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EPA REGISTRATION AND LICENSING

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Originally we had the old Federal Insecticide, Fungicide, Rodenticide Act (FIFRA) which involved Health, Education and Welfare, Interior, Food and Drug Administration but was administered by USDA. This has been changed by the passage of the Federal Environmental Pesticide Control Act (FEPCA). Now in certain cases you will find that EPA is working through the States under the FEPCA law to develop policy. You will find EPA and the amended FIFRA will play a very important role in your business for several years.

Ultimately the state licensing is the thing that you are concerned with. There may be initially a few states who try to hold out, or that do not meet Federal standards. Federal standards have not been agreed upon at this time by any means. There is quite a bit of discussion and argument, even yet, as to what a Federally-approved State licensing program will be.

The states will have to submit their plans to a Federal licensing and certification board for approval. Upon approval the state actually will be administering *de facto* law to you. The minimum Federal standards that have been set up will apply in all fifty states. At the present time it appears that the state can be more restrictive than the Federal law. As I understand, the state law will be pre-emptive of local law, except under certain situations.

One of the cases in point might be California, which has already submitted its petition to be able to implement the regulations under EPA. As far as I know their certification program has not yet been accepted by Washington, but it is assumed it is working.

Several other states I understand have submitted what is going to be a Federally approved plan. I cannot say that anybody has a clear go-ahead yet since they are making changes in it even today.

One of the things I think that you have to recognize, in dealing with the law, is the “intent” of Congress. Now I am sure none of you is interested in the details of political science, but the truth of the matter is that if you do not get into some political ties, if you do not understand the

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* This presentation was in a dialogue format with John Beck being the ”straight man” and Len Quattrochi supplying the answers. Because of his very untimely death, Len did not have the opportunity to review the conversation transcript.

difference between a regulation and a law and the intent of Congress, you are likely to get swept up in some of these arguments that eventually will be decided by the courts. Basically each court will go back in any decision that has to be rendered to what was the intent of Congress when they passed the law. And as far as licensing is concerned, the intent of Congress seems to be, and NPCA and other groups have researched this fairly well, that licensing is to be done at the supervisory and managerial level. It would not be the intent of Congress to license every service man that was involved in the pest con-, trol business.

That is contrary to some discussion that is actually going on within the walls of EPS in which some people are urging the registration of service men, but this argument is still unresolved. Of course the final authority will be the courts as to what the intent of Congress was when it passed the law (In this regard the OSHA law has really become a football, since not even Congress is too sure what their original intent was.).

EPA has declared the categories for certification more definitively than was in the original published law. These may change: one has already.According to the law itself, EPA was imposed to a deadline schedule for implementing this law. So far the first deadline of October, 1973 has not been met by EPA, at which date they were supposed to publish in the Federal Register what the certification requirements were. For some of you over at NPCA, they did acknowledge the fact that they had missed this deadline but hope to have it out either at the end of this year or next year. So far though their spokesman has said that it is basically set into two types of categories. One will be the public health type of official, which includes those who have demonstrations on pest control, the regulatory pest control people, and the public health pest control people, primarily those working at a Federal level. When you get into the individual categories which are basically both agricultural and structural pest control, we are talking about agricultural certifications in forests, turf, or lawn work, seed work, aquatic work - whether it be insecticide or herbicide. If you look at these four categories it seems as if they have been taken from a herbicide concept, industrial pest control, institutional pest control, structural and public health related. In actuality without further definition, which we do not have now, the PCO could be under health-related, institutional, industrial, lawn, and aquatic. Therefore under those 10 categories, he would have to comply with seven of them.

Supervision seems to be one of the key words in the law and is going to be one of the key words in the regulations; that is, what does supervision involve? If we license and certify all of the supervisory and managerial level people, and the applicator is exempted from licensing examinations, it seems to boil down to, is he supervised directly, or is he not supervised directly? Then we have the problem of the definition of what is supervision. What is direct supervision? As far as we can determine right now, it seems to be patterned somewhat after the Ohio law, but not exactly. The definition that seems to be acceptable to everybody is that the supervisor has to

be reasonably available to that man who is following a programmed set of applications. He has to be reasonably available in terms of time and/or access to the serviceman by means of telephone. These things are still going to be hashed around a bit, but I believe it is going to end up somewhere within a reasonable definition of supervision.

