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ENVIRONMENTAL PROTECTION AGENCY

LEPTOPHOS ADVISORY COMMITTEE MEETING

PUBLIC SESSION

ROOM 3906
WATERSIDE MALL
401 M STREET, S.W.
WASHINGTON, D.C.

WEDNESDAY, July 21, 1976
2:00 O'CLOCK A.M.

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P R O C E E D I N G S

(2:00 p.m.)

CHAIRMAN COON: I would like to convene the opening session, ladies and gentlemen. The purpose of this opening session, if you will recall from yesterday, was to submit to the -- to submit any questions to the Velsicol people the committee may have on its minds, as a result of the committee's deliberations in the last few hours.

And, I should add, I should say that the committee is really not loaded with questions at this point, but in answer to the few questions that we do have, there might be other questions generated in that we can proceed on that basis.

Gentlemen of the committee, would you ask any questions that you might have.

DR. FRIESS: Gentlemen of Velsicol, a question raised in the course of the committee work this morning, which really bears on the need for information relative to the toxic effects on humans by whatever routes or modalities of exposure these humans have experienced, you did tell us yesterday that information exists with respect to peripheral neuropathy in the human from certain kinds of exposures that have occurred.

We feel that it would be extremely important for the committee within the next month, which is between now and

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the time that we are going to put the report out, for us to have rough data on these relating to the following points, as much as you have and in as crude a form as you have is okay with the committee.

What we would really like to know is items relating to the airborne concentrations that personnel might be exposed to in the course of manufacture, over long periods of time, and rough estimates of time intervals of contact for personnel with these airborne concentrations, and however rough you give it to us, indications of peripheral neuropathy in these operational personnel as a function of the integrated dosage that they might have gotten.

It is asking for a lot, and it may not be in polished form at this stage, but what we would really like to know in the earliest possible form for release, is the effect in the human, this peripheral neuropathy as a function of dose that the human has been exposed to by the inhalation route. That is a primary need, because the human is the ultimate target that we are worried about and the animal models are great, but if there is this epidemiological information on the human, and if it is reaching report form in a month, what we would like to ask is a preliminary peek at the rough data, before the month is out. This would help us a good bit, especially in terms of the timetable for the production of the report, in which the committee would benefit

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by having the data at the earliesttime to have the longest consideration time. So we would very much appreciate that kind of information if possible, in the earliest part of August.

Secondly, it would be of some interest and considerable interest if data exists relating to single incidents or group incidents of accidental skin exposure, percutaneous exposure of the human perhaps in the manufacturing situation as much as possible relating to time and dose, and net peripheral neuropathy, this would be information of extreme importance to the committee, in looking at the biological situation in man, vis-a-vis that in the animal.

So, we really are saying that we would very much appreciate having inhalation and skin contact information in the human, in however crude a form you wish so that the committee members might have it as the earliest possible date.

And, we would thank you very much for such information.

CHAIRMAN COON: You are welcome to make any comment that you wish in connection with those requests.

MR. CALO: I think really the only comment that I could make at this time is I really don't know what information is available. I would have to ask for exactly what you asked us for.

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CHAIRMAN COON: Are there any further comments or questions along this line from the committee?

DR. McNAMARA: I have one. Do you routinely do cholinesterase monitoring on the workers in the plant?

MR. CALO: Yes, we do.

DR. McNAMARA: What kind of frequencies of cholinesterase do you see in this?

MR. CALO: I really can't give you an answer on that because I have not seen the data. I know of the particular facility that we are talking about, we have collected cholinesterase data back to 1969 and that information surely should be available.

I might add by way of an explanation, that our manufacturing facilities take care of themselves pretty well and that our contact with them is limited, and given on request, so that we are not as familiar with that type of data as we would be with registration data, which we are directly responsible for gaining.

Most data could probably be obtained, and if they are available, they will be given to you as soon as they can be, but we do not have those at our fingertips, as we do many aspects of our program, to get registration for the compounds.

