P.N. Kehoe

Tr. DS

EASTERN DISTRICT FOOD & DRUG ADMINISTRATION
201 VARICK STREET, NEW YORK, N.Y.

NEW YORK STATION HEARING

DATE: December 5, 1935.

SUBJECT: N.Y. 20113, Chicle.

PRESENT: Mr. Charles Wesley Dunn, Attorney,
Dr. Samuel C. Prescott (Dean of Science, Massachusetts Institute of Technology), Scientific Consultant,
Dr. Robert A. Kehoe (Medical School, University of Cincinnati), Scientific Consultant,
Dr. George E. Cowgill (Medical School, Yale University), Scientific Consultant, Chicle Development Co., 500 Fifth Ave., New York, N. Y.

Mr. W.R.M. Wharton, Chief, Eastern District,
Mr. Joseph Callaway, Jr., Chief Chemist, Eastern District
Mr. Olaf Olsen, Chief Inspector, Eastern District,
Mr. C. A. Herrmann, Eastern District,
Mr. D.M. Walsh, Chief, New York Station,
Mr. E.L. Anderson, New York Station.

****

Mr. Dunn: I want to say, Mr. Wharton and gentlemen, that since our last conference in this office we have instituted the control investigations which were discussed at that time. The Chicle Development Co. has issued instructions which are effective to send four representatives into the chicle production district in Mexico from which this chicle comes, and these representatives will make a thorough examination of the entire process of production and subsequent handling of chicle before its importation in order to discover any source of lead contamination. They have been instructed not only to examine the whole process from start to finish as to production and subsequent handling but also to forward a sample of all materials used throughout this whole period of production and handling for examination. In addition to that, the Wrigley Co. is sending two representatives into Mexico to make the same sort of an investigation, so that when these parallel investigations are completed we should know all actual sources of lead contamination as to chicle, and then, as fast as these sources of contamination are discovered, the proper remedies will be effected in order to prevent that contamination. I am sure you will be convinced from that statement that the proper investigations are being made and that the proper remedies will be adopted to control any contamination. Of course, at the moment this is an original investigation as to the companies effected, and we will know what the results are when the investigation is progressively developed and completed.

In addition to that, the laboratories of Dr. Prescott, Dr. Kehoe and Dr. Cowgill have instituted a series of chemical analyses both of imported chicle and of the materials used in the production of chewing

KE 0006326

gum and also of the finished gum itself to determine the facts which are pertinent to this matter under consideration, and I should have said in referring to our investigation of the production of chicle and its subsequent handling before importation that this investigation will include a thorough chemical analysis of the young bark of the tree and of the latex to determine whether or to what extent lead is natural in this chicle. Now, if it develops as a result of this investigation that, after we have corrected any lead contamination by discovering the sources and closing up those sources, there is lead natural in this chicle, then it is proposed to establish a proper chemical control outside of the country somehow. If that will be effective, we hope and plan to prevent the offer of importation of any chicle which may offend the tolerance for lead under the Food & Drugs Act.

In short, these various investigations that have been instituted, when they are completed, will accomplish two ultimate results. First, they will result in a thorough commercial control bureau both of the imported product and the manufactured product. It will also result in disclosing the facts which none of us knows today about the whole situation, which are decisive for the determination of the proper control. Now, because of the very difficult scientific problems that are presented -- the problems of analysis and problems of sampling -- we have to of course work through to a proper solution of these problems by actual tests and determinations.

The purpose of this conference is to give you the information and advice which I have just stated following our original conference, and then to have a more or less informal conference for mutual information and benefit in this situation. To start that conference off, I think perhaps it would be very helpful to us on our side if we could know several things. First, how does the government now sample this chicle? We would like to know, if that is agreeable and permitted, all the various facts about that, and then we would like to know how that part of the official sample which was sent to Dr. Cowgill was taken -- just what its relationship is to the 132 bags which are being detained.