There is some intent within EPA to license or register each service. If you think this means that everybody in the country is going to be doing pest control work the same way, under the same set of regulations and rules, put that out of your mind. It is not going to happen that way. There is still going to be a wide variation among states, because the states may be more restrictive in their requirements than the Federal regulations when they come out. The question whether you license, which you have in Pennsylvania, will be good in Ohio has not yet been determined. The matter of reciprocity between the states is unsettled at this time.

Some states, those in the east, have already determined that they will have reciprocity with any other state that is agreeable and that has approximately the same kind of regulations with the same degree of strictness. Therefore if there is no reciprocity between Ohio and any other state, those of you who are working the edge of the state would have to get a license not only in Ohio but also in Indiana, Michigan, Kentucky, or wherever it happens to be. But if Kentucky and Ohio would agree to reciprocity, if you are certified in one, you could be licensed to work in both. This is being discussed, but it is not a foregone conclusion that there will be reciprocity between states.

Let us talk about what certification means. A key note to the whole concept of certification is the establishemnt of competence. These people who are to be certified are to be competent in the type of work that they perform and have full knowledge of that kind of work. As a rough format for all of the categories that we have described previously, we can show what the basic segments are relative to establishing this competence. First, with regard to being involved with pest control, he has to be somewhat skilled in the biology of that pest. By that, it is inferred that he needs to know the basic life cycle of the specific pest, the particular type of damage that that pest might cause, what form the pest is when it causes the damage, what point of that life cycle is most vulnerable to chemical control, and at what developmental stage of the pest the chemical should be applied.

COMMENT: Maryland has already put their law into effect and several of us who are district supervisors are licensed, and the rest of our men are registered. There has been no charge for the registration, but there has been a charge for each of us who were licensed.

Thank you. Now pesticides…possibly this is more of my own opinion than anything that is directly said in the law, but I am basing it on why the law was established originally. I will say that Section B will probably have 50-60% value in the knowledge of what you are tested on, because it will particularly emphasize the pesticides. Now by that, what do I mean?

They expect you to associate the pesticide in a group, knowing some of the general characteristics of that group, the restrictions or the areas where these cannot be applied. A good example of that now is where we are

restricted on the use of chlorinated hydrocarbons relative to termites. The other aspect would be the relative toxicity of the material which would either forbid you to use it in certain places or restrict it to others. In addition to that, you will have to have specific information on that toxicant with regards to particular formulations.

Safety will probably be presented to you in an open book type examination, where you would work directly off the label; and why not, because you always have a label to work with. And as far as equipment, knowing about all the application equipment from the standpoint of properly demonstrating the use of the material, having knowledge of the use of the material, where it can and cannot be used, basic care and maintenance of the equipment, as well as having the knowledge of the proper procedures for employing all the chemicals. You would have to have knowledge not only of your state laws in this regard but also of the Federal laws regarding pesticides, and you would be directly responsible for knowing about what you are doing with chemicals to that specific environment that you are working in.

BECK: Wait a minute. These laws are hard for me to understand, and when I dig in there and try to read that stuff, it is just so much garbage to me. Surely they are going to give me consideration because I cannot read the law?

QUATTROCHI: Even though these laws are not implemented, ignorance of the law is no excuse. Even though, at this point, we have not received an adequate interpretation of the law, we could be convicted under that law, and we are at this moment liable, under the law. So ignorance is no excuse for non-compliance with the law.

One of the other things that has changed greatly with EPA is that pesticide registration has moved from the hands of USDA. For those of you responsible for obtaining labels you know that situations have changed drastically as to what is actually required for the demonstration of efficacy of a material.

BECK: What do I have to do when I send in a label for registration? You are EPA and I am sending you a label; what do I have to show you?

