expansion programs of our licensed processors in order to protect their own industry in spite of their leaders urging them to oppose the nitrite ban.

We ask no money for licensees or startup help. No processor is too small or too large. We welcome them to join in the national transition, to add their expertise to improve the exciting challenge of a whole new family of nitrite-free meat items for the consumer and for themselves.

By improving productivity, reducing costs and restoring confidence in the marketplace, we increase the sales of meat for the benefit of all members of the meat industry.

The format is ready now, that is today. If the industry fully cooperates, we could expect complete product transition within 90 days for over-the-counter and institutional trade. Retail packaging might take a little longer.

With the serious proven indictments that nitrite is contributing to our national cancer epidemic, and nitrite-free products are a proven reality, ready at once for national processing and distribution.

Poultry producers have no long public record of nitrite use to damage the sale and image of their products. These producers would be wise to examine the sales decline of nitrite-colored bacon before they paint themselves into a corner.

The self-appointed unity leaders have done this to the meat industry through continued delays and misrepresentations that the additional proven publicity brings to the public.

I respectfully appreciate the opportunity to present a positive and beneficial program outlining "The Other Side of the Story."

My wife cooked some samples of the other gentleman's nitrite-free bacon alternative. She is here and she would be glad to cook some of our homogenized nitrite bacon, which is perfectly safe.

This has been sold from coast to coast and is as close to here now as Norfolk, Va. It will be in this market within a period of 3 to 4 months.

Mr. ROSE. Thank you, Mr. Kennedy, for a very interesting and enlightening statement.

Your product, which I saw out in the committee office, appeared to be in a sausage format.

Mr. KENNEDY. The process, which is under patents pending at the present time, is one where we take the entire pork belly area of the hog, not just the cubed-out, sliced, streaky belly that contains 70- to 80-percent fat.

Our bacon contains 80-percent meat. It encompasses the entire meaty belly area of the hog which is normally used for lower-priced sausage products.

In this way we can guarantee the pork producer a higher yield for his hogs, not a lower price as he is being threatened with by our industry.

The price of our product for consumer use, then, is relatively one-fourth of the price of bacon, because the consumer eats four times the amount of bacon per pound with our products as he does with regular streaky belly bacon.

Mr. ROSE. You say your product is nitrite-free?

Mr. KENNEDY. Nitrite, nitrate free.

Mr. ROSE. Does it have any preservatives at all?

Mr. KENNEDY. No. As I said, we have a process under patent pending which we will divulge to any processor who comes with us who uses a combination of homogenizing, processing, thermal action, and freezing, to produce a product that is nitrite-free which we know, by comparison, has as long, or longer, shelf-life than bacon, because we know that bacon, as it is sold today, is truly a fresh product, not a cured meat product.

Mr. ROSE. Thank you very much. Mr. Wampler.

Mr. WAMPLER. We thank you for coming and sharing this information with us.

I recall you said your plant slaughters some 3,000 to 5,000 head of hogs a day?

Mr. KENNEDY. Yes.

Mr. WAMPLER. What do you do with the rest of the carcass?

Mr. KENNEDY. We sell it all fresh.

Mr. ROSE. Thank you, Mr. Kennedy.

Mr. KENNEDY. We are exporting roughly $1 million a week of products to Japan, so so we are in the business of helping our balance of payments.

Mr. WAMPLER. Is this shipped frozen?

Mr. KENNEDY. It is frozen, yes. The Japanese pay for it every week, so it is good business.

Mr. WAMPLER. Do you see a larger potential for this export market than what we now have?

Mr. KENNEDY. There is no question about it. We have lead the way, as far as pork producers are concerned, in producing the product for the Japanese market. Because of the balance of trade, they can pay a little more money to have us taken out the bone and get rid of the fat.

Their concern about fat is as great as mine is in our meat products because cholesterol is a problem as far as health is concerned, and the Japanese recognize this.

In traveling there, you find out that they use pork, but they use it in small pieces and they want pure meat, not fat. Therefore, we struck up the idea with them, through the Small Business Administration's cooperation, that if we were to take the fat and produce lard out of it, just as we do with bacon, we take that fat, which normally is sold to a housewife, and produce needy oil which is needed in underdeveloped countries of the world rather than throwing it away as you do when you fry bacon, but the same thing is true with the product we ship to Japan.

We do not ship them the fat. We ship them the meat. We process the bones locally there, and we process the fat into edible oil.

Mr. WAMPLER. I am glad to hear you say that. Many of us believe potential exists also for beef and other meat products.

Mr. KENNEDY. I believe astute businessmen would find a tremendous market in Japan, not only for pork, but other items, if they went there and talked with the people on their own level and found out exactly what they want, which is what you have to do in business anyway.

Mr. WAMPLER. We have been trying to lower some of the artificial trade barriers so we will be able to do this.

Mr. KENNEDY. We have had real good cooperation through the help of the Small Business Administration in making these arrangements. They have been successful with our company. That is how we can afford to finance this long drawn out battle we have had with the industry with respect to eliminating nitrites.

Mr. ROSE. We appreciate your being here.

We understand Mr. Bedell is your representative.

Mr. KENNEDY. Yes. He has been very cooperative with us. However, he is under the same kind of gun that all of you are.

The pork producer has been mislead through the very fact that he is penalized on prices when the people who contaminate his fresh product are caught. This is what causes the pork producer to be such an advocate of maintaining nitrites in his products. They have been terribly misled.

Mr. ROSE. A good point. Thank you, sir.

Mr. KENNEDY. Thank you, Mr. Chairman.

Mr. ROSE. Next we have Dr. Robert Harkins, vice president for scientific affairs, Grocery Manufacturers Association.