CHAIRMAN COON: You are referring to the cholinesterase data that Dr. McNamara asked about or all of the other

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MR. WHITACRE: Any aspects having to do with the manufacturing process.

DR. FRIESS: Just in terms of being able to sequester data, is all manufacturing done in one location -- all manufacturing of Leptophos done in one location?

MR. WHITACRE: Leptophos is manufactured in two places, in the world. It has been manufactured in Japan since about 1969, and in Texas, near Houston since 1971.

There has been no incident -- well, maybe I shouldn't say that, I am not familiar with the program, but in Japan there has never been any reports at all concerning that due to the manufacturing of the material, is that true

MR. CALO: That is correct.

DR. FRIESS: But, in this country, there is just the single plant in Houston?

MR. WHITACRE: Right.

DR. FRIESS: And, are the populations relatively stable of workers so that one might have expected certain workers to have prolonged and continuous exposure?

MR. WHITACRE: We have asked the manufacturing people to gather all of those data, and that is the report that I am referring to.

It might seem to you that we know a lot about that but in fact, we do not, simply because it is their responsibility in the company. We have asked them with the help of

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consultants to put together everything they can. They have conducted a monitoring program within the last year and a half or so, data from which should be available. I have not made any report or anything from that experience, and so when I see it, I am going to see it, and we will probably see it about the same time.

DR. FRIESS: Thank you.

CHAIRMAN COON: Are there any other questions? Dr McNamara, did you have another question?

DR. McNAMARA: Yes, I had another question, one that is definitely in mind. And, I was wondering, with a compound that is not registered, why would you want a tolerance level conducted?

MR. WHITACRE: For the sake of registering the compound principally. It is the first step, or at least after certification of usefulness is made by the agency, for this compound, the next step is to establish a tolerance, whereupon, if everything else is adequate, the registration can be obtained. Our intent in originally submitting the application for registration in this country, is for that purpose, to get the registration. It has just so happened certain occurrences have not permitted registration be issued.

Obviously, if the tolerances will not stand, we will not have the basis to ask for -- the basis upon which to issue a registration.

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So, very simply, the reason that we want tolerance is the first or second step to obtaining registration.

DR. McNAMARA: This is the general sequence in getting registered?

MR. WHITACRE: I would stand corrected by anyone from EPA, but that's the sequence for food items.

DR. ROSEN: I'm finished, I have no questions.

CHAIRMAN COON: I would like to ask one question in connection with your plans for a cholinesterase study in chickens. I want to be sure -- is this a feeding study, or a single dose per day administration?

MR. WHITACRE: It would please us greatly if the committee would take that proposal, which we have written, and look through it. It would answer two questions, and perhaps it would answer the question that you are asking, first, but second, you might want to make a suggestion before it gets under way.

CHAIRMAN COON: This proposal hasn't been made available to us, yet.

MR. WHITACRE: That is right. Would you like it, that is the question? I don't think that it has been made available, although I would be more than pleased to submit it, for your information and for your comments.

CHAIRMAN COON: I think that it would be important for the committee to have, yes.

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MR. WHITACRE: Incidentally in answer to your question, it was going to be -- well, we haven't decided in fact absolutely whether we should give -- whether it should be a feeding study, in which the material is incorporated into the feed, or whether we should administer the dose by gelat capsules, so that we would know absolutely what each bird is getting. Did we decide finally?

MR. CALO: No, we have not decided that.

MR. WHITACRE: Everything else being equal, I thin that we would like to go to the geletin capsule unless it is not necessary. We haven't had to make that decision, becaus we haven't lined up the facilities.

The only advantage, it is easier and cheaper to doing it with the feed, incorporate it into the feed, and it is adequate. But, the advantage of administering the capsul is that you know exactly what each bird has ingested, and fo control purposes, it might be a little bit better, I'm not sure.

DR. FRIESS: Mr. Chairman, could I address this point?

CHAIRMAN COON: Yes, go ahead.