QUATTROCHI: First of all, you have to establish a need for the material.

BECK: But it is perfectly clear that if I do not have a need, I would not send you the label.

QUATTROCHI: This was assumed under USDA. And one of the problems that we are now facing is that fact that this need is not documented in the existing folders. At the time of re-registration or at the time EPA is considering cancellation this documentation will be required.

BECK: You mean, it is not enough to say that English Sparrows have been a pest since 1600?

QUATTROCHI: Not unless someone has already given us all this documentary data, and we have it in their file. So you have to establish a need for the material. Next is to establish the efficacy or biological performance of the material.

BECK: Now wait a minute; efficacy, are you using that according to a dictionary definition or is that a bureaucratic term?

QUATTROCHI: What does efficacy mean? Efficacy as a framework of EPA means the degree of performance of a product under given situations for control of a biological field.

BECK: You are indicating some sort of a standard then?

QUATTROCHI: Again, now this is where we get into the problem, because in order to establish this efficacy on a uniform basis we need to have a protocol, and that is a blueprint.

BECK: There you go. You are using another word -- protocol.

QUATTROCHI: That is a blueprint on how to conduct the test to get the data. And unfortunately, there are very few established protocols. In other words, they will request the information for the efficacy data. You write them back and say well, what is the protocol for this test, and they will immediately inform you there is none.

BECK: Well, what do I do?

QUATTROCHI: You develop a protocol.

BECK: Well, how do I know you are going to accept it?

QUATTROCHI: Well, they will let you know after you give them the data.

BECK: Thanks a lot!

QUATTROCHI: One of the things that this should do, and I think it will improve in time, is establish required protocols for each set of efficacy data that is submitted. In addition to that, all of the toxicological data have to be submitted. You at least have to have feeding studies on the material, because it is a bait material. And I am sure there will be more.

BECK: You have already shot me down. What do all these things mean?

QUATTROCHI: All of these things mean that the material will not cause an undue hazard to people.

BECK: Or to the environment?

QUATTROCHI: That is not in those series of establishments. When no protocol has been established, we must know the degradability of the product in the soil, if it should go into the watershed, plant foliage, or indoor situations where we have potential residue.

BECK: Well, why don't I just let the Fish and Wildlife do that service for me?

QUATTROCHI: According to their new approach, they will be doing some of these studies. But I am sure they cannot do them in the framework of all the things that are required for pest control, and there seems to be some question at this moment whether or not they can even do them to get materials registered for bird control.

BECK: I have got ten million dollars, and I am as smart as I can be; I have got it all. Now what do I do?

QUATTROCHI: We have to submit a final label…

BECK: Here's the label.

QUATTROCHI: Well, does it have all of the use directions on it? How to use it under what specific conditions? Does it have all the cautionaries that are required because of the basic toxicity of the material?

BECK: They tell me that those cautions have to be in a certain size type even.

QUATTROCHI: That is right, and if they are not, the entire label can be rejected just on that basis. But once all of these things are accomplished, you can then get registration.

BECK: What shall I have to put on that label about what I put into my stuff? Can I still keep my little black box secrets?

QUATTROCHI: No, at the same time that you submit your label, you have to submit a list of all the confidential ingredients. It has gotten so bad recently that in addition to submitting your confidential list of ingredients, should you use any other materials for which you cannot account 100%, you must request the manufacturer to submit a confidential ingredients statement for the inert materials in the product. Commonly in formulations these days, there may be as many as three or four confidential ingredients statements needed. Let me give you an example of that: if you have a spray material which has an emulsifier, this has to have a confidential ingredients statement. That is four individual confidential statements.

BECK: In other words, I cannot say aliphatic hydrocarbons when I am talking about diluents.

QUATTROCHI: It has to be stressed to buy by brand name, since many of these now have registration numbers.

BECK: In other words I would have to indicate that I was using Standard Oil's solvent number such-and-so. Is that correct?

QUATTROCHI: That is correct.

BECK: Well, I do not want to do all that. I do not want a market outside the state where I have my operation. I am just going to get a state label and forget about all this stuff.