He is accompanied by Mr. Stephen A. Brown, vice president for law.

Mr. Harkins, without objection, we shall insert your statement in the record at this point.

[The prepared statement submitted by Mr. Harkins follows:]

STATEMENT OF

DR. ROBERT W. HARKINS, Ph.D.,
VICE PRESIDENT, SCIENTIFIC AFFAIRS
ACCOMPANIED BY
STEPHEN A. BROWN
VICE PRESIDENT AND GENERAL COUNSEL
GROCERY MANUFACTURERS OF AMERICA, INC.

Mr. Chairman, I am Robert W. Harkins, Vice President, Scientific Affairs of the Grocery Manufacturers of America, Inc. (GMA). Accompanying me is Stephen A. Brown, Vice President and General Counsel of GMA. We are pleased to have this opportunity to present our views on the necessity for risk assessment in food safety policy, particularly in regard to nitrites.

The Grocery Manufacturers of America 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 Wholesome Meat Act and the Poultry Products Inspection Act as they govern the use of food ingredients, and thus ultimately the food products, that may be marketed to consumers. We believe that this is a unique moment in the history of food production and processing and welcome your involvement in this important deliberative process.

It is not our intention today to review with the Subcommittee the history of the use of nitrite nor the story of its safety evaluation. Rather, we will concentrate our attention on developing a systematic process through which the practice of adding nitrite to food can be evaluated. We believe that a careful review of the various elements which surround the nitrite issue can result in a decision that is in the national interest, and one that will afford consumers full protection.

PRECURSORS TO A NITRITE DECISION

Applying risk assessment to the nitrite controversy would require several steps, including the following:

1) Publication of Dr. Newberne's study in the scientific literature so that his results may be subjected to peer review.

2) Assessment by FDA of the quality of Dr. Newberne's experiment. We understand that the Food and Drug Administration has conducted a "Good Laboratory Practices" evaluation of the MIT facility and that certain deficiencies were uncovered. We do not know whether these deficiencies jeopardize the quality of the results, but we believe that such criticisms need to be impartially reviewed. On at least one occasion, when the quality of a study was critical to rulemaking procedures, FDA turned to a third party to resolve the adequacy of the test results. If the Newberne study remains an essential component of the decision on nitrite, this study may likewise demand rigorous examination of its adequacy. Because of FDA's contractual relationship to the Newberne study, and because of its limited stewardship over the conduct of the study, a third party assessment may be the only sound way to assess the quality and adequacy of the study.

3) Review of all of the experimental and clinical data that are available which pertain to the safety of nitrite. There is a tendency in these situations to consider only the last study, casting aside all previous studies which are in conflict with the most recent test. The draft FDA Action Plan on nitrites states:

> A 1958 FDA study of nitrite alone and a similar 1963 German study both concluded that nitrite alone does not induce cancer in rats, but both studies used methods that are inadequate by current standards.

The deficiencies alluded to above need to be clearly set forth. Only

then can the scientific community judge whether these deficiencies compromise inclusion of the results into a comprehensive evaluation of nitrite.

4) Evaluation of the net effect a nitrite ban would have on the nutritional quality of the American diet is needed. Many people depend on nitrite-processed products as an important source of animal protein. We are troubled that these important sources may be lost from the American food supply. What foods will replace these products? What will they cost? Because of these uncertainties, we would ask that the U. S. Department of Agriculture be directed to complete what we will call a "Nutritional Impact Statement," that is, a comprehensive evaluation of the nutritional effects of removing nitrite-cured products from the marketplace. Until such an impact statement is completed, the Congress cannot adequately weigh the risks of continued use of nitrite against the risks of withdrawing nitrite-cured foods from the marketplace.

A "Nutritional Impact Statement" would examine the alternatives to nitrite-cured meats, their availability, their price, and the ability of economically disadvantaged segments of the population to compete for these products in the marketplace. Projections of the time frame needed to complete a substitution should be required in the Statement.

5) Completion of an economic impact statement is needed. This statement would project the costs and timing needed to discover, and receive agency approvals for, alternate ways of curing meat. Many producing interests are likely to be disadvantaged by a restriction or prohibition on nitrite-cured products. While economic concerns cannot surmount the safety of consumers, the government will need to consider

the effect of a nitrite restriction on pork producers, the agricultural community, consumers, and the economy itself.

6) Contemplation of the forthcoming results of the National Academy of Sciences' studies on food safety pursuant to the Saccharin Study and Labeling Act is essential. We would urge the Subcommittee to require FDA and USDA to put in abeyance any regulatory proposal until the recommendations from from the National Academy of Sciences and the Congress are available.

MODIFICATION OF THE DELANEY CLAUSE

It is quite likely that amending the Delaney Clauses of the Food, Drug and Cosmetic Act may be deemed essential. Thoughtful modification cannot occur if all parties feel compelled to act precipitously. Time must be provided for deliberation and consensus. Anything less would shortchange the already buffeted consumer. We believe that the steps outlined here are the minimum steps that should be taken to assure the safety of the American consumer.

We have developed a cancerphobia in this country which has grown beyond reason. The desire of regulatory agencies to be responsive to the concerns of consumers is understandable. Responsiveness, however, demands reasoned discussion and debate. The involvement of others in the scientific community is essential.

Other coutries have not followed the U. S. lead on such controversial issues as cyclamate, saccharin and FD&C Red No. 2. Regulators in these countries are as concerned about the safety of their consumers as are the Secretaries of USDA and HEW. But given the same facts, more modest regulatory proposals have evolved than in the U.S.

There are a number of factors which would affect a final decision on nitrite, only one of which is the current mandate symbolized by the Delaney

Clauses. With nitrite, we may be facing juxtaposed risks of cancer and botulism, depending on the national consensus. Finding a consensus position that balances those two risks requires a substantial deliberative process.