Mr. Wharton: I would like to comment first, Mr. Dunn, on your program. I think it is a very desirable and constructive program. I think it's the sort of a program which will give you the solution of your problem. With respect to the sampling of this particular product, I will answer your question first with respect to the sample on which action was based in detaining the particular shipment. That sample was taken by chipping pieces from various blocks and combining the resultant product into a composite sample. We rather feel that perhaps that particular method is as good as any form of sampling that may be applied to the product. We think that if a block is split in half and portions from the fractured part are chipped off, exercising some care to get a relatively true proportion of the outside and inside material, that will give a sample of the article which will represent the block. We have no idea that such a sample, even in composite, will represent a true average picture of what may be the case as to lead content in any particular shipment. Instead, we feel indeed that probably the lead content of this material varies so extensively, that obtaining a representative sample is very difficult or practically impossible. We base that conclusion on some recent very incomplete investigations we have made which go to this point. We took 5 bags of chicle material, sampled each block in each bag and composited

KE 0063327

the product of the five blocks in each bag. We kept the sampling from each bag separate. Thus we secured five composite samples. These we sampled one block in each bag (of the same five bags), thus obtaining five samples each representing a single block from each bag. Now, the results showed variation in lead content of from less than 1 part per million up to 21 parts per million.

Mr. Dunn: Were these analyses made since our last conference?

Mr. Wharton: Yes.

Mr. Callaway: These analyses were not on the lot from which the sample was furnished to Dr. Cowgill.

Mr. Wharton: No, from an entirely different lot -- not from the Chicle Development Co. That indicates to us that there are possibly a few blocks in the bags sampled that were quite high in lead, and that there are perhaps more blocks that are quite low in lead. For that reason we think it is relatively impossible to get a sample which will represent the lead average in a lot of material of as much as 100 bags or even less.

Mr. Dunn: Let's go back. I want to clear my mind up on your first statement about the sample that was analyzed from the 132 bags of the Chicle Development Co. How many blocks were represented by that sample and from how many bags?

Mr. Wharton: Well, I'm not sure that I can tell you that. In fact, I haven't made any inquiry as to just what the process was and, as I told you at our last conference, we are not so much concerned in general with getting a representative sample as we are with determining whether there is any material in a shipment which contains lead in excess of the tolerance. It is sufficient for our purpose to determine that there is in the shipment a quantity of material which violates the law, and in that case we may sample five bags and we may sample ten. I judge from the statement made by Mr. Anderson at the last conference that in the neighborhood of from five to ten bags were sampled in the fashion that I outlined.

Mr. Dunn: From the 132 bags?

Mr. Wharton: Normally, in an original operation, we wouldn't take a sample from more than five to ten bags in 132. We are not looking necessarily for a representative finding. We are looking to determine whether there is any illegal merchandise in the shipment, and the consideration on which that decision is based I tried to state and illustrate at the last conference we had. We have experimented to some limited extent in various methods of sampling chicle. We have some of the instruments we have used here. We find, as I have already said, that the chipping method is probably the best. We have here some bits and augurs and motor drills which we used.

Mr. Dunn: Can we take this block and follow through on the various steps now?

Mr. Wharton: Yes. Mr. Callaway, will you please demonstrate now?

Mr. Callaway: What you are up against in sampling is this. Ordinarily, a bag as it comes in weighs about 150 pounds. In that bag may be pieces or

XE 0006328

you may have from six to ten or fifteen blocks or pieces of blocks. The bags are sewed up securely.

Mr. Wharton: I wish you would describe the dimensions of the blocks.

Mr. Callaway: This is about as large a block as I have seen. This is roughly about a foot long and about 6 by possibly 8 inches on the end.

Mr. Wharton: Rectangular in shape.

Mr. Callaway: Yes. In one of the bags, which roughly will contain about 150 pounds of chicle when it first comes in, you will have as I say blocks or pieces of blocks which will vary in size but will be of the general shape of this block, and the number of blocks may vary from ½ dozen up to maybe 15. Now, each block is potentially of different composition. When you open a bag and take out the blocks, they are visibly different. Very often they have marks on them -- letters that were put on them when the product was molded or while still soft. Just what the significance of those marks on the blocks are, we don't know. In first sampling, our inspectors would take a hatchet and chip a piece off a block, chipping those places as a rule where the blocks were broken, so that they would get a part of the surface and a part of the inner portion.

Mr. Dunn: You wouldn't split the block?

