B. DISCUSSION

I. GENERAL

During the extended hearing of this case much of the material offered through the 125 witnesses and 365 exhibits was necessarily redundant, repetitive and of minor significance. But I am constrained to inject a personal feeling that no Hearing Examiner will ever enjoy the privilege that I had in listening to so many leaders in the field of scientific and medical achievement; from so many areas of expertise throughout the world, really; and including among them a recent Nobel Peace Prize winner, and the Surgeon General of the United States. No restrictions were placed on the parties as to the number of witnesses they could present, other than the necessary exhortations concerning relevance and materiality.

The pros and cons of DDT have been well aired.

To attempt to summarize the entire record cannot do justice to all the participants. In gleaning the main facets of the case we must necessarily summarize what appear to be the essential thrusts of the evidence.

During the quarter of a century of its use, the reputation of DDT grew to preeminent heights as a benefit to man in the area of public health and agricultural assistance. However, that ascendance has been followed by a decline, possibly spurred by Rachel Carson's "Silent Spring," on the charge that it is a pollutant and a dangerously toxic chemical that should not be continued at loose in the environment. At this hearing, most of the evidence was presented in

a manner removed from the hysterical and emotional state engendered in some discussions of DDT.

I think the right of cross-examination spurred a genuinely sober assessment of the facts available, particularly on the question of the benefits and risks of DDT; and it exposed those few instances where the purpose was to generate more heat than light on the subject.

There were some appalling instances of incredible inactions such as the publication of a paper containing faulty information which, after discovery, was never corrected and, apparently, is still being relied upon (Tr. 63:7234-7240). Likewise, the audacious refusal of a witness to answer a question on the grounds that the cross-examining lawyer (and I suppose the Hearing Examiner was included) wouldn't be capable of understanding the statistics (Tr. 36:4571).

However, practically every witness from the scientific community responded readily to this first-of-a-kind subjection of his professional work on DDT to the crucible of cross-examination; and that process is recommended as a tool of the truth in all future cases of this kind.

The thoroughness with which the topic of DDT was explored and analyzed has not made easier my task in evaluating, in a short space of time, the conclusions that result therefrom.

II. BURDEN OF PROOF

There is no need to spend much time on the question as to who, in this case, has the burden of proof and the initial burden of going forward with the evidence. Those burdens are on the petitioner - registrants who filed objections to the notices of cancellation and requested a public hearing. The point was raised at the outset of these proceedings and I ruled as above; relying on the Rules of Practice (now 40 CFR 164.20 at 164.28), Environmental Defense Fund v. Ruckelshaus (439 F.2d 584, 593 fn. 34), and The Report of the Hearing Before a Subcommittee on Agriculture and Forestry, United States Senate, Eighty-eighth Congress, First Session on S.1605, September 10, 1963.

I can see no reason to quarrel with placing the burden of proof on the petitioner-registrant. DDT is an economic poison which requires regulation as to its use. It is not unfair to rest the proof of disputed points on the one who seeks to maintain the registration.

Likewise, I can see no reason to quarrel with that part of section 4.c. of the Act that gives the Administrator the authority to determine, without prior public hearing, that a need exists for the cancellation of a registration; because that authority is balanced by the statutory requirement that "he shall notify the registrant of his action and the reasons therefor" which, in turn, can be the basis for a public hearing if the registrant exercises that option.

Perhaps there is a question as to what constitutes the burden of proof in this case. Rule of Practice 164.28, supra, provides that "at the hearing" the person whose objections raised the issues to be determined shall be "within the meaning of 5 U.S.C. 556(d) (formerly 5 U.S.C. 1006(d)), the proponent of the order sought, and accordingly shall proceed first at the hearing and have the burden of proof". The "order sought" in this case is an order of the Administrator that the cancellation notices issued by the Director of the Pesticide Regulation Division should not become effective.

So, what do petitioners here have to prove?

PR Notice 71-1 cites the concern of the "scientific community" and the results of a special study; and it then proceeds to predicate the need for cancelling all remaining DDT registrations on the grounds of "misbranding" under sections 2.z.(2)(c); -(d); and -(g) of the Act.

The framer of PR 71-1 did not articulate the relevance of the scientific community's concern or the conclusions of the special study, so as to furnish any detailed explanation as to any particular manner in which the labels involved here can be said to constitute misbranding.

Thus, it appears that, in the absence of specifics, the petitioners here have the burden of affirmatively proving only that the language on each label satisfies the requirements of sections 2.z.(2)(c); -(d); and -(g) and regulations in implementation thereof.

When the petitioners accomplish that goal, the duty of producing evidence passes to the respondent.

The Respondent argues 5/ that under FIFRA the burden of proof is not the preponderance-of-the-evidence test, but, rather, the standard of clear-and-convincing evidence. I have searched the language of FIFRA and find nothing upon which to base such an assumption. Likewise, as to Respondent's argument that in this case the burden of proof is identical to that in hearings involving an original application for registration. Such a position appears to be bottomed upon gratuitous assumptions not supported by FIFRA. There is no evidence to indicate that any party here challenges the seriousness of meeting the safety requirements deemed necessary to permit the granting of an application for a registration of an economic poison with the propensities of DDT. However, it does not follow that, once that application has been approved by the proper authorities, subsequent actions involving that registration should not be governed by their own requirement. For example, in this case, registrations once properly granted are now the subject of cancellation proceedings on a challenge of misbranding under the three sections 2.z.(2)(c); -(d); and -(g). As I see it, those are the sections of FIFRA that establish the guidelines for the quantum of proof necessary to meet the relative burdens of the parties.

5/ P. 3, Resp. Reply Anly. in of the Evidence and Summary of the [illegible].

In other words, as long as FIFRA remains a "misbranding" statute, the primary burden on any Petitioner-registrant in this case remains one of proving that its labels comply fully with the Act. I believe that a balancing of benefit against risk, if it has to err, should err on the side of safety; nevertheless, such a balancing must rest on solid grounds. The risk side should not be based on such factors as possible future risk, unforeseeable abuse, and a strict requirement of no-damage-to-wildlife. In my opinion, an unreasonable risk must be demonstrated in order to overcome the indicated or the proven benefits of DDT. If the Congress had desired to stress more strongly the maintenance of a higher risk standard, it would have enacted a "strictly prescription" type of usage; thereby giving the Respondent here complete control over the policy of overall usage of DDT rather than control merely over the label language. It might well be that the prescription-type procedure is the one to establish under this Act. However, until that is accomplished, the proof must fit the law as we take it.

III. THE LABELS

"Every economic poison shall bear a label containing the information specified in the Act and the regulations in this part." 40 CFR 162.4. That is the opening direction in the regulations setting out such particulars as: the language to be used; the contents of label and labeling; placement of label; name, brand or trademark; registration number; and the ingredient statement. As it should be, nothing is left to the imagination.

In this case every label has to meet the labeling particulars in the light of sections 2.z.(2)(c); -(d); and -(g).

A closer look at those sections might be helpful.

"(c)" reads: if the labeling accompanying it does not contain directions for use which are necessary and if complied with adequate for the protection of the public.

Thus, directions for use must be approved by the Agency as to the method of application, the amount to be applied, when and how often it can be applied, and the requirement, if any, for special protective equipment to be used during application.

"(d)" reads: if the label does not contain a warning or caution statement which may be necessary and if complied with adequate to prevent injury to living man and other vertebrate animals, vegetation, and useful invertebrate animals.