DR. FRIESS: This has been the subject of some discussion with the committee, and I think that points can be made in favor of the feeding experiment, that this is more realistic in terms of the time sequence of ingestion,

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1 as related to man's experience in eating food.

2 And, secondly, the absorption problems with respec

3 to compound tissue, rates of dissolution, carrying and meta-

4 bolism are much better approximated by the feeding experimen

5 than by the gelatin capsule experiment.

6 MR. WHITACRE: Incidentally what we normally do for

7 feeding experiments of this type is we use gelatin capsules

8 -- well, what I do, we try to absorb the material in the

9 grain so that it shouldn't be a major factor in terms of --

10 in other words, it is the same material --

11 DR. FRIESS: But in a small bolus of relatively

12 high concentration, which contrasts with taking in a larger

13 volume of food, with a smaller specific structure, and one

14 wants the model which is closer to man, eating food in bulk.

15 MR. WHITACRE: But, it is your recommendation that

16 it should be a feeding experiment?

17 DR. FRIESS: Personally yes, and I think that this

18 is reflected by the committee.

19 CHAIRMAN COON: This was our -- practically the

20 assumption of the committee, when it was discussing this

21 matter. It just entered my mind the possibility that you

22 might be considering the capsule approach to the administra-

23 tion, so I thought that I would ask questions, and that

24 conventionally in long term toxicity studies with food addi-

25 tives and pesticide residues in food, conventionally they all

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1 proceed by incorporating the material in the diet. And, Dr
2 Friess gave a fairly succinct reason why this is usually don
3 MR. WHITACRE: I would like to do it that way.
4 CHAIRMAN COON: You mentioned the theoretical
5 advantage of knowing exactly how much of the chemical the
6 chicken is getting.
7 I suppose as time goes on, and the weight of the
8 chicken changes, so that the amount administered would be
9 on a pretty low basis to keep that constant. Well, of cour
10 as the chicken grows, it eats more too, and so there is
11 sort of built in an automatic increase in the amount pro-
12 portionate to the weight of the chicken. Of course, that is
13 not exact, because sometimes the chicken will not eat, but
14 what he eats would be variable, but -- in the chronic
15 mouse and rat studies, they have an estimate of how much
16 the animals eat per day. In some tests they actually measur
17 the daily intake of the food, and know the concentration of
18 the chemical in the food, and they can calculate exactly
19 how much was consumed.
20 I suppose that there are other estimates of the
21 consumption, the food consumption of the chickens, on a weigh
22 basis for the type of food that they are taking.
23 MR. WHITACRE: There is -- yes, it is a matter
24 of the number of animals being used, if they show any measur-
25 able or significant variation in intake, then there will be

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an error there which will not be easily defined, but it should not be excessive on that basis.

I am not really concerned that the study involvin the feeding of the compound would be inadequate in any way, if everything goes according to the schedule we would like to define.

CHAIRMAN COON: Well, committee, is there anything further?

(No response.)

CHAIRMAN COON: Well, I might invite questions or comments from the observers who have arrived today, if the wish to ask questions or make comments, I would urge that if they do, identify themselves, and indicate whether they are speaking for themselves, or for the agency that they represent.

DR. CORODA: Dr. Rosen brought up a point yesterday about accumulation in fish, and in this regard I would like to ask Leptophos if they have completed their egg to egg feeding of the study of brook trout, and if not, I think that the data would be very interesting to the committee. I think that it should be turned over to them.

MR. CALO: The study is completed. We have every intention of turning the information over to the EPA and the committee. I understand that the report will be completed within the next three weeks. As soon as it is available, we

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will pass on the report to appropriate channels.

DR. CORODA: This was done by Ken Macy.

MR. CALO: It was done by Bionomics, that is correct.

DR. CORODA: I have one other comment. I heard that through the grapevine that Phosvel was banned in Egypt, do you have any comment?

MR. CALO: I guess really I can only give an unofficial answer. I have not heard that. The information that I have is that if they had an infestation as they have had in past years, they would probably request the material again. I know that it is actively being considered by a number of people in Egypt.