Mr. Callaway: If it were a whole block, it would be desirable to split it, but usually you will find broken blocks in a bag, so that you wouldn't have to split it. If they were all whole blocks, it would be my recommendation that the blocks be split.

Mr. Dunn: So that you would try to get chips which represent each block?

Mr. Callaway: Yes -- chips which contain some of the outer edge and the center but not an undue portion of the edges. Now, in considering the desirability of using other methods of sampling, we also tried drilling into these blocks, and we found that a motor drill is not very satisfactory because the drill goes so fast it throws the stuff all over the place. However, with a hand drill, with which you can go slowly, you can bore into them either with a wood bit or extension bit. Ordinary triers won't puncture a block -- the stuff is too hard.

Mr. Dunn: Is it naturally brittle?

Mr. Callaway: It varies a great deal. This represents an average block. Some of them have more moisture in them. Some of them are quite gummy. That depends how long they have been in storage.

Dr. Cowgill: Is it obvious on superficial inspection that the moisture content is different?

Mr. Callaway: Yes, it is quite different. On boring into them, it is visibly different. Where some of them have been in a warehouse a long time, the moisture has been reduced a great deal.

Mr. Anderson: Warehouse employees estimated 40% reduction in weight in some lots. Bags coming in weighing 150 pounds were down to about 80. That would

KE 0006329

Mr. Dunn: You didn't keep it 3 or 4 years in storage, did you?

Mr. Anderson: They figured it for us. There was a lot of it over in the warehouse.

Mr. Callaway: (Bores into block.) The material in this bag is from borings and has dried a little in the bag. If you are going to control moisture, you are up against a very difficult proposition in any method of sampling.

Mr. Dunn: What is your practice as to the drying out of the sample?

Mr. Callaway: We put ground samples into a Mason jar where we are going to preserve them, and then there isn't a great deal of change in the moisture content. However, in none of the samples which we have had, have we believed the moisture content to be significant. Where lead was found in amounts that were considered excessive, the amounts found were so much greater than the tolerance that it would not be important whether the calculations were based on a sample containing 40% moisture or 10% moisture. In the samples so far examined by us, we have found that they have either quite small amounts of lead, which come from some unknown source, or they have very considerable amounts of lead, which would apparently come from some definite contamination. In deciding on how a sample should be taken, it was our idea that, to secure a fair sample, we should get about the same proportion of outer and inner surface in the sample as was present in the block being sampled. However, we have no evidence so far that there is any more lead on the outside than there is on the inside. Some of the samples taken by boring had a very high lead content. Where the inspector's sample consists of chips and these are prepared for examination in the laboratory, we found the most feasible way was to use a knife and put them on a clean board or piece of paper and cut them up into small pieces. That (indicating sample) represents a sample which was originally chips which were cut up and the small pieces thoroughly mixed.

Mr. Dunn: What would be the total quantity of the final sample that you had?

Mr. Callaway: The sample that is weighed up for analysis has been 100 grams. That is, roughly, a little less than ¼ pound.

Dr. Kehoe: Do you take that at random or by a process of quartering?

Mr. Callaway: After a sample is thoroughly mixed, it would be weighed out at random, although there would be no objection to quartering it down, but after you have mixed it by rolling it, it is doubtful if quartering would make much difference. We put the sample on a big sheet of paper and thoroughly mix. When we bring in chips, we cut up all of the chips. You can't mix the chips. We take a large sheet of paper and we roll the small pieces out from chips and then we take a spatula and mix it as thoroughly as possible. Then we put it into a Mason jar and from this weigh out the sample. 100 grams would be something like that (indicating), I would guess roughly.

Dr. Cowgill: That is the weight of the natural product?

Mr. Callaway: Yes. Of course, if the moisture content is considered important, we would determine moisture on the sample in the beginning and

KE 0006330

k) Roughly speaking, I would guess that this sample con-
to 20% moisture near the surface and probably from 35%
center.

many analyses of 100 grams each would you make?