Here, the Act instructs the Agency to change focus to a determination of appropriate language adequate to give the necessary alarm. This section is the only one of the three that has been the subject of a specific interpretation by the Agency. I refer to

Interpretation Number 18; and I will discuss this more fully shortly.

"(g)" reads: if in the case of an insecticide, nematocide, fungicide, or herbicide when used as directed or in accordance with commonly recognized practice it shall be injurious to living man or other vertebrate animals, or vegetation, except weeds, to which it is applied, or to the person applying such economic poison.

This section refers to the economic poison as a compound. The Agency is responsible for the evaluation of the hazard involved despite the adequacy of directions for use and the adequacy of warning or caution statements.

When you study those three sections in the light of maximum effectiveness, you must conclude that the language used has to be addressed to all segments of the public that might have contact with the compound. But it is clear that there is no requirement to satisfy all levels of understanding, which leaves us with the yardstick that has served legal interpretation so well in so many areas: The reasonable, prudent man. If the directions for use, the warning or caution statement and the evaluation of the hazard appear on the label in language that can be understood by the reasonable, prudent man, they must be in compliance with the Act. In any event, that's the criterion I used in analyzing the labels involved in this case.

Now, I want to return to section 2.a.(2)(d) and Interpretation No. 18.

As noted earlier, sec. -(d) is the only one of the three sections in question that has been the subject of an official Agency Interpretation. It is found in 40 CFR 162.116. After referring to sec. -(d) it points out that Section 3.a.(3) of the Act requires that any economic poison which contains any substance or substances in quantities highly toxic to man must bear on the label the skull and crossbones, the word "Poison," in red, on a contrasting background, and an antidote statement.

The next part of the Interpretation provides for categories of toxicity and general provisions as to statements required for economic poisons, as follows:

> (1) Four general categories of toxicity of economic poisons are recognized. The first is the highly toxic class as defined in sec. 162.8.
>
> The second is the class immediately below the highly toxic, and in general includes formulations having toxicities down to one-tenth those of the highly toxic class.
>
> The third group embraces products having hazards below the class two but to a degree which still requires some cautions and usually includes toxicities down to about one-tenth of those in class two.
>
> The fourth class is comparatively free from danger.
>
> (2) Products in the categories specified in subparagraph (1) of this paragraph are to be distinguished from each other by the following general scheme:
>
> (i) Highly toxic products are required by the act to be labeled with the skull and crossbones, the word "Poison" (in red) on a contrasting background,

and an antidote statement. The antidote statement should include the sentence "Call A Physician Immediately." In addition, the label should carry the word "Warning" and instructions for handling to reduce chances of injury in use.

(ii) Labels of products which fall in the second category should carry warning statements equivalent to those required for highly toxic materials, but they do not need to bear the skull and crossbones, the word "Poison", or an antidote statement.

(iii) Labels of products in the third category should carry the word "Caution" and statements indicating the means of avoiding the principal hazards of use. Use of the skull and crossbones, the word "Poison", and antidote statements are not necessary for these products.

(iv) No warning, caution, or antidote statements are required for the few formulations in the fourth category, although unqualified claims for safety are usually not justified.

Interpretation No. 18 continued on with miscellaneous provisions contemplated to make the label more effective.

Before setting out the pertinent acceptable warning, caution and antidote statements, we must go back for a look at sec. 162.8 which defines the first-class, or highly-toxic, category referred to in the Interpretation. It reads:

(a) Economic poisons which fall within any of the following categories when tested on laboratory animals as specified in subparagraphs (1), (2), or (3) of this paragraph are highly toxic to man or contain substances or quantities of substances highly toxic to man within the meaning of the Act (such economic poisons being hereinafter in this part referred to as economic poisons highly toxic to man): Provided, however, that the Director may, upon application and after opportunity for hearing, exempt any economic poison which is in any of these categories, but which is not in fact highly toxic to man, from

the requirements of the Act and the regulations in this part with respect to economic poisons highly toxic to man:

(1) Oral toxicity. An economic poison which has a single dose LD_{50} of 50 milligrams or less per kilogram of body weight when administered orally to both male and female rats which have been fasted for a period of 24 hours (or to other rodent or nonrodent specified by the Director); or

(2) Toxicity on inhalation. An economic poison which has an LC_{50} of 2,000 micrograms or less of dust or mist per liter of air or 200 parts per million or less by volume of a gas or vapor, when administered by continuous inhalation for one hour to both male and female rats (or to other rodent or nonrodent species specified by the Director), if the Director finds that it is reasonably foreseeable that such concentration will be encountered by man; or

(3) Toxicity by skin absorption. An economic poison which has an LD_{50} of 200 milligrams or less per kilogram of body weight when administered by continuous contact for twenty-four hours with the bare skin of rabbits (or other rodent or nonrodent species specified by the Director).

(b) Tests on other species. Tests on other specified rodent or nonrodent species may be required by the Director with respect to individual economic poisons or to classes of economic poisons whenever he finds that tests on other species are necessary to determine whether an economic poison is highly toxic to man.

(c) Terms LD_{50} and LC_{50}. An LD_{50} as used in connection with oral toxicity and skin absorption toxicity tests specified in paragraph (a)(1) and (3) of this section is the dose and LC_{50} as used in connection with inhalation tests specified in paragraph (a)(2) of this section is the concentration which is expected to cause death within 14 days in 50 percent of the test animals so treated.

(d) Toxicity based on human experience. If the Director finds, after opportunity for hearing, that available data on human experience with any economic

poison indicate a toxicity greater than that determined from the above described tests on animals, the human data shall take precedence and if he finds that the protection of the public so requires the Director shall declare such an economic poison to be highly toxic to man for the purposes of this Act and the regulations thereunder.

Up to this point we haven't discussed where DDT fits into the toxicity classification. I could find nothing in the evidence that seemed to give toxicity classifications in the same context as sec. 162.8. Therefore, for my purposes here I am going to refer to a document entitled Pesticide Reference Standards of the Entomological Society of America, Committee on Insecticide Standards, Revised 1970. In there we find the following:

DDD: (see TDE)

DDT: Toxicity-
Slightly toxic; acute oral rats LD_{50} = 250 mg/kg.

TDE: Toxicity-
Slightly toxic; acute oral rats LD_{50} = 3400 mg/kg.
Non-phytotoxic.

Aldrin: Toxicity-
Toxic; acute oral rats LD_{50} = 55 mg/kg.

Carbaryl: Toxicity-
Moderately toxic; acute oral rats LD_{50} = 500-700 mg/kg.

Dieldrin: Toxicity-
Toxic; acute oral rats LD_{50} = 60 mg/kg.
Absorbed through skin.

Endrin: Toxicity-
Highly toxic; acute oral rats LD_{50} = 11 mg/kg.
Absorbed through skin.

Malathion: Toxicity-
Moderately toxic; acute oral rats LD_{50} = 900 - 5800 mg/kg.

Methyl parathion: Toxicity-
Highly toxic; acute oral rats LD_{50} = 15 mg/kg.

Parathion: Toxicity-
Extremely toxic; acute oral rats LD_{50} = 3 - 15 mg/kg.
Absorbed through skin.

Strobane(R): Toxicity-
Toxic; acute oral rats LD_{50} = 200 - 250 mg/kg.

Toxaphene: Toxicity-
Toxic; acute oral rats LD_{50} = 69 mg/kg.