RISK ASSESSMENT

We will direct our remaining comments to a broader discussion of risk assessment. When our current food safety policy was adopted in 1958, few questioned the wisdom of striving to establish a food supply free from risk. Today, the hint that our food supply may contain toxicants is distasteful. In the search for perfection, we have lost a perspective on the realities of our food supply.

In 1958, safety was defined as an absence--or zero level--of unwanted substances. At that time our analytical abilities were measured in mg/100 ml, or mg/100gm, that is, in parts per million. Since then, our scientists have effectively chased zero to parts per trillion. With these new-found skills, our regulatory framework has been rendered nearly inoperable in many ways.

We need a national policy on food safety which addresses the merits and deficiencies of food additives provisions in general and the Delaney Clauses in particular. We believe that the development of risk assessment options is the most important food safety debate of the 20th century. Can our food supply be risk free? While thinking persons understand that all activities have an associated risk, few have the opportunity to weigh the risk.

The Delaney Clauses were well intended. And, with cancer the most feared disease in the United States, the food industry would not create products which pose the hazard of cancer. However, every food is capable

of eliciting some adverse reaction in some consumer. In fact, there are a host of traditional foods under scrutiny today because they contain minute quantities of carcinogenic materials as unavoidable constituents.

If the Delaney Clauses were extended to ordinary foods, and if the search for carcinogens rigorously pursued, our ability to feed our people would be jeopardized. We know that many traditional foods, and essential nutrients such as vitamin A and calcium pose some hazard to animals in experimental situations. Although we can not eliminate all hazards, we have a societal responsibility to minimize these risks.

We believe that the Delaney Clauses should be modified, but not repealed. The thrust of the modification would be to permit risk assessment through a weighing of all the experimental and clinical evidence before a decision is made to approve a new additive or to delist a currently permitted additive.

Our suggested modification is modest in its thrust. Before a food ingredient, color additive, or animal feed ingredient is considered for risk assessment, it would have to fall into one of the following categories:

1. The substance is a unique food ingredient for which no "safer" alternative exists; or
2. The substance is an essential nutrient which can be used to enrich or fortify foods, and must be used by some as a dietary supplement; or
3. Removal of the substance would create a much greater risk to the general public than would its continued use. (Sodium nitrite in cured meat and fish versus the risk of botulism is one such current example.)

The intent of these eligibility criteria is to limit risk assessment to those substances whose use is truly essential. "Essentiality"

should be defined broadly and include substances which are needed for (a) food production, processing, packaging or distribution; (b) maintenance of nutritional value; or (c) palatability and acceptance by the consuming public.

We recommend that the Delaney Clauses be modified to allow the Secretary to take into consideration, for those ingredients which are demonstrated to cause cancer in animals, the following:

First, it is most important to consider the totality of all scientific evidence available on a food additive, including human experience.

Second, one should also take into account the level at which the additive is found to induce cancer in animals, and the amounts humans would reasonably be expected to ingest.

Third, the scientific validity of the animal tests in which the additive was found to induce cancer must be considered. Although many people question the wisdom of using the mouse in carcinogenesis testing programs, the mouse continues to be a preferred species. In addition, despite our utter reliance on a carcinogenesis bioassay program, we generally do not know whether a high level of ingestion in mice or rats for their lifetime is equivalent to a low level exposure in man on an intermittent basis for a much longer time. Studies can and should be performed to analyze how a particular chemical is metabolized by an animal, including the observation of whether or not the animal's defense system is capable of disarming its toxic effects at lower dose levels.

Fourth, it is important to consider the availability and safety of alternative ingredients to serve the same function in food as

the additive under review. So often we focus our attention only on the additive in question. Better safety decisions would be made if all ingredients in a functional class were assessed simultaneously. This would give the regulatory agencies a much needed perspective.

We believe that the application of the above guidelines will provide the regulatory agency, the consuming public and the regulated industry with additional alternatives. The judicious use of these guidelines will forestall the day when the agency is forced to delist the last ingredient in a product category.

CONSUMER INFORMATION AND EDUCATION

Even if a decision to prohibit an ingredient seems necessary, society may still ask to make an alternate choice. That alternative is consumer information and education. Consumers in a variety of ways are telling their government that the choice of whether to use a product or a food ingredient is one they want to make. There are now, and will be in the future, situations where consumers feel qualified to make a decision to use or not to use a product.

To make an informed choice, consumers must be aware of the presence of an ingredient. Awareness combined with appropriate education about the projected health risks arms the consumer with information to make an informed choice. Labeling of saccharin-containing products puts consumers on notice. Labeling of nitrite-containing foods would also put consumers on notice. However, this is only half the task. What is still needed is an educational program which frames the relative risks of consumption and avoidance of saccharin or of nitrite so that an informed decision is possible.

If one consumer prefers to eat nitrite-cured bacon, is it the responsibility of the government to ban this product? Our experience with prohibition suggests that there is a better alternative. The alternative is one of consumer information and consumer education.

Mr. ROSE. Thank you, Dr. Harkins, for your presence and your testimony. Congressman Wampler?

Mr. WAMPLER. I have no questions.

Mr. ROSE. I would like to thank all of the witnesses who have participated in these hearings today. I believe we have uncovered some interesting devices and interesting lack of information about this subject.

I hope everyone will read very carefully the work of Steven R. Tannenbaum. I believe we will be hearing from him in the weeks ahead.

Without objection, I would like to insert in the record a statement by Stephen F. Krut who is the assistant director of the American Association of Meat Processors.

If there are no further questions or further comments from our witnesses, these hearings will be adjourned.