Mr. Callaway: That would depend on several things. We have to be guided by the time consumed in making analyses. In an analysis that consumes from one to two days, we can't make as many of them as analyses of products which would take about ten minutes. On this chicle, in the beginning we would make two determinations on a sample; that is, if we had a composite sample where we were using one composite with the idea that it would represent several bags, we would take two 100 gram portions, but if we had several composites, we would take only one 100 gram portion from each composite. In anything which is necessarily a physical mixture, the mixture can't be perfect, and you will not get exactly the same results out of two analyses of portions of the mixture.

Dr. Cowgill: The calculations are all based on 100 gram samples?

Mr. Callaway: Well, we use 100 grams, because, with the type of muffle and the type of dishes we have, that represents as large a sample as we can conveniently use. If we were equipped to do so we would use a larger sample.

Dr. Cowgill: What would you think of a determination made on a 10 gram sample?

Mr. Callaway: You are increasing the difficulty of getting a portion which would represent the lot. Personally, I feel that, when you have a material which is in this condition, you should use just as large a sample as you can.

Dr. Cowgill: Your justification for the use of a large sample is that it would be more representative?

Mr. Callaway: Yes, and where you have lead, you have more lead in the sample for later titration.

Dr. Cowgill: Suppose you are using the dithizone method? This is even more sensitive than the electrolytic method. The size of sample makes a big difference.

Dr. Kehoe: You can get the same result there by taking a large sample and ashing it and then taking an aliquot of the ash.

Dr. Cowgill: But it's the ashing process in your muffle furnace that takes up so much time.

Mr. Callaway: We let samples ash overnight.

Dr. Cowgill: How many of those dishes can you put in one furnace?

Mr. Callaway: We have several furnaces. We have been working on this lead so long that we are in a different position than when we first started. We have several muffles. If we want to, we can start 12 determinations at night and have the ashing completed the next morning.

KE 0006331

re these muffles?

ey are small furnaces heated by electricity.

se 132 bags, how many 100 gram samples were analyzed?

Mr. Callaway: On those 132 bags, as I recollect, one analyst made a determination on a composite sample and it was turned over to another analyst for checking, so that there were two 100 gram samples run on that original composite. Since then, two other samples were collected from the lot, and those were run by one analyst.

Mr. Dunn: You informed us at the original conference of the range of the lead found in the first analysis, which is of the 200 grams. What was the range of the finding as to the second 200 grams?

Mr. Wharton: I gave you a range of results that we had obtained on all samples of chicle, not intending, Mr. Dunn, to apply that range to the 132 bags. If I did give you that impression, it was an erroneous impression.

Mr. Dunn: I was of the impression that our 132 bags had a range up to 22 parts per million. What was the range?

Mr. Wharton: I haven't the figures in mind at the present time, but it is my impression that the maximum in the 132 bags was considerably less than 22 parts per million. I can ascertain what the record shows and then I will give you an approximate figure in round numbers of the maximum found.

Mr. Dunn: May I ask that you also give me the approximate figures on the second 200 grams analyzed?

Mr. Wharton: I will give you the approximate maximum figure of our highest result. I don't think it would be appropriate to give you the variation in the results just at this time.

Mr. Dunn: I understand that. I am more interested to find out how much at the most you did find in the 132 bags.

Mr. Wharton: It is considerably less in this lot than it was in another lot tested. The maximum of the last test was around 21 parts considering the same high testing chicle.

Mr. Dunn: And 22 was the highest you found in any chicle?

Mr. Wharton: Yes.

Mr. Dunn: Dr. Prescott, do I understand that you have been to Yucatan and seen the production of this?

Dr. Prescott: No. I have been in the tropics and have seen trees that are supposed to produce chicle.

Mr. Herrmann: Do any of you gentlemen know how these molds are produced -- how the blocks are molded?

KE 0006332

Dr. Prescott: In a wooden box, and I should think by the markings on these in some instances those might be lined with burlap.

Mr. Wharton: The fact that we found on certain blocks imprints of lettering indicates the possibility that the molding in the case of those particular blocks, at any rate, may have been done in tin containers.

Dr. Prescott: With a pretty smooth surface.

Mr. Callaway: Yes, a very smooth surface. As smooth, almost, as a table. It's almost like sealing wax. The letters would be sunk in, indicating that somebody had either molded it or possibly they poured it into something.