Now, going back to Interpretation No. 18 (40 CFR 162.116(d)) we find:

> (d) Acceptable warning, caution and antidote statements for economic poisons containing specified ingredients. The following subparagraphs set forth or indicate acceptable warning, caution and antidote statements for economic poisons containing the ingredients specified therein. The exact wording used in the suggested statements is not obligatory, although the substance of all such statements will be required, unless under special conditions of handling or use it is unnecessary. The manufacturer is obligated to use any added warning, caution or antidote statements which any special characteristics or uses of his formulation indicate to be necessary. Where the notation (H.P.) for "household package" appears following a precautionary statement, it indicates that the warning will be required only on packages commonly stored or used in the household where there is greater danger of accidents involving children or pets. The insignia

Poison

always refers to the skull and crossbones and the word "Poison" (in red) on a contrasting background, and the

fire hazard caution prescribed in this paragraph in each case is based on the flash point of the chemical named.

At this point it appears important to recite the specific directions set out for DDT and certain other compounds known to be used in formulation with DDT in the labels involved in this case.

Dichloro diphenyl dichloroethane. [DDD] Treat on same basis as DDT.

Dichloro diphenyl trichloroethane (DDT) — (i) Technical emulsions, and wettable powders above 25%.

Caution: Harmful if swallowed. Avoid skin contact with solutions. In case of skin contact, wash with soap and water. Avoid breathing dust and spray mist. Avoid contamination of feed and foodstuffs.

(ii) Emulsifiable or petroleum oil solutions for agricultural and industrial use 25% and below.

Caution: Avoid contact with skin. In case of skin contact, wash with soap and water. Avoid breathing spray mist. Avoid contamination of feed and foodstuffs.

(iii) Emulsifiable or petroleum oil solutions for household use.

Caution: Harmful if swallowed. Avoid contact with skin. Avoid prolonged breathing of spray mist. Wash with soap and water after using. Avoid contamination of feed and foodstuffs. Remove birds, pets, and fish bowls from rooms being sprayed. Keep out of reach of children.

Note: See also Interpretation 15 (162.113). 6/

(iv) Self-propelled sprays.

Caution: Do not spray on skin or animals. Wash with soap and water after using. Avoid inhalation of mist. Avoid contamination of feed and foodstuffs. Remove birds, pets, and fish bowls from rooms being sprayed. Keep out of reach of children.

Note: See also Interpretation 15 (162.113). 7/

6/ Not pertinent here.
7/ Id.

(v) Dust and wettable powder formulations 25% and below.

Caution: Avoid breathing dust. Avoid contamination of feed and foodstuffs.

Toxaphene (chlorinated camphene containing 67 to 69% chlorine) — (i) Dry formulations 25% and above.

Warning: May Be Fatal If Swallowed! Do not breathe dust or spray mist. Do not get in eyes, on skin or on clothing. Wash thoroughly after using. Do not store near feed and food products. To protect fish and wildlife, do not contaminate streams, lakes, or ponds with this material.

(ii) Dry formulations below 25%.

Caution: Harmful If Swallowed! Avoid prolonged breathing of dust or spray mist. Avoid contact with eyes, skin and clothing. Wash thoroughly after using. Avoid storage near feed and food products. To protect fish and wildlife, do not contaminate streams, lakes, or ponds with this material.

(iii) Solutions and emulsions. Labels should bear precautionary statements covering the combined hazards of toxaphene and solvent.

(iv) Self-propelled sprays.

Caution: Do not spray on skin, or animals. Wash with soap and water after using. Avoid inhalation of mist. Avoid contamination of feed and foodstuffs. Remove birds, pets, and fish bowls from rooms being sprayed. Keep out of reach of children.

O,O-Dimethyl-O, p-nitrophenyl thiophosphate. [methyl parathion] Treat on same basis as parathion.

Parathion (O,O-Diethyl O,p-nitrophenyl thiophosphate) — (i) Above 2% (except aerosols; see below).

[redacted] Poison [redacted]

Antidotes: If swallowed. Give 1 tablespoonful of salt in a glass of warm water and repeat until vomit fluid is clear. Have victim lie down and keep quiet. Call a physician immediately!

If on skin. In case of contact remove contaminated clothing and immediately wash skin with soap and water.

Warning Poisonous If Swallowed, Inhaled, or Absorbed Through Skin! Rapidly Absorbed Through Skin! Do not get in eyes, on skin, or on clothing. Wear natural rubber gloves, protective clothing and goggles. In case of contact, wash immediately with soap and water. Wear a mask or respirator of a type passed by the U.S. Department of Agriculture for parathion protection. Keep all unprotected persons out of operating areas or vicinity where there may be danger of drift. Vacated areas should not be reentered until drifting insecticide and volatile residues have dissipated. Do not contaminate feed and foodstuffs. Wash hands, arms and face thoroughly with soap and water before eating or smoking. Wash all contaminated clothing with soap and hot water before reuse.

(ii) Dusts, 2% and below.

Warning: May Be Fatal If Swallowed, Inhaled, or Absorbed Through Skin! Rapidly Absorbed Through Skin! Do not get in eyes on skin or on clothing. Wear natural rubber gloves, protective clothing and goggles. In case of contact wash immediately with soap and water. Wear a mask or respirator of a type passed by the U.S. Department of Agriculture for parathion protection. Keep all unprotected persons out of operating areas or vicinity where there may be danger of drift. Vacated areas should not be reentered until drifting insecticide and volatile residues have dissipated. Do not contaminate feed and foodstuffs. Wash hands, arms, and face thoroughly with soap and water before eating or smoking. Wash all contaminated clothing with soap and hot water before reuse.

(iii) Aerosols -- greenhouse use.

☤ Poison ☤

Antidotes: Internal, Give a tablespoonful of salt in a glass of warm water and repeat until vomit fluid is clear. Have victim lie down and keep quiet. Call a Physician Immediately!

If on skin, Wash thoroughly with soap and water.

Warning: Poisonous If Inhaled or Absorbed Through Skin! Do not get on skin. Use only while wearing a full face mask of a type passed by the U.S. Department of Agriculture for parathion protection. Replace canister as directed. Wear protective clothing and natural rubber gloves. Wash hands, arms and face

with soap and water after using the bomb. Wash contaminated clothing with soap and hot water before reuse. Do not contaminate feed and foodstuffs.

1-Naphthyl N-methylcarbamate (Sevin) [Cartaryl] -- (i) Above 50%.

Caution: Harmful if swallowed or inhaled. Avoid breathing of dust or spray mist. Avoid prolonged or repeated contact with skin; wash thoroughly after handling. Wear clean clothing. Avoid storage near feed and food products.

(ii) 50 % and below.

Caution: Harmful if swallowed. Avoid prolonged breathing of dust or spray mist. Avoid prolonged or repeated contact with skin; wash thoroughly after using. Avoid storage near feed and food products. Keep out of reach of children (H.P.).

Endrin (hexachloro-epoxy-octahydro-endo, endo-di-methano naphthalene) -- (i) 2.5% and above.

☠ Poison ☠

Antidotes: If swallowed. Give a tablespoonful of salt in a glass of warm water and repeat until vomit fluid is clear. Have victim lie down and keep quiet. Call a Physician Immediately!

If on skin. Wash immediately with soap and water.