QUATTROCHI: Well, that may be a possibility, but we have no judgement on that. There is one section in the law that says under certain conditions state labels can be granted. However, despite the fact that they are granted, EPA would take a 90-day option, at which time they could cancel this label accepted by the state. Now there is another area which is still undefined: if EPA accepts the state as having the qualities and the capabilities of functioning for EPA in regard to registration, then the state would have the authority to grant a state label.

BECK: All right, but what you are saying is that all state labels are going to be pre-empted by the Federal government within a year? two years? How long is my state label good?

QUATTROCHI: The maximum time that you can have, depending on the state you are in, would be three years or the next two re-registration cycles in that

state. Some of the states have already refused to accept state registration. The product must have EPA registration. One of those is Colorado, and I am sure that there are other states - Pennsylvania - any others? The deadline in Texas is next September.

BECK: What about a bird control product that I want to put on the market, but I have not tested it enough? What do I do here? I cannot provide all that kind of data. If I need to test it, how am I going to test it?

QUATTROCHI: As the law now stands, you will either test it and comply with the law, or you will not obtain registration.

BECK: How about an experimental label, can I still get one of those?
QUATTROCHI: Yes, but if you do that, you would have to supply almost 90% of the same data that you would provide if you were going to get a regular EPA registration. So there does not really appear to be any advantage in doing this, with one exception. If you were establishing a label on a trial basis only to obtain a great quantity of field information, this would have merit.

BECK: How do you cancel a label?

QUATTROCHI: Ok, I am EPA and I declare that your product presents an imminent hazard, and I have sent you a registered letter telling you that I am going to cancel your label. I give you thirty days to respond.

BECK: Well, you are advising me then of a notice hearing. Is that correct?

QUATTROCHI: That is correct.

BECK: I have to answer you in that 30 days. Then what happens?

QUATTROCHI: If you continue and we cannot come to an agreement with regard to the product of cancellation, then we would settle it in court.

BECK: Are there not other processes? Can I not get an informal hearing?

QUATTROCHI: On an individual cancellation, yes.

BECK: What about getting an administrative review, can I do that? You have a bunch of dummies working for you, and they really do not know my product.

QUATTROCHI: You have the right to set up an appointment for an administrative review where there are people to represent you. In turn there would be EPA personnel who would be involved on the opposite side of the question. I can assure you, as EPA, I am going to take an authoritative stand on our position, and you will have to provide information to show that you have not created this imminent hazard.

BECK: Well listen, you are supposed to be neutral. You are supposed to represent my interests. You are supposed to be neutral in this subject.

QUATTROCHI: Under our established policy, we are now taking the stand that we are the advocate and you will supply the information that is required for the defense of the product.

BECK: In other words, it is just like tax court -- I have to prove that I am right.

QUATTROCHI: With the proper defense - that is true.

BECK: Well, suppose you are not neutral and you have given me a formal hearing. Then what happens?

QUATTROCHI: Well, let us use an actual case in point. Recently as a result of the cancellation of predacides a year ago last February, the conservation groups have put increasing pressure on EPA to follow through with these compounds and completely remove them from the market.

BECK: Are you talking about 1080, calcium cyanide, sodium cyanide and strychnine?

QUATTROCHI: Right. And of course one of these materials, strychnine, is registered for bird control. Now as a result of that, EPA published in the Federal Register last June a note to the effect that we were going to cancel these materials based on the information we had unless we had information showing their need, showing that they could be used and not create a special hazard either to non-target species or species which are on the decline.

BECK: All right, but we are going to have a formal hearing on this, and this is going to start in January -- right? (Editor's note: The hearings were cancelled and the cancellation withdrawn.)

QUATTROCHI: Yes, and we have already gone through the first step -- the request for people to state their intention of being involved in the public hearing or wanting to take part in it.

BECK: Are these people called interveners?