DR. CORODA: When you speak of infestations, are you implying that this compound is only used during periods of infestation and at other times when there is not an infestation it is not used?

MR. CALO: Relative to the efficacy of the compound I really can't comment. I just am not that familiar with these patterns whether they be here in the U.S. or overseas.

DR. FRANKLIN: Dr. Claire Franklin, Health and Welfare, Canada.

Could you tell me are there any other pesticides produced in the plant in Texas other than Phosvel?

MR. WHITACRE: I am not certain because again, I am

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not really involved with the manufacturing situation, but my impression is that Phosvel is the only labeled Methylparathion.

I think that there was a Methylparathion converted plant in --

DR. FRANKLIN: And, they are still actively producing it now --

MR. WHITACRE: Well, let me finish. I think that that was a Methylparathion converted plant that produced Phosvel up until early 1976, and it has been converted for EPN production, by Velsicol.

MR. ROSEN: Does that mean that you will no longer be producing it in the States?

MR. WHITACRE: I really don't know. I really do not know what the plans are for that plant, or for the compound until we go further.

DR. FUKUTO: This is jumping out of the pot and into the fire, EPN is a neurotoxic agent, and from what information we have, how seriously has the company considere this?

MR. WHITACRE: I am sure that they have considered it, and I really can't answer it from the corporate standpoin I'm just not in the position to do that, because I am not involved in their decision making, perhaps it seems so, and it may be so, but I can't really answer the question with any

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1 assurity.

2 DR. ZWEIG: Are you phasing out the Phosvel produc

3 tion?

4 MR. WHITACRE: I don't know if that is the case.

5 You've got me in an area in which I know little about it

6 from the company's standpoint. Phosvel is not now being

7 produced in the United States, and it hasn't been for some

8 months. That is all that I know.

9 DR. ZWEIG: It is being produced overseas?

10 MR. WHITACRE: As far as I know it is being pro-

11 duced in Japan, but I really don't know. It is not one of

12 the considerations that I'm required to look at or which

13 Charlie is required to look at. And, we haven't.

14 DR. ZWEIG: Questions can be answered if they are

15 cogent and the committee wishes to have them addressed.

16 MR. WHITACRE: Well, I can't answer with any degre

17 of certainty, because I just don't know.

18 DR. FRIESS: What did come to mind though, is that

19 the interval in which workers might have been exposed during

20 manufacture is now limited from 1971 to 1975, right, there

21 is a four year interval?

22 MR. WHITACRE: That was when the compound was

23 produced, domestically, that is what I understand, through

24 1975.

25 DR. FRIESS: That is the interval of course, for

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which we would like exposure data.

MR. WHITACRE: Indeed, yes.

DR. FRIESS: Is there any intent to follow up workers with respect to long-term delayed neurotoxicity, under the Occupational Safety and Health type regulations?

MR. CALO: I don't know.

MR. WHITACRE: I don't know what their long range plans are. We have not, at least I have not been asked to give my opinions on that, and I don't know what their lon range plans are.

CHAIRMAN COON: Does EPN have a registration now?

MR. WHITACRE: It is a registered product in the United States.

DR. CORODA: It is on the presumption against registration, it is on the RPAR list for delayed toxicity, so it is going to be examined for that property.

DR. ZWEIG: It is registered though?

DR. CORODA: Yes, it is registered, yes.

DR. ROSEN: Could you describe the fish study? Do you have any kind of information?

MR. CALO: I can describe it in general terms. I don't have any of the data. It is an egg to egg study, whic encompasses probably 13 months of work, wherein you expose mature fish to the chemical, during their adult stages, and during the period of time when they are reproducing. You

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then follow through the egg of the first generation until they reproduce. In general terms that is the whole idea of this study. It is a laboratory study, not a field study.

CHAIRMAN COON: The point of that is a reproductic study?

MR. CALO: Yes.

CHAIRMAN COON: You say that that is going to be available shortly in about three weeks?

MR. CALO: Yes, I believe the date given by Dr. Whitacre was the 20th of August, which is approximately a month.