Warning: Poisonous by Swallowing, Inhalation, or Skin Contact! Do not get in eyes, on skin, or on clothing. Do not breathe dust or spray mist. In case of contact, immediately remove all contaminated clothing and flush skin or eyes with plenty of water for at least 15 minutes; for eyes, get medical attention. Wear clean synthetic rubber gloves and a mask or respirator of a type passed by the U.S. Department of Agriculture for endrin protection. Wash thoroughly with soap and water after handling and before eating or smoking; wear clean clothing. Do not apply or allow to drift to areas occupied by unprotected humans or beneficial animals. Do not contaminate feed and foodstuffs. To protect fish and wildlife, do not contaminate streams, lakes, or ponds with this material.

(ii) Below 2.5%

Warning: Hazardous by Swallowing, Inhalation, or Skin Contact! Rapidly Absorbed through Skin! Do not get in eyes, on skin, or on clothing. Do not

breathe dust or spray mist. In case of contact with skin or eyes, flush with plenty of water, for eyes, get medical attention. Wash thoroughly with soap and water after handling and before eating or smoking; wear clean clothing. Wear clean synthetic rubber gloves and a mask or respirator of a type passed by the U.S. Department of Agriculture for endrin protection. Do not apply or allow to drift to areas occupied by unprotected humans or beneficial animals. Do not contaminate feed and foodstuffs. To protect fish and wildlife, do not contaminate streams, lakes, or ponds with this material.

Malathion (O,O-Dimethyl dithiophosphate of diethyl-mercaptosuccinate).

Caution: Harmful if swallowed. Avoid prolonged breathing of dust or spray mist. Avoid prolonged or repeated contact with skin; wash thoroughly after using. Avoid contamination of feed and foodstuffs. Keep out of reach of children (H.P.).

Note: For dusts and wettable powders below 20% the caution "Harmful if swallowed" may be omitted.

Aldrin (95% hexachloro hexahydro-endro, exo-dimethano napthalene) — (i) 60% and above.

o o
x Poison x

Antidotes: If swallowed. Give a tablespoonful of salt in a glass of warm water and repeat until vomit fluid is clear. Have victim lie down and keep quiet. Call a Physician Immediately!

If on skin. Wash immediately with soap and water.

Warning: Poisonous If Swallowed, Inhaled or Absorbed Through Skin! Do not breath dust or spray mist. Do not get in eyes, on skin or on clothing. In case of contact immediately remove contaminated clothing and flush skin or eyes with plenty of water; for eyes, get medical attention. Wash thoroughly with soap and water after handling and before eating or smoking; wear clean clothing. During commercial or prolonged exposure in spray-mixing and loading operations, wear clean synthetic rubber gloves and a mask or respirator of a type passed by the U.S. Department of Agriculture for aldrin protection. Do not apply or allow to drift to areas

occupied by unprotected humans or beneficial animals. To protect fish and wildlife, do not contaminate streams, lakes or ponds with this material.

(ii) 10% to 60%.

Warning: Hazardous If Swallowed, Inhaled, or Absorted Through Skin! Do not breathe dust or spray mist. Do not get in eyes, on skin or on clothing. In case of contact, immediately remove contaminated clothing and flush skin or eyes with plenty of water; for eyes, get medical attention. Wash thoroughly with soap and water after handling and before eating or smoking; wear clean clothing. During commercial or prolonged exposure in spray-mixing and loading operations, wear clean synthetic rubber gloves and a mask or respirator of a type passed by the U.S. Department of Agriculture for aldrin protection. Do not apply or allow to drift to areas occupied by unprotected humans or beneficial animals. To protect fish and wildlife, do not contaminate streams, lakes or ponds with this material.

(iii) Below 10%.

Caution: Harmful if swallowed, inhaled or absorbed through skin. Avoid breathing of dust or spray mist. Avoid contact with skin, eyes or clothing. In case of contact with skin or eyes, flush with plenty of water; for eyes, get medical attention. Wash with soap and water after handling and before eating or smoking; wear clean clothing. Avoid contamination of feed and foodstuffs. Do not apply or allow to drift to areas occupied by unprotected humans or beneficial animals. To protect fish and wildlife, do not contaminate streams, lakes or ponds with this material.

(iv) Fertilizer formulations.

Caution: Avoid prolonged or repeated inhalation of dust or contact with skin. Wash thoroughly after handling. To protect fish and wildlife, do not use where runoff will contaminate streams, lakes or ponds.

O,O-Dimethyl S-[4-oxo-1,2,3-benzotriazin-3(4H)-ylmethyl] phosphorodithioate (Guthion) — (i) Above 2%.

Poison

Antidotes: If swallowed. Give a tablespoonful of salt in a glass of warm water and repeat until vomit fluid is clear. Have victim lie down and keep quiet. Call a Physician Immediately!

If on skin. In case of contact remove contaminated clothing and immediately wash skin with soap and water.

Warning: Poisonous If Swallowed, Inhaled, or Absorbed Through Skin! Do not get in eyes or on skin. Wear natural rubber gloves, protective clothing and goggles. In case of contact, wash immediately with soap and water. Wear a mask or respirator of a type passed by the U.S. Department of Agriculture for guthion protection. Keep all unprotected persons out of operating areas or vicinity where there may be danger of drift. Vacated areas should not be reentered for at least two days. Do not store near feed and food products. Wash hands, arms, and face thoroughly with soap and water before eating or smoking. Wash all contaminated clothing with soap and hot water before reuse.

(ii) Dusts, 2% and below.

Warning: May Be Fatal If Swallowed, Inhaled or Absorbed Through Skin! Do not get in eyes or on skin. Wear natural rubber gloves, protective clothing and goggles. In case of contact wash immediately with soap and water. Wear a mask or respirator of a type passed by the U.S. Department of Agriculture for guthion protection. Keep all unprotected persons out of operating areas or vicinity where there may be danger of drift. Vacated areas should not be reentered for at least two days. Do not store near feed and food products. Wash hands, arms, and face thoroughly with soap and water before eating or smoking. Wash all contaminated clothing with soap and hot water before reuse.

Dieldrin (85% hexachloro epoxy octahydro-endo, exo-dimethano naphthalene) -- (i) 60% and above. Treat as aldrin.

(ii) 10% to 60% - treat as aldrin.

(iii) Below 10% for agricultural use. Treat as aldrin.

(iv) Fertilizer formulations. Treat as aldrin.

(v) 0.5% self-propelled sprays or pressurized and 1.0% dusts for household use.

Caution: Avoid prolonged or repeated inhalation of dust or spray mist or contact with skin. Do not

contaminate foods, utensils, dishes or drinking water. Do not apply to humans, pets, or birds, or near fish bowls. Keep out of reach of children.

Note: See also kerosene sprays.

O,O-Dimethyl-S-p-chlorophenylthiomethyl phosphorodithioate (methyl trithion).

Warning: May be fatal if swallowed, inhaled, or absorbed through skin. Do not get in eyes, on skin, or on clothing. Do not breathe dust or spray mist. In case of contact, wash immediately with soap and water. Wear clean clothing. Wash all contaminated clothing with soap and hot water before reuse. Do not store near feed and food products. To protect fish and wildlife, do not contaminate streams, lakes, or ponds with this material.

Terpene polychlorinates (chlorinated mixture of camphene, pinene and related terpenes, containing 65 to 66% chlorine) (Strobane).

(i) Dry formulations 25% and above. Treat as toxaphene.

(ii) Dry formulations below 25%. Treat as toxaphene.

(iii) Solutions and emulsions. Treat as toxaphene.

(iv) Self-propelled sprays. Treat as toxaphene.

