OFFICIAL TRANSCRIPT
PROCEEDINGS BEFORE

THE SUPREME COURT OF THE UNITED STATES

DKT/CASE NO. 85-664

TITLE FRANK YOUNG, COMMISSIONER OF FOOD AND DRUG ADMINISTRATION, Petitioner V. COMMUNITY NUTRITION INSTITUTE, ET AL.

PLACE Washington, D. C.

DATE April 30, 1986

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IN THE SUPREME COURT OF THE UNITED STATES

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FRANK YOUNG, COMMISSIONER OF :

FOOD AND DRUG ADMINISTRATION, :

Petitioner, :

V. : No. 85-664

COMMUNITY NUTRITION INSTITUTE, :

ET AL. :

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Washington, D.C.

Wednesday, April 30, 1986

The above-entitled matter came on for oral argument before the Supreme Court of the United States at 12:59 o'clock p.m.

APPEARANCES:

PAUL J. LARKIN, JR., ESQ., Assistant to the Solicitor General, Department of Justice, Washington, D.C.; on behalf of the petitioner.

WILLIAM B. SCHULTZ, ESQ., Washington, D.C.; on behalf of the respondents.

C O N T E N T S

P R O C E E D I N G S

CHIEF JUSTICE BURGER: We will hear arguments next in Young against Community Nutrition Institute.

Mr. Larkin, I think you may proceed whenever you are ready.

ORAL ARGUMENT OF PAUL J. LARKIN, JR., ESQ.,

ON BEHALF OF THE PETITIONER

MR. LARKIN: Thank you, Mr. Chief Justice, and may it please the Court, this case is here on a writ of certiorari from the United States Court of Appeals for the District of Columbia Circuit. The question in this case involves the proper construction of two interrelated sections of the Food, Drug, and Cosmetic Act of 1938, Section 402 and Section 406.

These sections establish alternative enforcement mechanisms that provide the FDA with the ability to prove that food is adulterated. It is our position and it has been the position of the Food and Drug Administration in the nearly 50-year history that the Act has been in existence that Section 406 authorizes the agency to adopt regulations, known as tolerances, but does not require the agency to do so. Put another way, Congress authorized the Food and Drug Administration to select between the alternative types of enforcement mechanisms that were established in the

1938 Act.

QUESTION: But it could do both.

MR. LARKIN: Correct. It could decide that in an individual case it should prosecute under the general adulteration standard, Section 402, or alternatively it could decide to adopt tolerances, regulations that would set precise levels of forbidden contamination, and that would lead to a different type of proof in court in an individual case.

QUESTION: But if it did the latter, adopt the tolerances, it couldn't proceed in order to -- it couldn't in a specific case insist on a lower tolerance?

MR. LARKIN: That's correct. By saying that they could choose between the two, I mean that they can't as a policy matter decide how to proceed to protect the public health. Once a tolerance is set, they cannot then proceed under the general adulteration standard.

QUESTION: But pending the setting of a tolerance, they could proceed on a case-by-case basis?

MR. LARKIN: Correct.

QUESTION: And by these so-called -- what do you call them?

MR. LARKIN: They are called action levels,

Your Honor.

QUESTION: Yes, action, they could proceed on that until a tolerance is adopted.

MR. LARKIN: That's correct. I would like to summarize the four principal reasons why we believe the Court of Appeals misconstrued the Act in this case.

QUESTION: May I just interrupt before you do? Do you contend that the determination of an action level is the promulgating of a regulation within the meaning of 406?

MR. LARKIN: No, Your Honor.

QUESTION: You don't. Okay. I misunderstood what you said.

MR. LARKIN: I am sorry, and I would like to be precise about this, because I think respondents have attempted to confuse the two. Action levels are informal and internal prosecutorial guidelines.

QUESTION: I understand that, but they are not regulations.

MR. LARKIN: Correct, they do not have the force and effect of law. Tolerances do; action levels do not, and they never have.

QUESTION: They are basically a policy statement that we will not prosecute if you don't exceed this action level.

MR. LARKIN: Well, it is more than just a policy statement, Your Honor, because the action levels represent the agency's judgment based on the available scientific data as to what level of contamination will result in adulteration, so the action levels also represent the agency's judgment as to what it can prove in an individual case will result in adulteration.

QUESTION: Well, that may be, but legally they have no different effect than just an announcement of a policy that we won't prosecute above this level.

MR. LARKIN: That's correct.

QUESTION: And they may go through a lot of thinking before they come to the conclusion, but none of that is statutorily required.

MR. LARKIN: Correct, the statute does not require the establishment of action levels, and the statute does not impose any legal consequences upon the violation of that --

QUESTION: And including -- you can -- and their --

MR. LARKIN: Correct.

QUESTION: Everybody knows about it.

MR. LARKIN: Correct.

QUESTION: But if a manufacturer relies on one, it isn't going to do them much good if you in an

individual case don't adhere to your action level.

MR. IARKIN: Well, the reason we made --

QUESTION: You may not want to, but suppose the prosecutor, he couldn't defend on the basis that he is in compliance with the action level.

MR. IARKIN: That's correct, because if the agency has new data that leads the agency to believe that its prior action level was insufficient to protect the public health, that in fact a lower level of contamination may result in adulteration.

QUESTION: Now, how are the action levels published?

MR. IARKIN: They are published in the Federal Register, Your Honor. If the agency discovers new information, as it did, for example, in 1974 with respect to PVB contamination in Michigan, it can lower the action level without going through the formal rulemaking process. That will allow the agency to act quickly in response to new developments.

QUESTION: You could just sue and say this is a new action level.

MR. IARKIN: The agency has the authority to prosecute before it lowers its action levels as well. That is correct.

QUESTION: But it couldn't do that if a

tolerance had been --

MR. LARKIN: That's correct, Your Honor. Once a tolerance is established, any food that contains a contaminant for which the tolerance is established that has a lower level of contamination than the tolerance permits is per se unadulterated, and the FDA cannot then go into court and prove that despite all the new evidence it has uncovered, for example, in the 1974 case, that this particular food may be adulterated.