Dr. Prescott: I imagine the different chicleros, depending on their social standing and their ability to buy things -- these Indians go out into the forest and camp out, and they have their trees which they tap and then they bring it in. It's one of the crudest forms that we have on the continent.

Mr. Wharton: The method of molding becomes important, because if they use tin cans, very naturally those tin cans may be supposed to have lead soldered joints, and that may be a source of lead.

Dr. Prescott: That is one of the things we called to their attention -- that we should have very definite information as to the way in which the stuff is collected. I have been told it is collected in bags. Those bags, of course, get covered over on the inside with a layer of chicle so that they become impermeable. Then it is transported to the man's hut, where he has some kind of melting up or mixing device. Then, he has a wooden box or an oil can in which he molds it. We will try to get all the information we can on that.

Mr. Dunn: In your analysis of this chicle, have you found tin present?

Mr. Callaway: We have not made any special attempt to identify tin in this chicle, but we have found no superficial evidence of tin. It is possible that, if we made a special examination for tin, we might find it. We removed any tin from the precipitated sulphites by washing with polysulphide. We did not examine the polysulphide for tin. If there are material amounts of tin present, you can observe tin sulphide being washed away, and this wasn't observed on these samples.

Mr. Herrmann: I think Mr. Dunn has in mind that the presence or absence of tin, as determined by our analysis, might be an indication of whether tin containers had been used in molding. I don't think that absence of large amounts of tin, as discovered by the method of analysis, would be an indication of whether tin containers had been used or not because the tin may be relatively inert chemically and the lead, on the other hand, if there were lead soldered joints, might have a great affinity for this hot material that is poured into the cans in the molding process, so you might find lead and not tin.

Mr. Dunn: Does this lead, in your experience and opinion, become chemically combined with this chicle or does it tend to be a foreign ingred-

KE 0006333

is a pretty difficult question to answer. On a broad , there might be a chemical combination. In the case oil exposed to lead soldered joints of a can, the inity for the oil and produce a lead oleate, which would be a chemical combination. In the case of dry tea packed in lead chests, the chances are that the lead is present in minute particles by the process of attrition.

Mr. Wharton: But that is not necessarily as metallic lead. It may be in the form of lead salts. One sees as lead sheets corrode some which give a black surface, and sometimes a whitish material appears on the surface.

Mr. Dunn: So really you have no information on that question -- as to how this lead remains in the chicle.

Mr. Herrmann: No.

Mr. Wharton: I am prepared to answer your question with respect to the finding of lead in the 132 bag lot detained and imported by the Chicle Development Co. Roughly, in round figures, our maximum result was 7 parts per million. We sent Dr. Cowgill a duplicate sample What result did you find, Dr. Cowgill?

Dr. Cowgill: The official sample was between 6 and 7 parts per million or thereabouts.

Mr. Dunn: That is substantially the same.

Dr. Cowgill: It was about 7, and we subtracted a slight blank which brought it down a little.

Mr. Dunn: May I ask these two questions? One is have you made any check analysis by another method as to the findings of lead in chicle?

Mr. Callaway: Not on these particular samples, but this method that we used has been checked time and time again against other methods and has given closely checking results with other reliable methods.

Dr. Cowgill: I might add in relation to those figures I just quoted that we analyzed that material by our dithizone method and by the electrolytic method which the government used, and the dithizone method yields slightly more than the electrolytic, but the figures are very close to the 7 which you mentioned.

Mr. Wharton: That is a remarkable check on a product of this type.

Mr. Dunn: It shows that the methods are fairly accurate.

Dr. Cowgill: We were just a little bit puzzled how to correlate that with the 21 or 22 parts.

Mr. Wharton: It has no relation.

Mr. Dunn: I'm glad that point is cleared up. It worried us.

KE 0006334

tion of all our results on chicle. You asked was. I quoted you from the highest result but that result did not apply to this par-

Mr. Dunn: I am very glad to know that. The other question I wanted to ask you is this. Part of the official sample that was sent to Dr. Cowgill -- what physical relationship did that have to the sample that you analyzed from these 132 bags.

Mr. Wharton: It was a part of the same sample which has been described here this morning. It was the remaining part that was left after we had finished our examination.