[Whereupon, at 4:05 p.m., the subcommittee adjourned].

[The statement referred to above and the extraneous material submitted to the committee follow:]

35-883 O - 79 - 11

September 15, 1978

STATEMENT ON NITRITES

Stephen F. Krut
AMERICAN ASSOCIATION OF MEAT PROCESSORS

My name is Stephen F. Krut. I am Assistant Executive Director of the American Association of Meat Processors, a non-profit trade organization representing approximately 1400 diversified small, independent, meat plant operations in nearly every state, with an average of approximately 10 employees each. AAMP is the nation's largest red-meat processing trade organization in terms of membership, and serves small businesses similar to nearly 18,000 meat plants throughout the country.

We have heard reports on the impact of a nitrite ban. Some assert that cured meats represents a $12.5 billion a year industry in this country. But there is an even larger cost than the value of the cured products involved. First, there are the physical plants that could be rendered useless by such a ban and their real worth would certainly total in the hundreds of millions, if not billions. And, since smaller plants tend to be more specialized, their physical facilities are not readily adaptable for other uses, meaning a possible major decrease in real value to those primarily "mom and pop" and family-owned businesses that would stagger the imagination.

The demise of these businesses would have further repercussions, in jobs, in payrolls, in taxes, to suppliers to the industry and to the farm producer. There is also a strong belief that the widespread competition provided by these small operations within the industry plays a key role in keeping prices down in the major packing house, the retail outlet and even in the supermarket. Action that forces the closing of these small operations could very well alter the entire superstructure of the meat and food industry.....simply by the elimination of competition. Those are the possibilities we must be aware of, but what of some specifics on the effects of a nitrite ban?

The Food and Drug Administration and the USDA concede that it will be necessary to double our freezing and refrigeration capacity in this country if a nitrite ban

is implemented. The Federal Energy Administration (Project FEA 8051) has shown that refrigeration and freezing already account for one half of the total electrical energy consumption in the typical small meat processing plant. That is one important economic impact of a nitrite ban. We have not had the time nor the resources to fully study the effects on transportation costs, the need for more frequent deliveries of product to the retail level, the decreased shelf life, nor increased refrigeration needs, but the impacts in those areas will be a form of taxation imposed by acceding to the wishes of some food faddists.

On one hand, proponents of a ban are asking for removal of an additive we have known for 20 centuries. In its place, to compensate for color and taste deficiencies in cured product, they are saying that other additives could be substituted, a clear case of trading the known for the unknown. But a bigger unknown is what will be substituted to control botulism and food poisoning. In short, there is nothing.

When small meat processors complained that they would be forced to overpack to comply with USDA's proposed net weight regulation, net weight rule proponents paid short shrift to the fact that it would add to the cost per pound of product. But that was when it was assumed that vacuum packaging would continue to be available. Since the potential for botulism development is enhanced in a vacuum, or anaerobic condition, the future of vacuum packaging for nitriteless cured meats is much in doubt. That means that if alternatives to vacuum sealed packaging are necessary to prevent botulism, an even more serious net weight problem could develop. The overpacking necessary to compensate for lack of vacuum packaging could be more than consumers would want to pay, or could afford.

Make no mistake about it, small processors are very afraid of botulism and the food poisoning problem in the absence of nitrites. Their products could be time bombs that result in death or disease. It would take only one or two such situations to have the entire industry subjected to the need for expensive liability insurance, the cost of which must ultimately be reflected in the product. Small processors, lacking in the ability to afford such insurance, would be the first to go. Those

that remained would turn to fresh meat processing and avoid the liability problem they would associate with so-called "cured" meats. For the hog producer, it may mean dealing only with the "big three or big four" who remain in the curing business. And what a lack of competition in the cured pork market would do to retail prices can only be surmised.

We have seen reports touting what is considered by some to be the "successful" ban Norway has imposed on nitrites. These reports tell us that after an initial 5% drop in sales and consumption volumes for cured meats, they restored to their former levels. Then, the reports say that there has been no botulism outbreak.

The Norwegian experience, if we look further, tells us some other things. It tells us first that even after the ban consumers still wanted products containing nitrites.....they wanted a choice. The public did not want the grey or brown cured meats and, in fact, an estimated 20% of the cured meat products have been exempted from the ban.

We must remember too that since consumers did not prefer off-colored cured meats, processors, some deliberately and some inadvertently, returned to getting nitrite into their products. For example, by smoking nitrite and nitriteless products together, nitrous gases began to react on the nitriteless products. Others put nitrite salts in the sawdust used in the smokehouses. Others salted sausage skins in brine containing nitrite. In still other cases, nitrite naturally present in production areas imparted the traditional pinkish or red flavor. And one cannot discount the fact that Norway is smaller in size than New Mexico, meaning distribution problems would be vastly different than in this country. Nor has adequate attention been paid to nitrite or nitrate naturally present in Norwegian waters, nor to the black market that developed in nitrite curing.

We might also remind ourselves that even in summer, Norway rarely experiences temperatures as high as 85 degrees Fahrenheit. Contrast that with Kansas, where this year alone temperatures of 100 degrees Fahrenheit or higher were recorded on 52 separate days.

Let's say more about a very important area of concern.....black marketing. In this country, we find laws passed that require sanitary slaughtering and processing facilities, spotless equipment, and close inspection by federal and state government. Yet, despite the efforts of government to stop it, illegal or shadetree slaughtering and processing takes place, not by the inspected plant operator who may be cited by the inspector for a small crack in the floor, but by the illegal operator who doesn't even have floors, or in many cases, walls. A quick check with USDA's compliance program will verify that fact.