The statute prevents the FDA from relying on the general adulteration standard.

QUESTION: What sort of a pattern of adjustments of the standards exist? Are they frequent, infrequent, or is there a great deal of variety in the subject matter?

MR. LARKIN: They are relatively infrequent both for -- primarily historical reasons, but also practical reasons. In 1938, when Congress adopted the statute, the primary added contaminant that they were concerned with was pesticides. And the FDA thereafter, after a period during World War Two when business was diverted to other matters, established a pesticide tolerance in 1944 for florium.

QUESTION: That is the only one you -- that is the only tolerance level there is, isn't it?

MR. LARKIN: There is one other tolerance level for PCBs. Now, after 1944 --

QUESTION: How many substances are there really that might be the subject of a tolerance level?

MR. LARKIN: There are at least eight substances that the FDA has action levels for at present, and it has 21 action levels for these eight substances, because the different substances may be ingested in different foods, different foods may be consumed in different quantities, and different foods may be --

QUESTION: And if you went at it by the business of setting tolerances, you would have had to set 21 tolerances?

MR. LARKIN: We believe that we would have to at least set that many different tolerances, and for substances for which we do not yet know, every time a substance is discovered we have to set a tolerance level under the Court of Appeals construction of the statute.

QUESTION: Yes, but meanwhile, while you were setting them, you could have your action level.

MR. LARKIN: That is true, but the agency has long concluded that the public is not materially benefitted by virtue of having tolerances in effect.

QUESTION: I know. Of course, it is a

question of statutory construction whether Congress told you --

MR. LARKIN: I agree, and for that I would like to, if I could, return to the four primary reasons why we believe the Court of Appeals erred.

QUESTION: Let me ask one more question, if I may, before you get into the argument. This figure of either eight action levels or 21, does that relate only to Section 406, the one where the added substance is unavoidable? Is it that category? Does that also include the pesticides and the food additives and action levels of that kind?

MR. LARKIN: The pesticides are now primarily regulated under Section 408 or 346.

QUESTION: Where they do have tolerances in every case.

MR. LARKIN: I believe the EPA sets the tolerances, and I am not sure if there is a tolerance set in every case. I believe there probably would be because there is a procedure that allows both industry and private parties to select --

QUESTION: Let me state the question a little differently. Is it correct that the eight action levels or 21, whichever it is, applies entirely to Section 406 cases, cases where the substance is unavoidably part of

the product?

MR. LARKIN: Yes, the eight action levels deal with substances that are either necessary or unavoidable.

QUESTION: Okay.

MR. LARKIN: The four reasons are as follows. First, the FDA's construction of the Act is eminently rational and entirely plausible. It is consistent with the text and overall structure of the Act, with the legislative history, and the '38 Act and subsequent amendments, and with the policies that Congress sought to implement through the statute.

QUESTION: How far back does that go?

MR. LARKIN: The construction goes back at least to 1940, when in a published letter that was sent to certain private parties the agency made clear its position. That letter is reprinted in a footnote to our brief at Page 17, Note 14. The agency's construction has been consistent throughout this period. It has never construed the Act as requiring it to adopt tolerances. It has always construed it as the authorizing agency to do so.

Second, the Court of Appeals upset the settled and successful administrative construction of a complex regulatory scheme largely by relying on one word in one

clause in one section of a multipart statute. By so doing, the Court of Appeals effectively misunderstood the function that Congress intended Section 406 to serve.

Third, Congress has been made aware of the agency's construction and the agency's regulatory position, and Congress has never criticized the agency for the practice it has followed, and in fact in 1954 Congress relied on the agency's views when Congress adopted an amendment to the Act.

Fourth, neither the Court of Appeals nor the respondents have offered a sound reason why Congress would have intended the regulatory process to be structured in an entirely different fashion or why it should be restructured in a new fashion at this late date. In fact, as we explained, restructuring the process in the way the Court of Appeals and respondents suggest would not materially benefit the public, and would in fact pose substantial risks that the FDA would not be able to protect the public in the way that it has historically seen best.

QUESTION: I suppose in the process you will explain why Congress thought -- ever required tolerances, or ever provided for them.

MR. IARKIN: Congress provided for tolerances

because the agency believed that the ability to adopt legislative rules would enhance its ability to protect the public health.

QUESTION: And you decided otherwise later.

MR. IARKIN: No, the agency with the initial problem of dealing with pesticides adopted a pesticide tolerance in 1944. In 1954, there was no longer any need to proceed under Section 406 because the pesticide amendment provided a new and speedier procedure to adopt tolerances. The types of added contaminants with which we are concerned today are unavoidable contaminants that for the most part were not discovered until beginning in the 1960s, when aflatoxin, for example, was discovered.

The data about that is still coming in in a variety of different cases, but more importantly, the FDA has believed that on the one hand the benefits of having tolerances adopted in every case do not materially advance its ability to protect the public health, and on the other hand there is a substantial risk that once a tolerance is set, the agency might not be able to respond quickly in order to protect the public health if there are new developments.

The events that gave rise to this suit occurred in 1980. In that year, the level of aflatoxin contamination in corn in three states, Virginia, North

Carolina, and South Carolina, was unusually high. Roughly 100 million bushels of corn valued at $319.5 million were affected. Because of the size of the potential loss, and because the corn could be used in a way that would not injure the public health, the three states asked the FDA not to recommend an enforcement action.

The FDA agreed with the request as long as certain stringent conditions were met, one of which was that the food not be used for consumption by humans. In a letter submitted to the FDA, respondents objected to the FDA's decision, and asked the FDA to rescind its decision in this respect. After the FDA refused to alter its decision, respondent brough this suit in the United States District Court for the District of Columbia.

On cross motions for summary judgment, the District Court granted the Secretary's motion. The three claims that the District Court addressed resulted in only one issue before this Court. That issue is whether or not Section 406 requires the agency to adopt tolerances. The District Court believed that when the statute is construed as a whole, Section 406 grants the agency the discretionary authority to adopt tolerances, but does not impose an obligation on the agency to do

so.