Mr. Dunn: What was the weight?

Mr. Wharton:, I don't know that we made any record of it.

Mr. Dunn: Dr. Cowgill, through my other associates, is now making a very exhaustive investigation of the deleterious effect of lead on the human body from the standpoint of metabolism. It is a personal investigation. It has no relation to any product. He is going into it very thoroughly. I have already received, a couple of days ago, one of his interim reports which is most informative. He is making these tests on rats, and now he is going to make similar tests on dogs to check.

Mr. Herrmann: You mean lead in general, because there is a tremendous background of toxicity tests on lead in general.

Mr. Wharton: It would be very interesting to have him say whatever he cared to on that.

Mr. Dunn: Dr. Cowgill, will you please state for the record, without referring to the sponsors of your present lead investigation, the investigation you are making and the point of view from which you are making it to determine the deleterious effect of lead in general on the human body. Just a broad statement.

Dr. Cowgill: We are interested in the problem of determining what is the lead tolerance for lead ingested as part of the diet. Most of the data that is available in the literature, upon which various suggestions of tolerance have been based, were obtained from industrial studies where it was in the atmosphere, and it is known that the toxicity of lead taken by the lungs is very much greater than lead taken as part of the food. Unfortunately, there isn't available in the literature the sort of data which one should like to see on which to base a statement as to what is the tolerance for lead taken by mouth. We are engaged in an experimental study of this problem in which we propose to measure the intake of lead and the output by way of the various excreta and the amount present in the blood, and from that study we hope to have some data to contribute toward the solution of this general problem.

Mr. Herrmann: Does that study you are engaged in take into account the cumulative effect of lead?

KE. 0306335

Dr. Cowgill: Yes, we expect to. We must know first of all how much lead is taken in, we must know how much is put out and how much is circulating in the blood during a given period, and from this data we should know how much is retained by the organism. At the end of the study, after we have done everything we can in the way of a balanced study of the animal, we will analyze the animal and check on our values by actual analysis of the organism. That is a necessary part of the study.

Mr. Wharton: We will be very much interested in your results.

Dr. Kehoe: My associates and I have been engaged, as most of you know, for quite a number of years in the study of this precise problem of normal lead intake and the source of so-called normal lead. It is now very definitely established that normal individuals are taking in not less than .25 of a milligram of lead daily and that does not lead to accumulation. The connection of our laboratories with this problem is dependent upon the fact that this field of experimentation fits directly into the field which we have been studying for a number of years. Our chief concern is not with the commercial considerations, which a university laboratory cannot take into account, but rather the question of the natural lead content of food materials--the extent to which that natural lead content is augmented by a thousand and one possibilities for contamination that exist, and the extent to which this total picture in the United States is fluctuating upward or downward as a consequence of additions at this point and subtractions at another point. I think it can be stated that the cross-sectional picture at the moment is, from a hygienic point of view, rather satisfactory, but that a number of factors have been shown to enter into it, of which perhaps the most significant is the spray residues on fruit materials, as the Department well knows. This is a small problem of the same sort we have been interested in here. As a consequence of that, I have been interested in making certain, through collaboration with the people working on this in Mexico, that we obtain bona fide samples which will make it possible for us to exclude beyond any reasonable doubt such lead as is there by accident and determine the presence of such quantities that are there as a matter of nature. I have been very insistent upon the collection of adequate and representative soil samples in relation to the trees from which the latex is to be obtained, obtaining the latex by such methods as will assure it hasn't been contaminated by bark or dirt or otherwise, obtaining also the latex by the standard methods and then following the material from there on until it leaves the final source of its handling. We are very definitely interested in that point because it is a matter of general scientific interest, and also in this case it is a matter of practical importance.

Mr. Wharton: That is very interesting to us, Doctor. I would like to ask whether the 30% chicle content of chewing gum which has been stated is stated on the basis of dry chicle or the chicle as it is used at the time the chewing gum is made.

Mr. Dunn: I think we want to answer that question only if we exactly know.

Dr. Kehoe: I can't answer that. All I can say is that the chicle as it finally appears in the gum contains from 3% to 5% of moisture. That doesn't tell what actually went into the process. It is weighed in a partially dried state.