Probably it isn't necessary to delineate in such detail the pertinent recitals of Interpretation No. 18, just above, in order to make the points that have to be made; namely, that DDT is indeed an economic poison the use of which has to be regulated; and that other economic poisons, with which DDT most often is combined, indeed need even more strict regulation to satisfy the misbranding sections. However, having checked each label involved here against Interpretation No. 18, I realize that the difference in impact, especially as to safety, between DDT and its associates needs to be shown as clearly as possible, and I think the content of Interpretation No. 18 does just that.

Involved in this action are 320 labels. Of these, 314 are under registrations issued to Group-Petitioners; 2 are under registrations belonging to the Plant Protection Division of USDA; one label each of petitioners Wyco, Inc., The Wallerstein Co., and Stark Brothers Nurseries and Orchards; and one label that Intervenor-Eli Lilly and Company had with its registration, the cancellation of which was not appealed seasonably.

The Respondent made no effort to furnish me with a list of registrations which he claimed were canceled by PR Notices 71-1, 71-3, or 71-5, or those registrations which he claimed had been canceled earlier. The Respondent made no effort to furnish me with copies of the labels involved. At my request, the petitioners furnished such copies. Thereupon Respondent filed a motion-to-strike certain of the labels. However, he did not pursue it to a conclusion, with the result that the motion fell under the rule of undisposed-motions (Tr. 81:9310). On April 17, 1972, a month after the hearing in this consolidated case was closed (Tr. 81:9311) I received from Respondent a letter presenting a argument in the matter of the registrations involved in Borden, Inc. I.F.&R. 210. A check of the records discloses that Borden's objections and request for public hearing was filed April 29, 1971, and contained a list of the now-disputed registration numbers. Respondent's "Answer to Objections" was filed May 21, 1971, [illegible] those registration numbers and in no way contesting their validity. Likewise, in the motion-to-strike, mentioned above, Respondent did not seek to

strike the registrations set out in Borden's Inc. I.F.&R. 210. Respondent has had ample opportunity to question the particular registrations. It is too late now to open up a controversial For the purposes of this case, the registrations in ..., I.F.&R. 210 are considered to have been subject to ...

On April 18, 1972, I received a letter containing a long dissertation about several registrations involved here that were the subject of his motion-to-strike mentioned above. Such belated attempts to do what could have been done in open hearing over a six-months period is a disservice to any attempt on my part to render an appropriate decision. This case must not be decided on any such ex parte approach.

Now, to get back to my discussion of all the labels.

One by one I compared all of the labels at issue with the pertinent directions set out in Interpretation No. 13.

In all cases, except two 8/, the language of the label was in substantial compliance with the requirements designated for DDT.

It is evident that if Respondent has no established procedure for frequent verification of all labels, it should inaugurate such a program at once.

Any question of the relative safety of DDT compared to such compounds as Parathion, Endrin, or Methyl Parathion is quickly

8/ Label accompanying Reg. No. 2460-46 did not contain statement "Do not breathe dust or spray mist." Label accompanying Reg. No. 3238-8 did not contain the word "Caution".

dispelled by an examination of the safeguards required of each by Interpretation No. 18.

At this juncture we could consider the evidence presented to show whether or not in actual practice the label language is adequate for the purposes of FIFRA's requirements in section 2.z.(2)(c); -(d); and -(g), respectively. Such evidence is necessarily dependent upon an evaluation of the benefits and risks involved in the use of DDT insofar as they go beyond the narrower issue of misbranding. While it must be borne in mind that each label is subject to a test of benefit-risk, such a task would not only be long and tedious, but is unnecessary because the evaluation can be more easily handled in the broader discussion of benefit-risk which will follow.

1. GP Model DDT Labels

During the hearing, Group-Petitioner submitted 15 documents which they recommended as models for future labels relative to the use of DDT. These suggested model labels were recommended for the following uses: for cotton; for military use on clothing; for peppers and pimentos; for fresh market corn; for peanuts; for cabbage, cauliflower, and brussel sprouts; for tomatoes; for lettuce; for potatoes; for sweet potatoes (southern states only); for use in commercial greenhouses and nurseries; for beans (dry, lima, snap); for bat and rodent control; for emergency use for agriculture, health or quarantine purposes; and for onions and garlic.

It is my opinion that I have no jurisdiction to consider the application or qualification of these models in connection with this hearing.

However, I think the submission of these suggested labels is an indication of the close cooperation that should exist continually between the respondent and registrants under the FIFRA. Therefore, I forward these suggested model forms along with this case and recommend that they be considered fully in the light in which they were offered and in which I send them forward. The model labels will accompany this decision in a separate file-folder, properly identified.

IV. BENEFIT VERSUS RISK

As explained earlier, although the issue raised by the cancellation notices is the sort of down-to-earth challenge where the proof is confined to precise application to statutory standards of FIFRA, there is the further issue, not spelled out in legislative history or enactment, which, in recent years particularly has been accepted generally in considering appropriateness of cancellation: --benefit against risk.

The basic point appears in Environmental Defense Fund v. Ruckelshaus, supra, at 594:

> The cancellation decision does not turn on a scientific assessment of hazard alone. The statute leaves room to balance the benefits of a pesticide against its risks. The process is a delicate one, in which greater weight should be accorded the value of a pesticide for control of disease, and less weight should be accorded its value for the protection of a commercial crop.

In applying that observation to the misbranding sections involved here the first thing that becomes clear is that an unlimited interpretation of the language used would not be helpful.

For example, section 2.z.(2)(d) requires the warning or caution statement to be adequate to prevent injury, inter alia, to useful invertebrate animals. To interpret that to its full impact would mean such animals as common ants, unharmful mites, and, no doubt, hundreds of other species that might abide in the area of our application, and all such species probably having some usefulness. Certainly, no one in this hearing has offered any theory of FIFRA that

extends protection to all useful invertebrates. If that were the case it would be mandatory to conclude that it is just impossible to frame a label that will meet the requirements of section 2.z.(2)(d). But no serious reader of FIFRA believes that the Congress intended such a result. In speaking of useful invertebrate animals, Respondent (Tr. 80:9168-69) talks in terms of "beneficial insects;" "the predator and prey" in cotton fields and other agricultural activities; "bees;" "aquatic insects" that are fish food; and "shrimp;" an indication that respondent recognizes the limitations of the broad term useful invertebrates.

Likewise there must be an assessment of what is meant in sec. - (d) by the phrase "adequate to prevent injury, etc., to useful invertebrate animals." By definition DDT is an economic poison. No economic poison is species specific; that is that it will kill only the target insect, e.g. a poison that can be applied on cotton that will injure only the boll weevil. And Interpretation No. 18 gives full recognition to that by providing for use of skull-and-crossbones, and the word "poison" with contrasting colors. If the implementation of the Act recognizes that such poison does in fact cause some injury, even to the extent of requiring an antidote, how can it be argued that the Act means that no injury shall be done to useful invertebrate animals. To me, it seems that the only acceptable rationale of [illegible] 2)(d) is that the Congress wanted the label to contain a warning or caution statement that

would be adequate to prevent all unreasonable injury to those invertebrate animals within the range of application who are known to be helpful in eliminating the pertinent pests when the immediate need for elimination does not demand the power of the economic poison. That is a balancing of the benefit against the risk.

Of course I don't mean that the whole scope of benefit-risk has a simple answer. There are two areas of contention: the global benefits and risks of DDT for all uses; and the particular benefits and risks of a specific use of DDT, such as on an agricultural product.