Now, the D.C. Circuit reversed. Relying entirely on the literal language of the statute, the Court of Appeals concluded that despite the agency's historic construction to the contrary, the Act required the agency to adopt tolerances in every case. The Court of Appeals found the legislative history unilluminative, and the purpose the that Court of Appeals gave for its reading of the statute, we believe, is narrow.

Now, the central issue in this case is what function did Congress intend Section 406 to serve. When that function is understood, we believe that it becomes manifest that the agency's construction of the statute is correct, and that the agency has been correctly applying the Act for the nearly 50-year period it has been in existence.

The pivotal provision in this regard is Section 406. Section 406 was added in the 1938 Act, which was not the initial Act that was adopted to protect the public health. That was the 1906 Act. In the 1906 Act, adulterated food was not allowed to be shipped in interstate commerce. The only way the agency could establish that food was adulterated was by proving in an individual case that the presence of a contaminant in the food may render it injurious to health. That was

the precise holding that this Court handed down in the Lexington Mill case.

Now, that was a valuable construction of the statute for the agency, because the agency did not have to prove that it would necessarily injure the public in every case. But nonetheless, the agency believed that its enforcement powers could be enhanced by gaining the ability to adopt legislative rules that would allow it to set precise levels of contamination.

In the 1933 version of the Act which was drafted by the agency, the agency sought approval to adopt the legislative rules known as tolerance. The agency did so because it believed that in some cases, the case-by-case method could be superseded by regulation. And it also believed that by adopting legislative rules it could take into account the presence of contaminants in other foods in the environment as well as the food that was under consideration.

Throughout the entire course, throughout the entire five-year course of this legislation through Congress, no one ever suggested that the agency should be required to adopt tolerances. In fact, the initial bill that the agency drafted and submitted to Congress contained the same word, "shall," that is now found in

the current version of Section 406, but the agency construed the statute as being discretionary, not mandatory.

QUESTION: I must say, if you just read it on its face, you would think that shall meant something.

MR. LARKIN: We believe that the verb "shall" has to be read in conjunction with the phrase, "to such extent as he finds necessary to protect the public health." When that is read as a whole, we believe it allows the Secretary the discretion to decide whether it is necessary to protect the public health to adopt tolerances, that the verb "shall" can't be isolated from that following phrase simply because there are a few other words that intervene in the statute, and that is amply demonstrated, we believe, by the legislative history. As I said, the FDA drafted the statute, and yet at the same time, even though it contained the same verb, the FDA construed it as being discretionary.

Senator Copeland sponsored the legislation, and Senator Copeland construed it as being discretionary.

QUESTION: Well, you would hardly draft it that way today. That isn't the best way of expressing the government's position.

MR. LARKIN: It may not be in that sense, but

the problem, the issue here really is that no one at the time thought that that made a difference.

QUESTION: And how has it been treated since then?

MR. LARKIN: Since then, this is the first Court of Appeals to have held that the agency cannot rely on its action levels.

QUESTION: I am not speaking of the Courts. I am speaking of the agency.

MR. LARKIN: The agency has consistently construed it from the day it went into effect as being discretionary. The agency has stated that on numerous occasions. The agency stated it in public correspondence issued shortly after the Act went into effect. That was in 1940. The agency said that in 1950, when it went before Congress to obtain a modification of the statute that it didn't believe it had to adopt tolerances, but that it wanted to, and wanted a speedier procedure to do so.

QUESTION: May I ask, Mr. Larkin, your view? You have to read, I guess, 406 together with 402(a)(2), or the second part of 402, and the first part says an added substance makes the food unsafe, I mean, makes it misbranded or adulterated if it is unsafe. Then there is the second alternative. It is also unsafe if it

doesn't comply with 406. And my question is -- and then 406 says -- provides for this tolerance procedure.

What is your view if something is not unsafe within the meaning of 402(a)(1) but has an additive in it that it unavoidable and is below the level of an action level letter? Is it unsafe within the meaning of the statute? Do I make my question clear?

MR. LARKIN: I think I understand your question, Your Honor. It would not because in part since it --

QUESTION: It is only unsafe if it exceeds an established tolerance. Is that your view?

MR. LARKIN: It is only unsafe under Section 406 and Section 402(a)(2)(A).

QUESTION: Right.

MR. LARKIN: If it exceeds an established tolerance.

QUESTION: And if there is no established tolerance, and therefore it doesn't exceed an established tolerance, and you also cannot prove unsafeness within 402(a)(1), it is not adulerated.

MR. LARKIN: Correct.

QUESTION: And that is regardless of whether it is below or above an action level.

MR. LARKIN: If it is above the action level,

that means we can probably prove that it is adulterated.

QUESTION: If you can prove, but you still must.

MR. LARKIN: Yes.

QUESTION: And I am saying -- I am positing a case in which you cannot prove in a particular case on safeness, but then it is as a matter of statutory construction not unsafe.

MR. LARKIN: That would be correct. We would have to prove if there is no tolerance in effect that it may injure human health.

QUESTION: Whereas if you have a tolerance, then the answer to the unsafeness question depends on whether it is below or above the tolerance.

MR. LARKIN: Right.

QUESTION: It is as simple as that.

MR. LARKIN: The tolerance would provide the answer in every case.

QUESTION: And if you lose one case, you will probably bring another, hoping to be able to prove it in that way. You are not about to change your action level as a result of one case, I don't suppose.

MR. LARKIN: It may depend on the type of evidence that was adduced in the particular case.

QUESTION: Yes.

MR. IARKIN: Let me turn to the statute then so that I can explain why we believe the Court of Appeals erred. One of the reasons given by the Court of Appeals for reading Section 406 as mandatory is that it believed that in the absence of the tolerance, food containing any contaminant such a aflatoxin, that is, a necessary or unavoidable contaminant, was automatically adulterated, and that the tolerance was necessary to allow this food to be shipped in interstate commerce.

QUESTION: I know you said that about the Court of Appeals opinion, but I didn't find that in the Court of Appeals opinion.

MR. LARKIN: We think that at three different places the Court of Appeals makes that position clear. For example, at Page 4A, the first full paragraph, the second sentence, beginning, "Hence," the Court of Appeals says, "Section 342 would, except for the saving grace of Section 346, define any aflatoxin-tainted corn to be adulterated and such corn would therefore be banned from interstate commerce."