MR. WHITACRE: I don't think that I mentioned that report yesterday, even though it was in that manuscript that I talked about, but that is true, it is available, it will be submitted.

DR. FRIESS: We hadn't heard about it.

DR. FUKOTO: That's the third study that you are talking about?

MR. WHITACRE: I don't know what happened. I don't think that I mentioned it yesterday, because I don't remember it, but on the other hand it was in the thing that I read from, I think that when the charges were restricted on the environmental aspect came out, I cut it, and we got back into that yesterday, it broadened again.

DR. FRIESS: Because it is broadened.

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DR. ROSEN: Are there any other studies that are going on that might be pertinent to this?

MR. WHITACRE: There are no other studies going on to my knowledge.

DR. FRIESS: The question that I have is with respect to the increasing need to have mutogenic data on all chemicals in the food chain as well as the environment. I wondered, does the company have any plan to include Velsicol in systematic and vitro screening for mutogenesis?

MR. CALO: The whole area of mutogenesity is right now a very difficult one for us. We have spent tons of hours discussing what we should do. Routinely we have been doing at least a dominate lethal study, and in some cases we have gone beyond this. In terms of the in vitro studies, we have not made a decision as to what we will be doing. We have been told by EPA that some time this year, there will be some guidelines out as to what tests would be appropriate. Really, we are waiting for some direction in that area.

DR. FRIESS: It hasn't been done yet to the best of your knowledge, and the in vitro system, there is no plan at the moment?

MR. CALO: For Leptophos?

DR. FRIESS: For Leptophos, right. Speaking of in vitro system.

MR. CALO: It has not been done. The mutogenisity

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1 studies that have been done on Leptophos have been a domina
2 lethal study, a host mediated study, a reverse mutation and
3 recomination asset study.
4 DR. FRIESS: And, are reports available on all
5 four of those in the petition?
6 MR. CALO: They should be a part of the petition
7 or an amendment to the petition. It is as an amendment to
8 the petition.
9 MR. WHITACRE: As a recent amendment, because they
10 were submitted about a few months ago.
11 MR. CALO: With the exception of the dominate
12 lethal, that was some time ago.
13 MR. WHITACRE: Let me ask Dr. Painter, if we sub-
14 mit something to the file, but not as a part of an amendment
15 is it available?
16 DR. PAINTER: I really don't know if that is a
17 true statement, perhaps the project manager knows about thes
18 sort of things, and can answer this question, but it is not
19 something that I am familiar with. I really don't know the
20 answer to that.
21 DR. GEE: Franklin Gee. What do you mean, Dr.
22 Whitacre, if it's available?
23 MR. WHITACRE: There are some items within the las
24 year since Phosvel has been in limbo, so to speak, that have
25 been submitted to the file but not as part of any amendment.

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MR. GEE: When you say it is available?

MR. WHITACRE: To the committee in the basket.

MR. GEE: It is not part of the basket?

MR. WHITACRE: No, we have it in our files. It is not part of the petition.

DR. FUKUTO: We have some items -- there are some items that came fairly recently like the degradation studies in water, and is that the thing that you are talking about?

MR. WHITACRE: It would have to be from Velsicol.

DR. FUKUTO: It is from Velsicol, and it is called a report, we have those things.

MR. WHITACRE: What I am trying to determine is if something was submitted that was not part of the petition, or the amendment to the petition, it was submitted simply to fill the file, is it available to the committee's review, or must we submit it separately to the committee or must you submit it separately to the committee?

MR. GEE: Let me say the files there contain all petition information, the information that you are talking about recently we received and I know what you are talking about, and we've added it to the file. It is not part of our basket. We have it in our files here in the main office.

If the committee wishes to see it, it can be made available.