KE 0006336

Mr. Wharton: The reason for the question is this. We understand that this chicle is kept in a warehouse for long periods before it is actually used -- one of the purposes of that procedure is to obtain a drier article for use -- and that there is a loss in weight in storage of about 40%, so that these factors would have to be taken into consideration; that is, whether you are figuring your percentage in chewing gum on the basis of dry chicle, moisture free, and the loss in weight during the time of storage, in order to correlate the question of transfer of the amount of lead that we find in this chicle as we sample it that goes into the chewing gum.

Mr. Dunn: I will get you the answer to that question from the manufacturers, but let us assume, Mr. Wharton, for the sake of the present discussion, that the figure is, generally speaking, 30% of chicle to the weight of the finished chewing gum. Inasmuch as the only way in which the consumer gets this chicle is through the chewing gum, isn't the necessary and reasonable and logical conclusion that, in appraising under the Act the amount of lead in imported chicle, that appraisal ought to be made upon the basis of the amount of chicle that enters into the finished chewing gum?

Mr. Wharton: I will try and answer that question as well as I may. The theory in general, applied to food products in general by the Food & Drug Administration, in the absence of any authority or ability to control the disposition to particular channels or uses or the quantities employed in food products of various composition, has taken the position that the raw materials used in the manufacture of food products should comply with tolerances set for food products. Administratively, it is exceedingly difficult under present conditions of authority of the Food & Drugs Act, as you well know Mr. Dunn, to establish even administrative tolerances which will vary one from another, depending upon the use, the quantity factor of consumption and the like. Therefore, tolerances under the Food & Drugs Act have been applied on a general basis rather than on a basis of quantity of use or conditions of use. However, it does seem to me, and this is only my personal opinion, that this particular issue, lead in chicle, presents perhaps a different picture from any that might be compared with it, since chicle must be recognized to go only to one food source, and that is chewing gum, and therefore, having no other use as food, cannot be diverted as many other products can, and second, there is a dilution factor of at least two to one. I believe that, since Mr. W. G. Campbell, the Chief of this Administration, has been seeking authority to establish tolerances that will differ with respect to materials and because of different quantities of consumption and methods of use, I rather believe that the Administration would take into consideration those factors in arriving at a decision on the question of action against chicle in any specific or general way because of lead content. However, I cannot commit the Administration. I am only expressing my personal view about the matter.

On the other hand, it seems to me, from an industry standpoint, that this particular question presents possibly a hazard to the industry that the industry cannot afford to let remain in existence. It's a strange thing that industry in this country is diligent to remove practically all of the commercial hazards that can be recognized and they are diligent to search out these commercial hazards in order to eliminate

KE 0006337

and reduce their liability under those hazards. On the other hand, ry in this country in many, many instances has hazards much more ially dangerous to their business in matters involving questions r to those we are discussing here today, and so it seems to me that ly, rather than to seek a liberalized tolerance for this class of al, and perhaps this is a gratuitous additional statement over any ight be expected by your question, it seems to me that, instead of this industry ought to endeavor to eliminate the lead as nearly as possible from this material.

Mr. Dunn: I join you in that statement. That is our policy as an industry. However, I would like to go on to say this -- that on the one hand the industry, as represented by these three gum manufacturers who produce more than 90% of the gum consumed in this country, would collaborate with the government to the extent of always assuring the government of the maximum chicle content of the gum manufactured and sold by these three companies, which would fully protect the government in modifying the tolerance on the basis of the amount of chicle used in the manufacture of a product. Now, my second observation is this; that we hope, of course, that our investigation may establish that the problem here is one of contamination and that it can be corrected accordingly without any difficulty after the necessary period of determining the facts and making the necessary corrections. On the other hand, of course, there is this possibility. This is merely a speculative possibility at the moment. We may find that normally and naturally there is an amount of lead in chicle which does exceed the present tolerance. If that is so, then the industry has got these courses, as I see it, to follow -- either to withhold the importation of any chicle which does offend that tolerance or to clean the chicle or recondition it in some way so as to bring it within the tolerance, or if that amount of lead naturally in chicle when translated in the terms of the finished gum does not make that gum per se offensive to the Food & Drugs Act, that they should secure a liberalization of the tolerance accordingly. I am not in a position to say at this moment whether that natural improvement of chicle will prove to be a fact or whether it will be feasible in any commercial sense to withhold the importation of chicle which naturally contains more lead than the tolerance. There is a possibility that all chicle may be of that sort.