At Page 7A, the Court of Appeals goes on to say, "Since the existence of a regulation operates to render the food legally unadulterated, the statute in our view plainly requires the establishment by

regulation of tolerances before aflatoxin-tainted corn may lawfully be shipped in interstate commerce, and" --

QUESTION: You don't disagree with that sentence, do you?

MR. IARKIN: We disagree because they confuse to contepts there.

QUESTION: The existence of the regulation would operate to render it legal, unadulterated.

MR. IARKIN: It would, if the contaminant were an amount below the tolerance, but the second half of that sentence doesn't follow from the first.

QUESTION: Oh, okay.

MR. IARKIN: The existence of the regulation would allow the food to be shipped in interstate commerce if it contained less than the tolerance level, but you don't need to establish the tolerance in order to exempt a contaminated food from being adulterated. The tolerances operate in the other sense.

The Court of Appeals believed that you had to adopt tolerances because they were the only way of rendering a food unadulterated, and we think the statute doesn't reach that far. The second clause itself refers to tolerances so fixed, which means the tolerance has to be in effect.

QUESTION: All that really demonstrates is,

that is an incorrect reason for the result they reached.

MR. LARKIN: That's correct, and in fact respondents have now abandoned that argument themselves, but in addition, the Court of Appeals' construction of the statute also renders the general adulteration standard in Section 402(a)(1) superfluous, reasoning as follows.

If a contaminant can be avoided or is not necessary, the first clause of Section 406 forbids its addition in food. Any food containing that type of substance is adulterated. So what you are left with then are contaminants that either are necessary in food, and at the time, by necessary they were referring to pesticides, or that are unavoidable.

Now, in the FDA's view it could regulate --

QUESTION: You left the exception out of the first sentence of 406. It says it shall be deemed unsafe unless it is within the tolerance, doesn't it? Isn't that when you read the whole thing together?

MR. LARKIN: No, I am saying the first clause in Section 406, it is intricate, and I am trying to refer to --

QUESTION: Is it the except clause you are talking about?

MR. LARKIN: No, from where it begins, "Any poisonous or deleterious substance."

QUESTION: And it says, "except where it is unavoidable."

MR. LARKIN: That is right. Now, if it is unavoidable or necessary, the FDA believes it can regulate its presence either by proceeding in individual cases or by adopting tolerances. Under the Court of Appeals construction, until a tolerance is in effect, the food is automatically adulterated, so that there is never a need for the Secretary to refer to the general adulteration standard in Section 402(a)(1).

Under respondents' construction, they have said that the general adulteration standard in Section 402(a)(1) serves as a transitional device. In other words, until a tolerance is adopted, the agency can rely on the general adulteration standard. But all the respondents have done is delay the final day of reckoning. Under their construction of the Act, the general adulteration standard is rendered superflucus, not today, and not when the statute was enacted, but it is rendered superfluous once a tolerance is adopted.

There is no reason to believe that Congress intended Section 402(a)(1) to be superflucus. It was adopted as part of the same statute that adopted Section

406, and Congress endorsed this Court's construction in the Lexington Mill case, which allowed the agency to prove in an individual case that food was adulterated.

There is also no reason for Congres to have intended this to operate in a transitional fashion because Congress was not dealing with a licensing scheme, as Congress has in later statutes, so either the construction adopted by the respondents or the one adopted by the Court of Appeals necessarily renders the general adulteration standard superfluous for these types of substances, and there is nothing in the legislative history or the background or the purposes that suggest that was the reason that Congress intended Section 406 to play.

What emerges from the legislative history is that Congress intended to provide the agency with alternative mechanisms. As I said, Congress endorsed this Court's decision in Lexington Mill and reincorporated the standard in the new general adulteration standard that this Court had considered in the Lexington Mill case. That allows the agency to operate on a case by case basis. At the same time, Congress adopted Section 406, which deals with the promulgation of regulations.

Congress never considered the presence of the

word "shall" in Section 406 to be material. Different bills that were introduced in this five-year period used the verb "shall" and is authorized to interchangeably, but every committee report said that this section authorizes the agency to adopt tolerances.

QUESTION: May I interrupt you again? Is it not true that 402(a)(1) refers to substances which include all substances, whether they contain additives or not, and 402(a)(2) deals with additives?

MR. LARKIN: 402(a)(1) does deal with added or inherent substances.

QUESTION: With no additive present, so it is not totally redundant. It covers all substances in which there is no additive.

MR. LARKIN: But it is clear that Congress intended 402(a)(1) to apply to added substances, and to have some effect there.

QUESTION: Yes, but that is the general basic prohibition in the statute.

MR. LARKIN: That's right.

QUESTION: It covers everything. The whole 402(a)(1) is not totally redundant by their reading of 406.

MR. LARKIN: It is redundant insofar --

QUESTION: Insofar as it relates to

additives. Yes.

MR. LARKIN: Added substances, and --

QUESTION: And there is an elaborate code on additives of which 406 is a part.

MR. LARKIN: But there is no reason to believe that Congres intended it to be --

QUESTION: To be partially redundant.

MR. LARKIN: -- to be partially redundant in this respect.

QUESTION: Mr. Larkin, I know that both sides agree that aflatoxin is an added substance, but it isn't immediately apparent to me why it should be considered an added substance at all. Doesn't it grow naturally in certain crops?

MR. LARKIN: It is the FDA's position that it is not an inherent constituent of food because it is not the natural product of the genetic code of whatever is the food that is at issue.

QUESTION: I see. So anything that isn't part of the genetic code of the substance is added?

MR. LARKIN: Or anything that would be added either by man or nature the agency has construed it in this fashion.

I would like to reserve the balance of my time.

QUESTION: One more -- there is no redundancy -- even if you had to adopt tolerances, 402 wouldn't be redundant because you would resort to it to control a situation until the tolerance was adopted.

MR. LARKIN: We would submit that it doesn't serve solely as a transitional device. Congress never said that 402(a)(1) was intended to --

QUESTION: You said it would be redundant, though, which it certainly wouldn't be.