Concerning the global significance of DDT I would feel compelled to join the forces seeking the cancellation of all economic uses of DDT if the evidence here gave proof that the use of DDT created an "imminent hazard" to man 9/, either directly through carcinogenic effects on humans, or indirectly by destroying man's food chain and environment so as to make the earth uninhabitable. Similarly, if the evidence gave proof that DDT was completely innocuous, non-persistent in the environment, of absolute safety to man, and injurious only to a few non-target organisms of no significance, I would have to find that the use of DDT presented no global risk

9/ Respondent has specifically rejected this contention, since the action to be taken under FIFRA would be immediate suspension of all uses of DDT rather than cancellation. See p. 12, Environmental Protection Agency, Reasons underlying the Registration Decisions, etc. March 18, 1971. (Exh. CP-19.)

and, therefore, find unwarranted any cancellation of registrations on the basis of the benefit-risk approach to the problem.

Respondent argues that because of its persistence, transportability, bioconcentration in animals, and its toxicity, DDT is such a risk to wildlife and the safety of man, that most, if not all, of its present uses should be banned.

Group-Petitioners counter-argue that DDT has had a long history of human safety, and that the minimal risks to the environment from its use do not diminish substantially the record of overwhelming benefits derived in the areas of public health and agricultural betterment, including increased yields of food and fibre.

The proceeding here concerns itself with the cancellation of the registrations of uses of DDT and its metabolites. It is not a trial of every pesticide or other chemical compound the use of which may have a deleterious effect on man or his environment. In analyzing the benefits and risks of DDT it should be of some significance to determine whether or not replacements 10/ for DDT may be more or less safe, efficient and economical; however, much of such information is conflicting, hypothetical, and, generally, of limited value.

10/ Most of the testimony and arguments throughout the hearing when talking of other pesticides have labeled them "alternatives." It is noted that if DDT were canceled for all uses, other chemicals would thereby become "replacements." I believe this distinction is significant. When discussing present uses, therefore, I have attempted to use the word "alternative" while discussing possible future action should DDT be generally banned, I have attempted to use "replacements."

Similarly, this case is involved only with those uses of DDT as to which the Department of Agriculture has issued a statement of essentiality. 11/ As an indication of the extent to which the use of DDT has been curtailed by prior cancellation action, the evidence shows that whereas 79 million pounds of DDT were used in 1959 12/, the domestic sales of DDT in 1970 were 11,966,196, of which over ten million pounds were used on cotton 13/. The sales from January 1 to August 1, 1971, as listed by the only basic DDT producer as of January 1st, are listed as 8,827,900 lbs. 14/.

For a better assessment of the benefits and risks of DDT under present uses, and a reasonable projection into the future, a summary history of DDT, as portrayed by the evidence, is in order.

DDT was first used as an anti-malaria insecticide during the closing years of World War II. It was found to be of immense benefit to Armed Forces personnel, particularly in the Pacific Theater where the anopheles mosquito was the problem.

Thereafter, the use of DDT was extended to control vectors of many other diseases, such as typhus, encephalitis, yellow fever,

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11/ See Admission No. 2, supra, which lists Pome Fruits; Stone Fruits; Citrus Fruits; Papaya; Chestnut; Blueberry; Caneberries; Cranberry; Strawberry; Cotton; Hops; Mint; Peanuts; Sugarbeets; Beans; Broccoli/Cabbage/Cauliflower; Carrots; Lettuce; Peas; Peppers & Pimentos; Potatoes; Fresh Market Corn; Sweet Potatoes; Tomatoes; Weed Crops; Cutworm Control; Forest Insect Control (Seedling dip); Commercial Greenhouse and Nurseries; Turf & Lawns; Fabric Treatment; Public Health Pests; and Agricultural, Health, and Quarantine Treatments in Emergencies.

12/ Exh. CP-19

13/ See Admission No. 7.

14/ See Admission No. 6.

tick fever, bubonic plague, cholera, and dengue fever. Its uncontradicted primary [illegible] the area of public health is still being heralded.

Later, a major use of DDT was for agricultural crops. As the world population has increased, the necessity has arisen for a domestication of food plants. With the organization of crops and animals, came the outbreak of major pest problems. Both man and pests were relieved of the necessity of searching for food. As the escalation of organized agricultural procedures advanced the hosts for pests, the need for insecticides, with their concomitant hazards, escalated. DDT proved to be one of the most successful weapons in the armory of insecticides.

Accordingly, DDT's effectiveness against insect pests caused its use to become so widespread, unrestricted, and indiscriminate that some forests and aquatic areas were inundated with DDT in order to control black flies around aquatic areas, such tree-destroying insects as the spruce budworm, and the gypsy moth.

As time went on, the other-side-of-the coin began to show. Injury to certain species of wildlife was charged to DDT, and the restrictive powers of FIFRA were invoked to stop apparent excesses and unnecessary uses. Surveillance was increased to monitor real and potential hazards to the environment from the use of DDT.

Since 1960 the [illegible] of DDT has been drastically curtailed.

Past accomplishments of DDT in the public health area, and its present use for such purposes and on agricultural crops overseas are not a part of the determination in this hearing. Likewise, the former uses of DDT which, as pointed out above, have since been cancelled or restricted are not in issue here. But both furnish helpful background data.

V. BENEFITS

The hearing concerned itself predominantly with witnesses called by Respondent or Int.-EDF et als; all of whom testified generally in opposition to the continued use of DDT. Witnesses were presented by Group-Petitioners and USDA in anticipation or rebuttal of the criticisms of the use of DDT. Benefits resulting from the use of DDT are sometimes too easily presumed and consequently ignored.

There seems to be little question of the far ranging public health and welfare benefits from DDT, historically. For example, a simple recollection that in 1945 some 1.8 billion of the world's population lived in malarial areas; and that by 1969 eradication programs had acquired control or elimination of that disease for 700 million people, and that another 700 million were in the process of the administration of similar programs. DDT was the genuine warrior against the deadly mosquito. 15/

The evidence here showed that few persons seriously advocate the banning of DDT for use against the ravages of disease in the expanding disadvantaged nations. Actually there was substantial testimony to the effect that DDT should be kept available for emergency health purposes here in the United States.

Although less dramatic, the fight DDT makes against insects in the agricultural betterment programs, which are necessitated by expanding world population, has wide-ranging dynamic effects.

15/ Exh. GP-6.

The confidence placed in the ability of DDT is clearly indicated by its widespread use with agricultural crops; despite the necessary restriction from the aquatic and forest areas where wildlife was said to be damaged by the type of use.

VI. RISKS

1. Human Safety

DDT has been the most widely used pesticide for the past twenty-five years. It has also been the most widely studied for possible effects on human health.

When considering its record of safety, it is perhaps ironic that the exposure by humans to DDT is the natural result of its extensive worldwide use for public health purposes.

Dr. Simmons 16/ in a statement entitled "Brief History of the Pesticide DDT In Disease Control," said (Tr. 9:1086):

> Malaria control campaigns have extended over 2 decades, and no toxic effects have been reported among the hundreds of millions of people who live in houses that have been sprayed nor among the 200,000 or more spraymen applying the material.

This viewpoint of human safety was also recognized by Surgeon General Steinfeld who after confirming the foregoing statement, testified further on the point (Tr. 11:1347-48):

> Although DDT has been studied more extensively in man than any other known insecticide, no concrete evidence has been presented that it presently constitutes any health hazard to man, even among industrial production workers whose daily exposure to it for more than two decades has greatly exceeded that of the general public. Its use record, with respect to human safety is unparalleled in the history of insecticides. DDT is not recommended as an out-of-door treatment for antimalaria programs and contamination of waterways, soils and vegetation from spraying the interiors of houses with DDT is minimal. The safety, long-lasting action, and low

16/ Samuel W. Simmons, former Director of Pesticide Community Studies, EPA, Atlanta, Georgia.

cost of DDT make it the only known insecticide that can be used on the scale required in malaria eradication programs within the resources currently available to such programs or that can be reasonably expected to be available to them in the foreseeable future.