Mr. Wharton: We know that you can't set up a theory of that sort. We know from actual test that the vast majority of chicle has a very low lead content. We also know that if chewing gum had been made from the 5 bag lot of chicle which we recently sampled, to which I referred earlier in this conference, even though it was diluted in the process of manufacture with the use of only 40% of chicle, then the finished chewing gum would have in the neighborhood of 5 parts per million, even though the entire 5 bags were included in the batch.

Mr. Dunn: Of course, we are hoping that the ultimate result of our investigation will establish that most of this lead problem is due to contamination and may be corrected accordingly, and that any resulting lead which may be naturally present in the chicle will not present a legal problem under the Act because it will fall way below the tolerance.

Mr. Wharton: Of course, it is remotely possible, but it is so remote as to almost be unworthy of consideration as a possibility, that some chicle

KE 0006338

might have the amount of lead naturally in it approximating the present tolerance, but we hold the theory that this lead in excess in this chicle is the result not of the lead being in the product naturally but by contact with some method of contamination with lead.

Mr. Dunn: We certainly hope that is a fact, because it can be corrected then. Of course, the ultimate point you come to out of all this discussion is that we are not going to know what the situation is or what must be done until we complete our investigation which we have instituted. We are dealing in the dark now and dealing with possibilities and probabilities. Therefore, Mr. Wharton, it is just essential that we have some form of a transition period here in which to make these investigations and to work out this problem satisfactorily with you. When I say you, I mean the Administration, and I would like to add here that Mr. Campbell has written me a letter to the effect that he will be glad to discuss this matter with us on December 19th at 10 A.M. in the morning. I am wondering whether, in view of your familiarity with this situation, it would be possible or feasible for you to attend that conference. We want to have a thorough discussion and a discussion based upon the actual experience here in the New York office as well as our own experience and investigation.

Mr. Wharton: Of course, I would be very glad, upon instructions from Mr. Campbell, to attend the conference, but in view of the fact that we habitually follow the practice of keeping the Administration fully advised in detail on all of these questions, and since the Administration is advised on this matter, it would not be essential that I be there.

Mr. Dunn: No, it would not be essential except that I suggested in writing to Mr. Campbell about this matter that anybody be present who has anything to do with this situation in any decisive way, and I should think you would be one of the very important people to be present at a general conference. Would there be any objection to my suggesting to Mr. Campbell that you be present?

Mr. Wharton: None at all, Mr. Dunn. There is one other question which I want to raise, and that is this product chicle appears, in some cases at least, to be handled in a way that might be improved from a sanitary standpoint. We find that some of the blocks are sour smelling. Some of them are bordering on putrid in odor. We find that the outer crust has sticks and more or less extraneous matter adhering, and we think it is possible that some improved methods of production and handling may improve the quality of the product.

Mr. Dunn: That will be thoroughly looked into through our investigation. As soon as I get back to the office, we will make arrangements to include the investigation you mention. The great difficulty with which we are confronted here is that we are dealing with a crude method of production; with Indians out in the jungle collecting this material. Therefore, we have all of the resulting problems.

Mr. Wharton: We are familiar with the difficulty by reason of having experience with literally hundreds of products of world production in backward countries where sanitary conditions have not improved over the generations. Generally, however, there is a method of securing better-

KE 0003339

Mr. Dunn: 'e will institute any improvements that are necessary and us. I assure you of that.

Dr. Prescott: The question of course is, Mr. Wharton, that the gun goes y severe cleaning process before it is used in the manufac-

Mr. W We recognize that is true.

Of course, I appreciate the point of your remarks, too, .t may be possible to lay out some relatively simple sanitary ıe importers can insist upon. The problem of inspecting to those are carried out might be difficult, but at least requirements, and that is the first thing to do.

ırned.