MR. LARKIN: Unless it was to serve solely as a transitional device, it would be superfluous, because the tolerance would always provide you with an answer to whether a food was adulterated.

QUESTION: Mr. Schultz, you may proceed when you are ready.

ORAL ARGUMENT OF WILLIAM B. SCHULTZ, ESQ.,

ON BEHALF OF THE RESPONDENTS

MR. SCHULTZ: Mr. Chief Justice, and may it please the Court, this case raises important public policy issues concerning the process to be used by the Food and Drug Administration in setting a standard for poisonous and deleterious substances which are unavoidable and which are added.

And before I proceed I would like to say I agree with you, Justice O'Connor, that it is not

immediately apparent that aflatoxin would be added, but it is very clear in the legislative history that Congress intended to cover substances added by nature as well as those added by man, and the FDA, as Mr. Larkin said, consistently construed that word in that way.

For example, the legislative history talks about lead, which can get into the environment, and describes that as an added substance.

The substances that we are concerned with here are substances such as mercury in fish and aflatoxin in corn, the specific substance around which this case arose. And I would like to begin by responding to Justice White's question, which is, why would Congress have wanted to intend, wished to intend that FDA use the public participation and rulemaking processes in regulating these added poisonous and deleterious substances?

And to start, I would like to talk for a few minutes, one minute about what decision it is that the FDA is going to have to make when it is regulating aflatoxin or another one of these substances. Essentially it is a two-part decision. In the first instance it will have to look at the evidence and determine how dangerous is that substance.

The parties here agree that aflatoxin is an

extremely potent carcinogen, but obviously one of the issues that the agency would have to look at is exactly how potent. The second issue is how avoidable.

Aflatoxin occurs in a mold that grows on corn, but the mold can be controlled by dampness or other storage conditions, and so the agency would want to look obviously and see whether there were ways to limit the public exposure to the substance, and regardless of whether the FDA uses the action levels which it chooses to use or the rulemaking procedure we are advocating, it is going to have to decide each of these two issues.

The difference is that public participation would require the agency to do several things that we regard as advantageous. First, it would have to marshall the evidence and inform the public of what evidence it is relying on. Secondly, it would have to allow the submission of additional evidence by either consumers or by industry.

Third, it would have to hold a hearing if someone requested a hearing and if there were material issues of fact, and fourth, it would have to explain the reasons for its decision and put them together in a record which would be subject to judicial review.

The advantages of such a system are that it disciplines the agency in its thought process, it allows

for more information, and it enhances the agency's credibility. Our conttention here is --

QUESTION: Are those things that we presume Congress wanted from the agency?

MR. SCHULTZ: I don't believe we need to presume it. What our contentiocn is here is, not only is public participation a gocd idea, but --

QUESTION: What difference does it make whether it is a good idea or not? Isn't it a questicn whether Congress intended it?

MR. SCHULTZ: That is precisely the issue. The issue is whether in Section 406 Congress mandated public participation. And if I may, what I would like to do before I get to the issue is spend a few minutes talking about action levels, which are the way, the device that the agency uses now to regulate these substances, so we can see the contrast between what the agency dces and what we ccntend Ccngress required it tc do.

The FDA's use of action levels, and, we would ccntend, the disadvantages of not allowing public participation can be seen in the way the agency regulates aflatoxin. In 1969, it set the acticn level for aflatoxin at 20 parts per billion, and it did that simply by issuing a press release announcing it to the

press. It gave no explanation of its reasons. It created no record. It provided no opportunity to comment, and it provided the public with no way of determining whether the agency had done a good job.

Three times in recent years the FDA has granted exceptions to those action levels of a temporary nature, and at most what the FDA has done to provide for public comment is after the fact publish its decision in the Federal Register and invite comments. In 1983, the Community Nutrition Institute did indeed comment, but the FDA never even responded.

It is our contention that these action levels in most respects operate like a tolerance even though they are not promulgated through the tolerance setting procedures, and they do that because we would contend they act really as a license to the industry, and they are the FDA's approval of corn, for example, as long as it contains less than 20 parts per billion aflatoxin, and I would like to take a moment and cite a couple of the places in the record to demonstrate this, because it has just recently become an issue in the case.

The first place is in the answer to the complaint. The complaint in Paragraph 13 on Page 110 of the joint appendix alleges FDA has set an informal action level which is an administrative determination

without notice and comment rulemaking as to the level of aflatoxin contamination below which no regulatory action will be taken against the product, and the agency admitted that contention in its answer at Page 125.

In addition, each of the times the FDA has granted these exemptions, at Page 104, 118, and 227 of the joint appendix, it has said something like it said in 1983 or similar language, and that language is, the FDA will not object to the shipment of corn containing between 20 parts per billion and 100 parts per billion aflatoxin. That is on Page 227 of the joint appendix.

Additional authorities are cited at Pages 8 and 9 of our brief, and I guess the final authority would be the FDA's actual practice. It has never prosecuted a company who has complied with one of its action levels, and at least in my mind it is hard to believe such a prosecution could be successful.

I would like to now turn to the statute, because I regard the key flaw in the government's argument to be the fact that it simply doesn't talk about the actual language of the statute.

Section 406, which is the statutory provision at issue, covers a substance which meets a three-part test. It must be poisonous and deleterious; it must be added; and it must be unavoidable. There is no doubt

that aflatoxin qualifies under all three of those parts. And so the issue turns around later language of the statute which says in Section 406, "If such a substance is unavoidable, the Secretary shall promulgate regulations."

Now, there is other language in the statute that the government relies on, and I would like to talk about that in a minute, but for the moment I would like to focus on the words, "the Secretary shall promulgate regulations." It is clear under the statutory scheme that if the statute requires the Secretary to promulgate the regulations, they must be issued in compliance with the rulemaking procedures contained in Section 701(e) of the statute.

And we regard at least this language taken by itself as dispositive of Congress's intent and as dispositive of the issue as to whether the Secretary is indeed required to issue those regulations. The agency relies on language which appears later in the statute to argue that the Secretary has discretion as to whether -- Section 406, and that language is as follows.