In illegal slaughtering or processing, the concern is with dust, dirt or flies contaminating meats in uninspected or clandestine facilities. In a blackmarket situation with cured meats, we may find complicated brine solutions or formulae being worked in those same clandestine facilities by individuals without any measurement equipment. And, that is a very serious problem.

The home canner, we would have to assume, would also be told under such a discussed nitrite ban, that sodium nitrite could no longer be used for that purpose. Look at your botulism cases in America during the last 10 years.....particularly those from home canning.....and then weigh the risk of a nitrite ban.

In our industry, consumers are not special interest professionals, they are customers. We survive by servicing them and catering to their needs and wishes. A nitrite ban would not only do them a great disservice, it would also endanger their health and infringe on their liberty. A great disservice? Yes! When you are forcing them to change their shopping patterns, forcing them to pay more than is necessary for a product and force feeding them food of a different color, aroma and taste than they want, that is a tremendous disservice.

Endangering their health? Most assuredly! Our customers are a little bit spoiled and pampered because of us. They can take our products, use them and abuse them, and are still not hurt by them. They can take these cured products in picnic coolers, pack them in school lunch boxes, leave them unattended in the trunk of a car in the summertime, lay them out on the kitchen counter and refrigerate them later.

And, if a product goes bad, the smell and the color signal a warning that all have come to know. Without nitrite, such product abuse could be toying with death. The brown or grey color could be the same whether nitriteless products were fresh or spoiled. The warnings could not be there. And adding artificial colorings and flavorings to disguise the product's true nature could be dangerous. It might convert toxic meat into a pleasant smelling, pleasant tasting and colorful death trap.

So ingrained are the American consumer's shopping, preparation and use of cured meats that a major change in the nature of these products would hardly be a conversion without sizeable risks. Who will be responsible for those among us who do not read labels? Who will tell the elderly, the mentally retarded, or the blind that there may be risks they have never known before in their next pack of hot dogs, ham, bacon, lunch meat or sausage? Who will tell the energy conservationists in our midst that a 40-degree setting is needed in their refrigerators, those that most likely feature high-low dials that are probably set on high? Who will design the inexpensive picnic cooler that holds a 40-degree temperature? Who will invent the refrigerated lunch pail?

More importantly, who will tell those who prefer the taste, color, aroma and safety of nitrite products that they are denying them the right to decide for themselves? Where are they who would steal this liberty from the majority?

But botulism is not the only consideration in a nitrite or nitrate ban. Many traditional regional products.....such as Lebanon bologna.....could no longer be produced without such cures. Such products turn out to be grey-brownish in color, rancid in smell, tasteless, non-sliceable, green in the center and possessing absolutely no holding capacity. Oh yes, they are not toxic and could be considered microbiologically wholesome and unadulterated. But who would eat them? Thus, on some regional products, a ban would have the effect of totally eliminating them from the marketplace.....again denying the consumer the right to another slice of Americana.

We're being told that there are alternatives to nitrite, but no curing ingredient is even in sight that will do the job, even though more than 700 have been tested! We're told to go to irradiation of products, even though the American taxpayers have spent $51 million over the last 25 years in Army research projects, projects that have failed to come up with even a single product that the FDA has certified as fit for human consumption. We're not even going to try to imagine the cost or the danger to meat plant workers of installing irradiation equipment in meat plants, but we're sure OSHA would have a field day with that problem.

The real alternatives are energy-intensive and expensive refrigeration and freezing, which will work if the American public is willing to pay the price and if we had some guarantee against blackouts, brown-outs, power failures or faulty electrical equipment. Another real alternative is the dangerous black market that would exist only because it can give the public what it wants and demands and is willing to risk in areas of safety.

No, we are not willing to accept the limited studies that have been done on nitrite as conclusive proof that even a significant cancer danger exists. Dr. Newberne of MIT has called for more research, Dr. Kennedy of FDA has speculated that the Delaney Amendment may need "fine tuning", and Assistant Agriculture Secretary Carol Foreman has said she is interested in specific language to change the Delaney Amendment. From those who are said to be sources or proponents of a nitrite ban seems to be coming an unmistakable message: more research, time and evaluation of risk versus benefit is in order before any hasty action is taken to impose an outright ban on nitrite.

Even a non-statistician should be able to surmise that the chances of a consumer eating the 500 or 600 pounds of nitrite cured meat per day to get the same dosage as was given to a cancer-prone strain of laboratory rats are far more remote than having that same person, at least once in his or her lifetime, being subject to a mishandling, abuse or refrigeration storage problem involving nitriteless cured meats that may be laced with botulinal toxins.

If we at the American Association of Meat Processors were sitting on any kind of secret information or studies that showed that even heavy consumption of cured meats were related to cancer in humans, it would be folly for us not to reveal it. The simple fact remains that we have not seen a conclusive indication that nitrites pose a cancer danger to anyone. Vegetables, water and even the air contain nitrites and nitrates. If this danger from nitrites is so acute, we can only hope that those in responsible positions will not attempt to ban all vegetables, or require warning labels on water fountains or the air we breathe.

Thank you for the opportunity to testify on this important matter.

Respectfully submitted,

Stephen F. Krut
Assistant Executive Director

STATEMENT OF HON. JAMES ABDNOR, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF SOUTH DAKOTA

Mr. Chairman, I appreciate this opportunity to present my thoughts on the nitrite controversy and to express my support for enactment of HR 13984 and HR 13985 of which I am a cosponsor.

We are all somewhat overwhelmed by the countless opinions and reports that have been placed before us. To appropriately weigh conflicting evidence is a challenge Congress is ferquently called upon to perform, however. I am confident that the Committee will arrive at a decision which will fairly consider all interests.