QUATTROCHI: Those are interveners. And after this was established, we had informal regional hearings. Those were held in six areas in the United States. And after that we had what we called a pre-hearing conference, and we are looking forward to another pre-hearing conference before the final formal trial. All of these procedures are covered in about a ten page reprint of rules and regulations for cancellation under EPA.

BECK: All right; now the hearing is over. What happens then?

QUATTROCHI: Now that the first hearing is over, in an effort to try to define what issues we will discuss at the formal trial, a second hearing will be held on February 18.

BECK: After all the pre-hearings, and after the formal hearings have been completed, who decides what is going to happen?

QUATTROCHI: The judge makes the judgement based on the input from EPA and the interveners.

BECK: I do not like what the judge says -- what happens then?

QUATTROCHI: You have the right to an appeal to the EPA Administrator.

BECK: What if he does not do what I want him to do?

QUATTROCHI: Then you can appeal to the Federal court if your money has not run out.

Well I think we have covered the registration process in a very sketchy manner, but it gives you an idea of what is going on. In conclusion we would like to make a few points. Number one is cost factor -- the market for most avicides is small. It is too small to justify this type of expensive procedure. That is one of the conclusions we can make. It is going to cost an awful lot of money not only to get a new product, but to keep what you have. The second conclusion is that we can no longer depend upon a Federal agency for data or defense, if they develop the material at their expense through taxpayer funds. The third is that small business is going to be pretty much left out. A good case in point: from the 18 people that were formulating strychnine, there is only one manufacturer who intends to be in the formal hearings; there is not enough market to justify going.

One of the other related things is that EPA can put out a stop sale action prior to the cancellation hearing and demand immediate recall. In other words, while I am going through all this procedure, they can say there is too much hazard to the environment, stop sale, recall your product; and then I have to go through the expense of proving I am right before I can even continue to sell what I have on hand. Not only that, the individual distributor will be responsible for recalling the material, because of another section we did not discuss, which is known as “Books and Records”. By this it means that every manufacturer has to have a quarterly report prepared for information to the government indicating the package sizes and all of the product that was sold in that quarter, the people he sells to, the end market. If they are restricted materials or for certified use, he will have a list of all of those people that he sold the product to. And should EPA come back to him, he will have to use his list and actually get back that material.

BECK: Do you mean that if I sell strychnine, I have to keep a record on whom I sell it to?

QUATTROCHI: As we now interpret the law these types of materials would be under the restricted classification, and so there would need to be a record of their sales.

I might comment at this point that there is another organization becoming involved in this particular area. We have talked about the lack of protocal and the lack of standards which exists in the whole area of vertebrate animal control. EPA has gone to a private corporation which has a long history in the development of standards, and that is the American Society of Testing and Materials. They have asked ASTM to help develop regulatory standards that can be added as appendices to the guidelines which will set forth new protocols and new standards. All of us can reference this document in order to find out what is going to be involved in the marketing, the registration, and the certification as related to avicides.

The development of these protocols under ASTM was started about two years ago. This organization is a private corporation based on consensus, and it does have court standing in this country; and standards developed by this organization do meet Federal standards and the requirements of Federal courts, because they are not developed with bias intent. ASTM is a three-part type participation organization, that is they have people who represent

manufacturers, consumers of pesticides, and general interest people and others who are working now to try to put together some of these standards. Now the question comes up, how does this differ from CSMA or NACA, and I think one of the basic differences is that ASTM requires people in amany areas of technical competence. It is a private corporation, and its main job is the production and publication of standards.

BECK: Does this mean that we are going to have a new protocol for bird control?

QUATTROCHI: ASTM will have a meeting tomorrow afternoon for those interested to look at recommended standards for the use of strychnine and avicides and also a preliminary draft for the standard method of tests for the efficacy of a new avicide.

The problem that we face in the field of vertebrate animal control is really simple: we have never brought the sophistication level of our testing on vertebrate animals up to that which is required for insecticides. And I do not believe that we are going to be able to continue to develop new vertebrate animal products unless and until we are able to demonstrate that we have a level of sophistication more nearly like that which is required to register insecticides. So we have some real problems on this.