The statute says, "The Secretary shall promulgate regulations limiting the quantity therein or thereon to such extent as he finds necessary for the protection of the public health. The agency says the

words "to such extent as he finds necessary for the protection of the public health" modifies the word "shall," and that the Secretary need only use Section 406 when he deems it necessary.

As the Court of Appeals explained in its opinion, probably better than I can, the problem with this argument is that it is not consistent with the structure of the sentence. The better reading of the sentence is that the words were intended to describe the standard.

QUESTION: Wouldn't you have to say the only reading of the statute, the only sensible, rational reading?

MR. SCHULTZ: That would certainly be my position.

QUESTION: Not just the better.

MR. SCHULTZ: Yes. I was trying not to be too extreme --

(General laughter.)

MR. SCHULTZ: -- but my position would be, the plain reading of the statute is that the Secretary was required to issue the regulation, and that those words were intended to tell the FDA the standard it was to employ.

QUESTION: Well, the FDA has read that

language, has thought forever that that section would bear a construction different from yours, and you say just no rational person could possibly read that language the way the FDA has for 50 years?

MR. SCHULTZ: Well, I suppose I look at the history a little bit differently than they do.

QUESTION: The history? How about the language?

MR. SCHULTZ: I meant their practice. No, I look at the language very differently than they do.

QUESTION: Can you say that it is absolutely irrational to read the thing as modifying something that close to it?

MR. SCHULTZ: I think it is stretching the language to a very large degree, and I think you can see that if you look at another section of the statute, Section 401, which Congress adopted in the same statute in 1938, because there --

QUESTION: Then the agency has been irrational for nearly 50 years. Not quite that much.

MR. SCHULTZ: Well, that is why I was saying I regard the FDA's actual practice a little differently than they do. They set out to issue these regulations after the statute was passed. They in fact issued one. The war intervened, which is a time when they did very

little, and then in the late 1940s they were engaged in a proceeding to issue 100 tolerances under Section 406 for pesticides, and they found that they felt the statute was too cumbersome for them to use it for pesticides, and so what the agency did is, it went to Congress and said, this is unworkable, we need legislative change. And in 1953 Congress adopted the pesticide amendments, taking pesticides out of Section 406.

Now, we would say that if in fact the FDA had thought for all these years that it wasn't required to use Section 406, and that it had all this discretion, it would have never needed to go to Congress in the early 1950s. It could have simply used action levels or some other procedures other than those required by the statute.

QUESTION: When was the first time they ever resorted to action levels?

MR. SCHULTZ: They actually used action levels even before 1938, so that was --

QUESTION: It is your position then, I take it, that it just couldn't directly bring an enforcement action absent a tolerance?

MR. SCHULTZ: No, what we would say is, the statute plainly requires the FDA to issue tolerances,

but that until it has done so, it may bring case-by-case enforcement action under Section 402(a)(1), the general adulteration provision, and so the Congress provided a comprehensive scheme that really provides for both, and the problem here is not so much the use of action levels, but the use of action levels in place of the tolerances that Congress, we think, plainly required.

QUESTION: How many tolerances has the FDA actually issued under 406?

MR. SCHULTZ: Two, one in 1944 and one in the 1970s. Only two times.

QUESTION: And that is the very last one.

MR. SCHULTZ: Yes. And I think they have made it pretty clear in this case and before this case that they don't intend to use Section 406 because they don't believe they have to use it.

QUESTION: When did it first become clear that the agency wasn't about to regularly issue tolerances?

MR. SCHULTZ: Well, that is hard to say, Justice White.

QUESTION: In the forties?

MR. SCHULTZ: Well, in 1977 they issued a final rule setting out their pratice for action levels and tolerances, and if you read that rule you would think that they in fact intended to use tolerances when

the evidence was static, and in fact they began a proceeding to issue a tolerance for aflatoxin in peanuts.

QUESTION: But it also was perfectly clear that where that wasn't so, they weren't about to issue tolerances.

MR. SCHULTZ: One thing that I think was clear certainly by the 1970s is that they read these sections as discretionary, and that they didn't believe they had to issue tolerances.

QUESTION: Wasn't it clear before that time that that was their view?

MR. SCHULTZ: I think it may have been. It is not discussed anywhere, but if somebody had looked at their nonaction --

QUESTION: Well, it is discussed here. That has been their view since the beginning.

MR. SCHULTZ: Well, yes, they do say that, but if you go and look at the testimony they are talking about, in each case the testimony says Section 406 authorizes the FDA to issue action levels. Well, that is true. It does. We agree. Section 406 authorizes the FDA to do this.

They never testified that in our view we are not --

QUESTION: You mean it authorized them to issue tolerances, not action levels.

MR. SCHULTZ: Excuse me, tolerances. Thank you. They never testified that in our view Section 406 also would allow us to regulate substances either through action levels or tolerances. They merely talked in terms of their authority. They never talked in terms of what their interpretation of the word "shall" is, and I think that if what we are trying to do here is divine Congress's intent, that one way to do that is to look at Section 401 of the statute, which was passed at the same time, where Congress used the same word, "shall," but it gave the Secretary discretion by putting the qualifying phrase right before the word "shall."

So, what Section 401 says is, when in the judgment of the Secretary such action will promote honesty and fair dealing in the interest of consumers, he shall promulgate regulations in that case concerning standards of identity for food. Well, then, Congress gave the Secretary discretion, and if it had wished to do so here, I think it can be assumed that it would have put the qualifying language next to the word "shall."

QUESTION: Mr. Schultz, what do you do with your opponent's argument that the tolerance is really kind of a two-edged sword? On the one hand, it

establishes a minimum that can't be exceeded, but also it establishes protection for the user of a product, I mean, the manufacturer of a product, and that if you freeze the level at a certain point, then there is an exemption, and they discover more information, they put it too low, the public is jeopardized by not being able to change it on short notice.