DR. FRIESS: Mr. Gee, if you do indeed have those

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1 four studies on mutogenesis, if you can submit it, and they
2 are in the file, the committee would like those.
3 MR. GEE: If you have submitted them -- you have
4 submitted them to us?
5 MR. WHITACRE: As I recall, they have been sub-
6 mitted in the last four or five months.
7 MR. GEE: We have them.
8 MR. WHITACRE: The host mediated study is an
9 old one. Right?
10 DR. FRIESS: Isn't the dominate lethal the first
11 one filed?
12 MR. CALO: Yes, the other three were submitted
13 at the same time.
14 MR. WHITACRE: So, the three studies should be
15 available, all except the dominate lethal.
16 DR. FRIESS: Right, the dominate lethal infor-
17 mation is available, that is out, the other three are not.
18 MR. CALO: That is correct.
19 MR. BOWEN: The three studies that have been
20 sent to the Registration Division is what the committee
21 desires to have.
22 DR. FRIESS: Right.
23 MR. BOWEN: And, Mr. Frank Gee will furnish those
24 to the Secretariat when they are given to the committee.
25 CHAIRMAN COON: I take it that these results came

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in too late to be entered in the petition, is that right?

MR. WHITACRE: These were studies that were run in 1975.

MR. CALO: Yes, 1975.

MR. WHITACRE: Just to update our information on the compound, we were not required to do them, but they were done as part of the accumulation of information on the behavior of the compound.

CHAIRMAN COON: I don't understand fully why they are not in the petition.

MR. WHITACRE: Because we were not required by EPA to submit them, in support of the petition or in the amendment to the petition. We conducted them on our own, but yet submitted them to the file, to the EPA file, after the petition was submitted and amended.

CHAIRMAN COON: So, it was a matter of timing, it was too late for the petition.

MR. WHITACRE: And, in addition to that, it was not information which was specifically required by EPA to support -- to support.

CHAIRMAN COON: Is there anything further?

DR. FUKUTO: I would like to ask a question, and Dr. Painter might be the appropriate person. Why are not chronic feeding studies requested for delayed neurotoxicity?

DR. PAINTER: Why are they not requested? I think

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the best answer that I can give to that is that this is the first compound for an extremely long time where we have face this kind of a problem.

I am going to say something now that I do not have a direct involvement in. On some of those compounds which are currently registered, which show this effect at extremel high levels, and I believe Food & Drug did require long term chicken studies. I say that because I have been personally involved with some of those chicken studies.

So, I guess the answer is when you come up agains it, that is what you ask for, and in fact I have been personally involved with some of these gentlemen from Velsicol, in recommending that chain study.

DR. ZWEIG: I would like to call to the attentio of the committee, unless -- at least it wasn't clear to me when the representatives from Velsicol yesterday were mentioning studies on water buffalo, there are two reports in your possession, one is'47 and the other is'68. I don't know which one is which, but as I recall the very first study which was carried in 1971, although the report is not signed by anybody, and I agree that it probably would not -- could not be scrutinized as closely as published reports, but at least in that report, from an observer, there were some delayed neurotoxicity symptoms in the water buffalo at the highest level fed, and there were, as I recall, four

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levels, 1X, 2X, 3X, and 4X. When that experiment was repeated, apparently under the auspices of the Egyptian Government, and partially from Velsicol, is that correct?

MR. WHITACRE: That is correct, yes.

DR. ZWEIG: These animals were only fed, 1 and 2X level. In other words, they did not repeat the experiment as had been done before, and as I recall, they did not observe any neurotoxic effects. I would just like to call to your attention that there were two separate water buffalo studies and neither of them are very well authenticated, as far as authorship is concerned.

I think that in your examination you should be made aware that there are two separate studies, one was positive and the other negative. And, the only difference that I could see was the positive one was at a higher level fed than the negative one.

CHAIRMAN COON: Thank you. Are there any other questions, or comments?

(No response.)

CHAIRMAN COON: If not, we then declare the open session adjourned. And, I want to thank the Velsicol representatives for making themselves available today, and I am sorry that we didn't make more use of it to justify it better, but so be it.

Thank you very much.

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MR. WHITACRE: Thank you.

(Whereupon, the open session was adjourned at 2:39 p.m.)

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