The health and safety of our citizens is of paramount importance, but the economic well-being of the multi-billion dollar livestock and meat production industries deserves consideration as well. To inflict needless economic injury on the industry, particularly in an inflationary economy, would be unfortunate for all Americans. Indeed, a ban or phase-out of nitrites at this time would not only significantly raise the price of processed meats, but would render irreparable damage to the current meat market with the greatest damage inflicted on the smaller livestock owners and meat producers.

To the uninformed, the question seems to be: "Do we forfeit many meats as we now know them (as nitrite-cured products), or do we eat nitrite-cured meats and take our chances on contracting cancer?" This is not an accurate portrayal of the nitrite controversy, however, since there does not seem to be conclusive evidence that nitrosamines form from nitrites in cured meat and, subsequently, cause cancer. Furthermore, the MIT study conducted by Dr. Newbourne does not offer the conclusive evidence that Assistant Secretary of Agriculture Carol Tucker Foreman, and FDA Commissioner Donald Kennedy cite in support of their proposed ban.

The USDA's own Expert Panel on Nitrates, Nitrites, and Nitrosamines conducted a series of hearings from February, 1974, to September, 1977. A majority of the Panel concluded that "* * * orally ingested nitrosamines of the type present in nitrite-treated meats do not lead to the formulation of the type of tumors prevalent in the United States population." The only concern they expressed is the potential formation of nitrosamines in the frying of bacon, "* * * even though the amount of nitrosamine present in bacon is in the parts per billion (ppb) level, and the effects of such small amounts of carcinogens in man and animals are not known." Therefore, it is not clear that the ingestion of meats treated with currently approved levels of nitrite indirectly causes cancer, and conclusive evidence on which to base a ban from meat processing, therefore, is lacking.

The study conducted by Dr. Paul Newbourne at MIT has been cited by many as proof that nitrites themselves *directly* cause cancer and has been labeled by one interest group as "* * * the capstone on the argument that consumer groups have voiced for many years—that the use of nitrite poses human risks beyond measurement * * *"

The study suggested that there was a correlation between a large dose of nitrites and a rise in the incidences of cancer in the test rats. In response to this suggestion, Dr. Weisburger, Vice President of the American Health Foundation, in a testimony before the Senate Agriculture Committee, said that "* * * the lesions described were localized spleen mostly. No one has ever died of a local disease." Further, it was pointed out in those hearings that Dr. Newbourne's study, besides using many questionable experimental procedures, lumped together the results from three different diets in summarizing the experiment. It was observed that if the three diets and the four modalities of treating the test rats were separated, and if one picks out the normal laboratory diet that scientists use in testing animals for cancer, there was no effect or only minimal effect observed on rats whose food was treated with large doses of nitrites.

Further question is raised when examining the percentage differences in the rats that contracted cancer. In those rats fed no nitrites, 8.3% were found to have malignant lymphomas, or cancer of the lymph system. In those fed 1,000 parts per million (ppm) of nitrite, quite a large dose, 12.7% of the rats were discovered to have malignant lymphomas. This difference is cited as statistically significant and is cited as evidence by proponents of the ban that nitrites caused the increase in malignant lymphomas. What no one can seem to adequately explain is why of those rats fed 2,000 ppm of nitrite, only 8.3% were discovered to have malignant lymphomas—the same percentage as those fed no nitrites!

In the Netherlands and Denmark, long-term studies of meats treated with amounts of nitrite closer to what a human might consume showed no effect when fed to test animals. Even Dr. Newbourne admits that the data of his experiment are suggestive at best and that their biological significance is unclear. The experiments to date, therefore, simply have not determined that nitrites do cause cancer. Nitrites should not be withdrawn from use as a food preservative unless research more clearly establishes a carcinogenic characteristic in nitrite or its chemical derivatives.

Salt containing nitrites has been used for many centuries as a meat preservative. It was not known until this century that a derivative of nitrate, nitrite, prevented the growth of micro-organisms such as Clostridium botluinum, commonly known as botulism. In 1925 the Department of Agriculture approved the direct addition of nitrites to meats in the preservation process.

A joint statement issued by Assistant Secretary Carol Tucker Foreman and Commissioner Donald Kennedy on behalf of the U.S. Department of Agriculture and the Public Health Service of HEW said:

"C. botulinum can grow and produce its toxin even without a foul odor or other sign of contamination that might warn the consumer. This unsuspected growth of C. botulinum could occur in any spore-containing product that receives sufficient heat processing to destroy the normal spoilage bacteria, but not enough to destroy the spores of C. botulinum. For example, it could occur in hot dogs and luncheon meats, were it not for the use of nitrites in their preparation."

C. botulinum spores can be found virtually anywhere and are a natural contaminant of meat. The health danger that C. botulinum poses makes it essential that preventative measures are taken to eliminate the possibility for its spores to grow. This led the Expert Panel on Nitrates, Nitrites and Nitrosamines to conclude:

"Over the years, the use of nitrite in meat curing has performed as a built-in safety factor and thereby significantly protected the public health * * *. The Panel is of the opinion that the botulism threat is a serious one and therefore feels continued use of nitrite in the curing process is warranted."

Meat processing with nitrites in the United States has had an excellent track record in the prevention of botulism, with, at most, a couple of cases reported each year. In parts of France and Spain there are numerous outbreaks of botulism in home-cured meats where nitrites were either not used at all or were improperly used. Withdrawal of such a protectorant until a suitable alternative has been offered would seriously jeopardize the health of all who consume nitrite-cured meat products.