MR. SCHULTZ: I would agree with part of the argument, but I believe it is overstated. Let me tell you why. I would agree that the FDA does have somewhat less flexibility, but I would argue that Congress gave them sufficient flexibility to act when they need it, and essentially if the FDA had a tolerance here and there and there were an emergency, they could reduce the tolerance on an expedited basis, and indeed in Section 701(e), there is a provision that says the FDA -- there is a general provision in 701(e) that allows 90 days before a final order goes into effect, but in the case of an emergency situation the FDA can exempt itself.

QUESTION: Yes, but what exempts it from going through the regular procedure for amending a regulation?

MR. SCHULTZ: Nothing, Your Honor. Justice White, the FDA would have to go through the procedure, but it --

QUESTION: Calling for comment, publication,

putting out a proposal, going through their regular administrative procedure.

MR. SCHULTZ: Yes. The FDA has only lowered --

QUESTION: Subject to judicial review.

MR. SCHULTZ: Subject to judicial review, but the agency's decision would be effective prior to judicial review.

QUESTION: Well, not necessarily.

MR. SCHULTZ: That would be up to the Court, but there certainly is authority in the statute to make the agency's decision effective immediately at the time it is rendered. I think it is relevant that the FDA has only lowered an action level once. The example is cited in the government's reply brief, and in that case it took six months to lower the action level, and what we would contend is that under the procedures Congress gave it it could act at least that quickly or even more quickly.

QUESTION: Do you agree that normally it takes many months or in some cases years to go through the regulation of action procedure?

MR. SCHULTZ: The one time the FDA has done it, it did, but that was not an emergency situation. But I think it took much longer than it should have, but I would agree that normally it would be expected to take

months to go through the procedure, but we would say that that is the choice that Congress made, and in fact the legislative history demonstrates the choice was not inadvertent.

QUESTION: But the choice was -- when was the Congressional choice made that you claim was made, about when?

MR. SCHULTZ: 1938, when it issued Section 406.

QUESTION: Well, they had never of a lot of these substances at that time, had they?

MR. SCHULTZ: No. They had heard of some of them. Lead, for example, there is an action level on lead.

QUESTION: But isn't there an awful lot being learned about some of these substances that was never known before?

MR. SCHULTZ: Yes, but in 1938 there were over 100 substances that came under the statute. Today there are only eight, according to the FDA, so I don't think they can credibly argue that the burden today is greater than it was in 1938.

QUESTION: Congress had never heard of the Administrative Procedure Act in 1938, had it?

MR. SCHULTZ: It hadn't been adopted, but that

is why when Congress wanted public participation it adopted the specific procedures in Section 701.

QUESTION: They were adopted in '38?

MR. SCHULTZ: At the same time, in 1938. And 701 lists the number of Sections in the statute where the agency is required to go through rulemaking, and one of those sections is indeed Section 406. I think --

QUESTION: If there is a new substance provided obviously they can use action levels or direct enforcement until there is a tolerance established. You agree with that?

MR. SCHULTZ: I agree with that. Our interpretation of the statute, I think, is shown by what happened with aflatoxin. It was discovered in the early 1960s. At that time the FDA could immediately issue an action level, but in our view it was also required to begin the process of setting a tolerance, and then once the tolerance is in effect, the tolerance would replace the action level.

Congress initially drafted the bill to authorize the Secretary to use regulations. The bill that was adopted by the Senate, instead of saying "shall," said the Secretary is authorized to issue regulations. That is the reason that so much of the legislative history talks in terms of authority.

QUESTION: Well, if the Secretary under your view, the Secretry is supposed to establish a tolerance.

MR. SCHULTZ: Yes.

QUESTION: But until -- and he is supposed to get started, but until then he can prevent by action level or just by direct enforcement the sale of what he calls adulterated foods.

MR. SCHULTZ: That's correct, and --

QUESTION: Why couldn't he, if he had issued a regulation, why couldn't he then by the same token say, I want to amend this regulation, I have discovered some things I don't want to, and until I amend this regulation I can use a different action level?

MR. SCHULTZ: The problem is that there is a specific provision in Section 406, it is the middle sentence, that says, "While the tolerance is in effect, that general adulteration provision does not apply." So the tolerance would have to be revoked.

QUESTION: He really is -- things become rather inflexible when a tolerance is adopted.

MR. SCHULTZ: They become less flexible than with an action level, but this is the same procedure that Congress has adopted for a variety of substances that the FDA licenses, drugs, food additives, color

additives, animal drugs. If we focus on food additives and color additives, in each of those cases the FDA is required to consider applications for licensing. There is a hearing procedure.

Once the license is granted, it is good until revoked, and there is the same opportunity for a hearing before it is revoked, so while it is true that Congress gave the agency less flexiblity in all these cases, we don't regard that as a reason for interpreting the word "shall" to mean that. It is perfectly consistent with what Congress would have intended.

QUESTION: You referred earlier to the experience with pesticides where they had 100 different action levels, and they were going to get tolerances for all of them. Was the initiative for getting tolerances for all the pesticides, did that come from the FDA or from industry asking for the levels that would enable them to operate safely? Do you know?

MR. SCHULTZ: It is unclear. I think it probably came from both.

QUESTION: And there is no initiative from the farmers, I guess, here to get tolerance level for this particular additive.

MR. SCHULTZ: No, I think it is fair to say that up to now the industry is satisfied with the way

the FDA is regulated. It could be that some time in the future the agency will revoke its action levels, and there would be a lot of uncertainty that could make the industry very uncomfortable, and I think that is one of the reasons that Congress chose the tolerance setting procedure, to put some certainty into this whole process.

In deciding whether Congress thought about this or not and what it intended, we regard it as relevant that the words "is authorized to" in the original bill were changed to "shall," and they were changed not only in Section 406, but in four other places in the statute. And in order to adopt the FDA's argument, you essentially have to disregard that change and assume it was meaningless, because the FDA argues that the statute ought to be interpreted as though the House never changed the language of the statute.

In summary, the plain meaning of Section 406 requires public participation. We believe it is apparent that that requirement was not inadvertent on the part of Congress. Under the cases in this Court, in order to disregard the plain meaning, the FDA would have to demonstrate that the result that follows was absurd, to use the court's word, and here it is not an absurd result. It makes sense that it is a result Congress

intended, because indeed Congress has required hearings in order to revoke approvals for drugs, food additives, color additives, and a variety of substances regulated under the Act.