Those that would ban all use of DDT because of the possibility of some damage to man, the evidence of which is said to consist of the results of a few experiments with animals, would do well to compare such skimpy evidence of risk with the well-documented proof of the benefits which DDT has bestowed on mankind.

Granted that the past successes of DDT in the area of public health cannot by itself justify any future use on agricultural crops, it must be noted that the DDT record of safety to man, particularly in comparison to other pesticides which might be used as replacements, is an item to be considered in any balancing of risks versus benefits in the case of DDT.

2. Carcinogenicity

Just as the highest benefit of DDT is in the area of public health, so the greatest concern should be as to any potential risk to human safety. The potential is aided by the evidence of the persistence, mobility, and possible biomagnification of DDT, placing it in the environment where it can be an indirect hazard to man.

The hazard of the carcinogenicity of DDT has been the subject of many scientific studies. In these proceedings the Respondent takes the position that DDT is a carcinogen. Nevertheless, it seems to be generally agreed that the carcinogenic properties, if any, of DDT do not present an "imminent hazard" to man's safety.

With any studies of the carcinogenicity of DDT there is the immediate difficulty of the moral and ethical considerations of experimenting with humans.

Although some studies have been made of possible effects of DDT on employees in a manufacturing plant 17/; on pesticide workers 18/; and on volunteer prison inmates 19/; no such studies can be conducted with humans with the scientific thoroughness that can be applied to experimentation with animals. The man-studies and the observation of the effect on the millions of people, both recipients and applicators, in the malaria programs has furnished no actual instance of the development of cancer in man from the use of DDT.

17/ Exh. CP-32. Men With Intensive Occupational Exposure to DDT, Laws, 1967.
18/ Donald P. Morgan, M.D. Tr. 17:2069.
19/ Exh. Int.-USDA 39A. Effect of Known Repeated Doses, etc., Hayes, 1956. Exh. Int.-USDA 39B. Evidence of Safety, etc., Hayes, 1971.

Therefore, the argument over the potential carcinogenicity of DDT revolves around experiments with animals. The significance of the various experiments with mice and rats, and the propriety of extrapolating the results to man, is the crux of that issue.

Group-Petitioners and USDA argue that extrapolation from mice and rats to man cannot be undertaken so as to produce answers based upon reasonable medical certainty. On the other hand, Respondent urges that while the continued development of adequate testing protocols and facilities is necessarily a priority undertaking, the in-the-meantime extrapolation from small scale laboratory analyses must err on the side of safety 20/. Reference is made to the Delaney anti-cancer amendment, so called, 21/ as a clear demonstration of the intent of the Congress in this question.

Despite the fact that the Delaney amendment has application only to food additives under the Food, Drug and Cosmetic Act, and has been held specifically not to apply to pesticides, the general concern created by chemical compounds with carcinogenic propensities places a heavy burden on an administrative officer to explain the basis for a decision to permit the continued use of a chemical known to produce cancer in experimental animals 22/.

The key to the application of the Delaney Amendment is the word "known", viz, known to produce cancer in experimental animals; and

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20/ EPA. Reasons Underlying the Registration Decisions, etc., March 18, 1971: Exh. GP-19 (Tr. 5:603).
21/ 21 U.S.C. § 348(c)(3)(A).
22/ Environmental Defense Fund v. Ruckelshaus, 439 F.2d 584, 596 (1971).

the key to the value of results of animal experiments is the validity of their extrapolation to man.

The evidence in this proceeding clearly indicates that extrapolation cannot be a reliable tool. Several expert witnesses freely opined that they thought extrapolation was justified; and several others were emphatic as to the impossibility of depending upon that device as a bridge.

The best explanation of why extrapolation should not be attempted came, strangely enough, from a respondent-witness who gave every indication of espousing the extrapolation theory except for this answer to a question by the Hearing Examiner:

> The biological response of animals, such as these commonly used for testing, to a variety of chemical agents and physical agents, that leads to the development of tumors is very comparable as a biological phenomena as a disease process to what we see in man, and, therefore, the qualitative correlation holds true. * * *
>
> I would say there is a fairly common belief and scientifically based point of view in the scientific community of people familiar and expert with cancer research, experiments in this field, that the quantitative extrapolation is essentially impossible at the present state of our knowledge, between the results of those response studies in animals and those in men. [23/]

The necessity of establishing both the qualitative and quantitative bases for extrapolation is clear. No matter how closely, physiologically, the structure and functions of the mouse or rat can be compared to a human, there is no reliable way to arrive at

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23/ Umberto Saffiotti, M.D., Associate Scientific Director for Carcinogenesis, National Cancer Institute, NIH, HEW. (Tr. 34:4277-78.)

a reasonable, medical conclusion as to similarity of impact of DDT, or any other chemical compound, upon a human if the dosage given to the experimental animal can not be the equivalent of the dosage to which the human is exposed.

No facet of any issue before me in this consolidated hearing received more attention from counsel on both sides of the aisle then did this question of cancer experiments on animals; principally mice and rats. The knowledgeable scientists who testified left their mark on this case record; and to make the presentation of the evidence on this point more forceful, the total testimony was subjected to a critique by two medical men whose formidable stature in this field is acknowledged and accepted by the scientific community. These men are Dr. Samuel S. Epstein 24/, who believes DDT is carcinogenic; and Dr. William H. Butler 25/ who believes that carcinogenicity of DDT has not been medically demonstrated.

Dr. Epstein proceeded to review the literature available in this hearing on the question of rodent studies on the carcinogenicity of DDT. He divided the studies into three groups according to his evaluation of their authenticity, genuineness, and reliability as a basis for a sound conclusion.

In the first category were four studies which he believed provided definitive evidence of the carcinogenicity of DDT. These

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24/ Samuel S. Epstein, M.D., Professor, Environmental Health and Human Ecology, Case Western Reserve University, Cleveland, Ohio.
25/ William H. Butler, M.D., Pathologist, Toxicology Unit, Scientific, Medical Research Council Laboratories, Carshalton, Surrey, England.

were: The Bionetics (Innes) study; the Fitzhugh (unpublished, 1969) study 26/; the Milan study sanctioned by the World Health Organization (WHO); and the Lyon study, also sanctioned by WHO, performed by Dr. Higginson under the direction of Dr. Tomatis.

In the second category were the ones that were merely suggestive of carcinogenic properties, but which did not contain sufficient information to be completely reliable. This class included: Fitzhugh and Nelson (1947); Kemeny and Tarjan (1969); and Halver (1967).

The third grouping of studies included those which Dr. Epstein declared were inappropriate to negate the carcinogenic properties of DDT because the dosage used was too low; or the route of administration was too low; or too few animals were used; or the length of the experiment was too short; or a combination of those defects. In this category were: two papers by Hayes; the Laws' study (1967); Hogg, et al (1947); Kimber (1964); Cameron and Chang (1951); Dall et al (1963); Agthe et als (1970); Radomski (1965); and Kreon and Pledland. 27/

Dr. Epstein's conclusions are summed up as follows: (Tr. 65:7370)

> * * * DDT has been shown to be carcinogenic in a series of well designed experiments on the basis of standard toxicological carcinogenesis procedure and philosophy. We have no reason to exclude the fact

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26/ The validity of the results of the Fitzhugh paper was questioned (Tr. 79:8915-46; Tr. 81:9248-51) because of an error not disclosed in the item Dr. Epstein was citing. See Exh. R-131.