Alternatives have been suggested by various groups as a botulism preventative. Clostridium botulinum is a spore-forming bacterium that produces seven known types of toxin which are designated by the letters A to G. Types A and B are the most common types formed in meats. These two types have a high heat resistance and are the major causes for botulism in home-canned meats and vegetables placed in pressure cookers for preparation. Commissioner Kennedy and Assistant Secretary Foreman pointed out that many meat products "* * * receive only limited heat treatment because sufficient heat to destroy the spores would make the products unpalatable." If meats as we know them are to continue to be available, heat does not seem to be a viable alternative to nitrite.

Extensive freezing is also cited as a major alternative to nitrite. Some 95%-plus homes are reported to have refrigerators. This, along with claims by proponents of the ban that meat processors should make large and costly additions to their current freezer capacities, is cited as evidence that nitrite is not needed for prevention of C. botulinum. I seriously doubt that over 95% of American homes have refrigerators that operate at a temperature sufficient to prevent the growth of C. botulinum spores. Even if they do, there is no way to ensure that meat will not be left outside refrigeration units for unsafe periods of time. Nitrites offer protection against the certainty of such neglect and mishandling.

Other possible alternatives also falter when weighed against the protection offered by nitrites from C. botulinum growth. The addition of more salt in amounts needed for proper protection would encourage the growth of one of the biggest killers in our country—high blood pressure. Other chemical preservatives have not undergone the analysis nitrite has and may be dangerous to human health.

Removal of nitrite would mean removal of the characteristic red color of preserved meats. The red color is a useful indicator that meat is still likely to

be safe from bacterial growth if it has been properly handled and treated with nitrites. The greyish color of meat not cured with nitrite would give consumers little clue as to the safety of consuming the meat. Removal of nitrite would also mean removal of the characteristic taste that nitrite imparts to cured meats. Alternation of meat products Americans have grown to enjoy could reduce the demand. The magnitude of that demand and its significance in our economy must be carefully considered.

Finally, as has been pointed out by every pertinent study, elimination of nitrite as a curing agent would eliminate only a portion of the source of nitrite from the diet of consumers. As the Council for Agricultural Science and Technology points out:

"Current information indicates that saliva is the principal source of nitrite entering the stomach, supplying upwards of 80% of the total, with cured meats less than 20% * * * (to eliminate nitrites in cured meats) would only reduce to a small degree the ingestion of nitrite and the possible cancer hazard it may entail."

Mr. Chairman, no one opposes reasonable actions to reduce the incidence of cancer in the population of the United States, provided that adequate evidence is available to support such action. The available evidence does not support the proposed ban on nitrite as a food preservative, however, and additional research should be undertaken to resolve the controversy.

HR 13984 and HR 13985 would prohibit a ban unless conclusive evidence is discovered and I support their enactment at the earliest possible date.

Thank you.

STATEMENT OF HON. MICHAEL T. BLOUIN, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF IOWA

Mr. Chairman, I realize that it is often fashionable to seek out "band wagon" issues. The matter I want to bring to committees' attention, however, is a very serious one and could result in a disastrous state of affairs, economically speaking, for my home State of Iowa if agencies of the Federal Government make any hasty determinations as it relates to the use of nitrites.

I do not believe that there is one person in this country who is not genuinely interested in the physical well-being of their fellow man. Nitrites are not a "convenience," but rather a "necessity" in the fight against botulism.

As most of the Members of this Committee are aware, I have the honor of representing a state whose economy is dependent upon pork production. The question we address today, however, is not one of who we represent, but rather how can we find a reasonable and common sense solution to protect the physical and economic health of this country.

In an attempt to address this problem before any arbitrary action is taken on this matter, I recently joined with Congressmen Wampler and Mathias in co-sponsoring legislation that effectively prohibits the HEW and USDA from banning or phasing out nitrites unless certain requirements are met.

Both bills would require that it be proven beyond a reasonable doubt that nitrites as a food preservative have a significant carcinogenic effect on humans. Secondly, the bills require that there be a commercially available substitute before there is a ban, but most importantly that such a substitute is as effective in preventing botulism. Finally, the bills require that any "substitute" be economically affordable for both producers as well as consumers.

Most reasonable people agree that banning nitrites in meats will not eliminate these chemicals from the digestive tracts of individuals. I do believe, however, that it is important that the Congress enact legislation of this type to assure that reasonable guidelines will be followed in dealing with this matter. It is my belief that these bills represent a modest approach in dealing with this issue and I strongly urge that they be given the speediest of consideration.

STATEMENT OF
CONSUMER FEDERATION OF AMERICA

TO THE
HOUSE COMMITTEE ON AGRICULTURE
SUBCOMMITTEE ON DAIRY AND POULTRY

Concerning
The Use of Nitrite in Meat and Poultry Products

October 1978

Consumer Federation of America is a federation of 240 national, state and local non-profit organizations that have joined together to espouse the consumer viewpoint. CFA and its member organizations represent over 30 million consumers throughout the United States. Among our members are: 60 state and local consumer organizations; 83 consumer cooperatives; 16 national labor organizations; and 27 national and regional organizations ranging from the National Board of the YWCA to the National Education Association.

Health Hazards of Nitrite

Even before the five-year MIT study commissioned by the Food and Drug Administration recently concluded that nitrite is a carcinogen, nitrite was long known to pose two other major threats to humans.

One is methemoglobinemia, the prevention of hemoglobin in the red blood cells from carrying oxygen. When methemoglobin, the inhibiting substance, equals 10% of hemoglobin, it can produce cyanosis, or oxygen starvation characterized by bluish discoloration of the skin. At 20-25% of hemoglobin, methemoglobin produces weakness, difficulty in breathing, rapid heart action and loss of consciousness. Levels in excess of 60% result in the possibility of death from respiratory failure, shock, and circulatory disruption.