Finally, public participation will result in better and more informed decisions by the FDA. It has all the advantages which have been identified over the past 40 years by this Court and by Congress in the Administrative Procedure Act and the Food, Drug, and Cosmetic Act.

QUESTION: How often -- perhaps you have already said it. How often are action levels changed?

MR. SCHULTZ: I didn't say it. One of the problems with this whole process is, there is no way of knowing the answers to some of these questions, because there is no public record.

QUESTION: I thought the action levels were published.

MR. SCHULTZ: The agency has recently adopted a practice of publishing action levels, but in the past it didn't even do it in one place. It simply issued press releases. In the case --

QUESTION: Does anybody know when they are about to change an action level or are considering changing it?

MR. SCHULTZ: In the case of aflatoxin, when the FDA is granted an exemption, it did it at the request of the industry, so the industry knew they were considering it, but no one else did unless they heard it through the grapevine. There is no formal process or even practice by the FDA of telling the public they are considering changing an action level.

QUESTION: But to make an action level -- to enforce an action level, they have to enforce. They have to go to court, and then they have to prove that a food is unsafe and adulterated. I would suppose there would be more amicus briefs in a case like that than you could count.

MR. SCHULTZ: Amicus briefs saying that that was unacceptable?

QUESTION: Well, unless the entire industry was in agreement with the action level, I would suppose they would say so.

MR. SCHULTZ: Well, I think they are in agreement with the action level.

QUESTION: That is one way of public participation.

MR. SCHULTZ: But part of the problem is the rest of the public has been excluded from participation, and there is, you know, we still don't have the

advantage of an explanation by the FDA -- let me answer the question this way. It may be that in some of these cases the agency chose the same action level that it would choose for a tolerance, but we have no way of knowing that because we don't know the evidence the agency relied on, and we don't know its reasons, and the result that we are advocating in this case would provide us with the kind of record that agencies routinely provide under the Administrative Procedure Act, so that those judgments could in fact be made.

QUESTION: Well, your client wouldn't be excluded from any -- from an amicus position in an enforcement action, would he?

MR. SCHULTZ: No, but --

QUESTION: You could get your licks in somewhere.

MR. SCHULTZ: Well, we have to do it in hundreds of cases all around the country, I suppose, is part of the problem, and --

QUESTION: Just like the FDA would.

MR. SCHULTZ: Well, if the tolerance are adopted, the --

QUESTION: Well, a tolerance is a different matter.

MR. SCHULTZ: That is true. The FDA has to

bring a lot of cases around the country, and one of the advantages of a tolerance is that once you go through all this work, you have got a number, 20 parts per billion, that you can take into court, and as Justice Stevens pointed out, the only issue in the case is whether the company has exceeded the tolerance.

QUESTION: Yes.

MR. SCHULTZ: So in that sense the tolerance is far more efficient --

QUESTION: Yes.

MR. SCHULTZ: -- than the procedure that the FDA has chosen.

CHIEF JUSTICE BURGER: Very well.

MR. SCHULTZ: Thank you.

CHIEF JUSTICE BURGER: Do you have anything further, Mr. Larkin?

ORAL ARGUMENT OF PAUL J. LARKIN, JR., ESQ.,

ON BEHALF OF THE PETITIONER

MR. LARKIN: Yes, Your Honor. I have a few points I would like to make.

First, we have heard a great deal about public participation being the purpose that the Act was adopted. As a factual matter, I would like to point out that the FDA will receive comments from parties either asking to have tolerances or action levels set or

changed, and therefore if respondents want to have some input in the process they need only apply to the agency.

But I think more importantly, since the question is what Congress intended in 1938, and since the legislative history makes crystal clear that the public Congress was concerned with were the people who produce food at that point, I don't think respondents can reasonably expect to place a contemporary construction on a rather old statute.

Secondly, respondents argue that action levels are the equivalent of a license to add contaminants to food or to market contaminated food, and that is just flat wrong. Action levels are informal prosecutorial guidelines, and tolerances are regulations having the force and effect of law. The two are materially different, and respondents have attempted to equate the two throughout this case.

I would also like to point out that as we explained at Page 45, Note 45 of our brief, it is not that easy to change tolerances. Once we tried to change the PCB tolerance in food and found out it took seven years to do it, it can't be done as easily as changing an action level. The agency in '74, when there was PBB contamination, changed its action level in a relatively brief period of time. Changing a tolerance in order to

respond to an emergency takes a drastically longer period.

I would also like to say that respondents have attempted to prepare the regulatory scheme here to the regulatory scheme for color additives, food additives, and drugs. The schemes are entirely different. If you want to market a food with a food additive, you have to prove that it is safe. Here the agency has to prove that the contaminant will result in some injury to health. The burden of proof is in an entirely different place in the two different types of postures.

And finally, I would also like to point out that agency action levels -- excuse me -- agency action levels are published in the Federal Register. They have been since the agency's regulations were adopted in 1977, so anyone can learn where they are, and the last point is that we don't ask the Court to say that the House amendment to the bill had no meaning. All you have to do is read the House report, and you can see that the House stated quite clearly that it didn't intend this change to have any substantive effect. The House reported stated that it authorized the agency. It also stated that in all of the other places.

Thank you very much.

CHIEF JUSTICE BURGER: Thank you, gentlemen.

The case is submitted.

(Whereupon, at 11:54 o'clock a.m., the case in the above-entitled matter was submitted.)

CERTIFICATION

lderson Reporting Company, Inc., hereby certifies that the ttached pages represents an accurate transcription of lectronic sound recording of the oral argument before the upreme Cour.. of The United States in the Matter of:

#85-664-FRANK YOUNG, COMMISSIONER OF FOOD AND DRUG ADMINISTRATION,

Petitioner V. COMMUNITY NUTRITION INSTITUTE, ET AL.

nd that these attached pages constitutes the original anscript of the proceedings for the records of the court.

BY Paul A. Richardson

(REPORTER)