The danger of nitrite poisoning is greatest with children, especially infants. In cases where victims already have problems with the oxygen-carrying capacity of their blood, it can be fatal. Overly nitrited bologna and hot dogs have been known to cause methemoglobinemia.

A second known danger of nitrite is its susceptibility to react with other chemicals, such as secondary and tertiary amines, to form nitrosamines which have been found to cause cancer in laboratory animals. While not all nitrite poses the same degree of risk, nitrite in food is more likely to react with amines than nitrite in the salivary glands. Nitrite combines with amines at high temperatures of cooking (such as frying), or in the stomach. Common amines are derived from natural sources and proteins such as eggs, fish, cereals, meat, and from common substances such as beer, tea, wine, and cigarette smoke. Amines are also found in some widely used drugs such as antihistamines, anesthetics, tranquilizers, nasal decongestants, oral contraceptives, and analgesics. These are reactions based upon known amines; there may be hundreds more, the effects of which are still unknown.

For more than a decade consumers have been known to be exposed to the carcinogenic hazards of nitrosamines, most commonly found in bacon. Yet despite overwhelming evidence that bacon poses the most serious threat to consumer safety, the U.S. Department of Agriculture has only recently moved to lower the permissible level of nitrite in bacon to 10 parts per billion. According to the Food and Drug Administration, lowering the levels of nitrite in bacon will not preclude the formation in the frying process. Only a total ban on nitrite would prevent this formation.

Recent Research on Nitrite

The MIT study completed last August for FDA concluded that nitrite alone as an additive produced cancer in test animals. This cancer took the form of lymphatic tumors and changes in the immunal system. It was supported by a 1975 FDA study which concluded that nitrite produced malignant cancer in rats similar to leukemia, malignant lymphoma, and Hodgkin's disease in humans.

Both FDA and USDA assert that the "results of properly conducted animal testing do provide a sound basis for assessing human cancer risks." Furthermore, with the exception of arsenic and benzine, all substances known to cause cancer in humans also cause cancer in laboratory animals.

The amount of nitrite which poses substantial danger to humans is not known. Significantly, there is also no known level below which a carcinogen is safe. Furthermore, a society is exposed to several carcinogenic compounds, and never a single carcinogen. Dr. Preussman of the Institute for Toxicology and Chemotherapy in West Germany maintains that even "sub-threshold doses give rise to tumors in combination with other carcinogens."

Nitrite-Free Products Today

About 20% of the average human dietary exposure to nitrite now comes from cured food products, mainly meat products. Yet there are alternative methods to preserving meat. The "nitrite-free meats" rule of April 23, 1978 by USDA stated that safe alternatives do exist. A recent study by the Monsanto Company showed that nitrites are not necessary when a certain percentage of sorbate is used alone or in conjunction with lower levels of nitrite. Other studies of safe alternatives by Michigan State University and Virginia Polytechnical Institute are soon to be released. Also, botulinum toxin cannot grow in meat which is sterilized, dry, cool, salty, and/or acidic, or a combination thereof. At the consumer end, normal refrigeration and cooking deters growth of the toxin.

In many instances, preservation without nitrite is already in use. Bratwurst, a frankfurter-like product, is made without nitrite and no problems exist with botulism. There has also never been a known case of botulism in connection with nitrite-free bacon and hot dogs now on the market.

In 1972, Norway outlawed the use of nitrite in knockwurst and frankfurters. Since then, there have been no known cases of botulism and no noticeable increases in the prices of those products.

With respect to poultry, there are a number of poultry products already on the market that are processed without nitrite. One example is chicken roll, a product which resembles bologna. Although it is a vacuum-packed product with the potential for botulinum growth, botulism has never occurred in this product. Pressed poultry deli meats and sliced chicken loaf are also produced without nitrite. These products undergo processing similar to nitrite-cured luncheon meats and are sold in the same grocery store sections as beef and pork nitrite-cured products. There are no special labeling or handling precautions included on these packages. Despite all of these factors, there have been no incidents of botulism poisoning.

CFA is persuaded that American consumers are willing and anxious to buy nitrite-free products. However, current labeling requirements have confused the public, made nitrite-free products difficult to identify, and thwarted that willingness. Arguments by the meat and poultry industries that the exclusion of nitrite would cause a drop in sales or a substantial danger of botulism poisoning are largely unfounded.

Conclusion

On the basis of past and present findings, FDA has concluded that since ingested nitrite causes cancer in rats, it presents a significant risk to humans. FDA and USDA have jointly declared that nitrite in meat is a poisonous and deleterious substance and are presently looking into plans to phase out its use.

Such a phase-out can be enacted in a relatively short period of time by neither endangering the public nor causing severe economic hardship for

the affected industries.

It should be noted that a recent study of American opinion by U. S. News and World Report reveals that consumers by a margin of 54% - 37% believe that the government should ban the sale of products shown in any laboratory tests to have caused cancer in animals.

Since the health-related problems associated with the use of nitrite have been known for some time, industry has had ample opportunity to develop alternatives for preserving meat. Some are already in use. Others are close to perfection. With improved production controls a number of meat products (sterile canned products, dry cured meats and fermented sausages) could be safely marketed immediately without nitrite. Other nitrite-cured products could be phased out using alternative methods and, when necessary, accompanied by comprehensive labeling to alert consumers to special handling procedures.

Finally, despite the fact that Dr. Paul Newberne, the author of the MIT study, has graciously expressed the opinion that he welcomes additional studies to reinforce his findings, neither FDA nor USDA are under any obligation whatsoever to commission those studies nor to await the results of other studies. Both agencies have the authority to act at once on the basis of existing evidence.

We therefore strongly urge this Congressional Committee to encourage FDA and USDA to move as quickly as possible to eliminate the use of nitrite.

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