27/ Bionetics, Innes, Exh. GP-24; Milan study, Exh. R-2; Lyon study, Exh. R-2; Fitzhugh and Nelson, Exh. GP-22; Kemeny and Tarjan, Exh. GP-25, fn. 4, 5; Halver, Exh. GP-25, fn. 3; Hayes, Exh. Int.-USDA 39A and 39B; Laws, Exh. GP-32; other papers not readily identified as exhibits or cites.

that DDT represents a significant carcinogenic hazard to man, especially, over and above the factors which I mentioned, we are dealing with material which is highly persistent, highly mobile, highly complicated in the environment and stays around a long time.

It appears to me that what Dr. Epstein has said is that, in his opinion, the material he has evaluated supports a conclusion that DDT has not been proven to be not carcinogenic as far as humans are concerned.

Dr. William H. Butler, presented as a rebuttal witness by Group-Petitioners, also critiqued the same cancer studies referred to by Dr. Epstein.

Dr. Butler disagreed specifically on the Bionetics paper. He believes that the protocol of that study would not permit any sound conclusion that DDT is a carcinogen. Concerning the unpublished 1969 Fitzhugh paper 28/, he questioned the unusual results, viz, a predominance of hepatic carcinogens in the females whereas usually a four-to-one ratio in favor of males is the result of such tests. Dr. Butler also disagreed as to the Lyon study. He said he doesn't believe the results support any finding that DDT is a carcinogen. He agreed that the nodules developed in the test animals could be defined as hepatomas, but he doubted any showing that they were neoplastic. He also testified that the Milan study did not support any conclusion that DDT caused cancer in the mice used. 29/

28/ The challenge for error had not been made at that time.
29/ Dr. Butler says he thinks now that mice are not appropriate animals for cancer tests. (Tr. 78:8828-29.)

Dr. Butler's summary:

> From the evidence I have read * * * I would suggest that [DDT] is not a carcinogen for man.

I think what Dr. Butler's testimony shows is a failure in the methodology of such tests to develop facts that can be interpreted with reasonable medical certainty. I have no doubt that both of those men of medical expertise have a consuming concern for human safety. Both demonstrate the need for continued study of the causes of cancer. So, we have Dr. Epstein saying the equivalent of there-is-no-clear-proof-that-DDT-is-not-a-carcinogen-for-man; and Dr. Butler saying the equivalent of there-is-no-basis-for-interpreting-present-knowledge-as-any-proof-that-DDT-is-a-carcinogen-for-man.

The MRAK Commission Report 30/ to which reference was frequently made during this hearing, contains this statement:

> * * * accordingly, with the evidence now in, DDT can be regarded neither as a proven danger as a carcinogen for man nor as an assumedly safe pesticide; suspicion has been aroused and it should be confirmed or dispelled.

In my opinion the evidence presented demonstrates a continuing need to pursue the truth as to the fact of DDT as a carcinogen for humans. Although the evidence at times appeared to deny the carcinogenic properties of DDT for animals and at other times seemed to confirm it, there was no showing of any evidence that man himself was not safe from cancer from the present dosages to which we are exposed. Really, it can't seriously be contended that the fact that

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30/ Report of the Secretary's Commission on Pesticides and Their Relationship to Environmental Health, Parts I and II, Dec. 1969. Judicial notice taken of certain material therein, Tr. 56:6374; Tr. 68:7797.

DDT has NOT been proven NOT to be carcinogenic in man, is a logically basis for advocating a complete ban on all future uses of DDT.

I give a lot of weight to the testimony of the Surgeon General, Dr. Jesse Steinfeld. In the first place, he has no-axe-to-grind, as the saying goes. He has to consider the health of all the people in the United States. And judicial notice can be taken of the prompt and forthright official actions he has taken in this regard. In addition, Dr. Steinfeld is a highly competent doctor of medicine who prior to his appointment did extensive research in the area of cancer. Through his present position Dr. Steinfeld has available to him all the literature, including the MRAK Report, concerning the problem of the possible carcinogenicity of DDT. So, his statement quoted here earlier (Tr. 11:1347-48), and which was subject to cross-examination in the same manner as other testimony, covered as well his conclusions regarding DDT as a carcinogenic hazard for man.

The risk of DDT as a carcinogen was presented fully by the parties, including the present levels of intake and other impacts of DDT to which the human population of this country is presently subjected. The testimony is sufficient in amount and quality to permit appropriate findings and conclusions.

3. Mutagenicity and Teratogenicity

It is well recognized that serious and irreversible harm could result if a seemingly safe chemical should later be discovered to have mutagenic propensities. Likewise, there is difficulty in discovering mutagenic agents. No more compelling reasons are needed to encourage continued and accelerated extensive research to find the truth of the matter.

In this hearing, the evidence shows at the outset a conflict of experts on the question as to whether carcinogenic agents are ipso facto mutagenic; and vice versa. Then there is the agreement that in humans it takes so long, generations in fact, to obtain adequate and satisfactory data. The Respondent here, in support of the position that DDT is a mutagenic hazard, relied basically on the testimony of one witness who had conducted in vitro experiments with kidney tissues of the kangaroo rat; and in vivo studies with hamsters. The scientist-witness 31/ has unquestioned competence; and his work was directly under the authority of the Surgeon General, to whom his results were forwarded. The Surgeon-General testified: (Tr. 11:1360)

> I don't think we have any evidence that [DDT] has caused any genetic changes in man.

There was evidence, also, that experiments with rats and dogs, all exposed to high doses of DDT, showed no reproduction difficulties after three generations of observation. (Tr. 33:4096; 4122.)

31/ Marvin S. Legator, Ph.D., Geneticist. Chief of the Toxicological Branch, Food and Drug Administration.

There is no serious testimony which would support any theory that DDT has been shown to have teratogenic effects.

There is no serious testimony which would support any theory that DDT has been shown to have teratogenic effects.

4. Effect on Aquatic Organisms

Respondent argues that DDT has acute, chronic, sublethal and lethal effects on freshwater insects and other aquatic invertebrates as well as important ecological implications in its introduction to seawater. DDT has been wisely banned from use in or on aquatic areas. 32/ Nevertheless, Respondent claims, by run-off, drift and through volatilization and subsequent rainfall DDT does get into aquatic areas under present usage.

A particular problem with fish is biomagnification, making predator fish susceptible to high concentrations of DDT in its body. Testimony brought forward by Respondent and Int.-EDF et als enumerated some disturbing observations concerning DDT's effect on aquatic organisms. There is evidence that DDT is accumulating in phytoplankton, a source of food for many sea animals and the dominant vegetation in the sea (Tr. 44:5193-96). DDT in fish is often in the order of 20,000 times the level of DDT to which they were exposed (Tr. 27:3187).

Random examples of "global" level of residues of DDT found in fish were: 68 ppm in blubber of a pilot whale off the Faroe Islands (Tr. 28:3293), 1.24 ppm in fat of a dolphin in the Mediterranean (Tr. 28:3293). Average DDT residues in all fish monitored at various monitoring stations generally in the Cotton Belt of the United States in 1969 and 1970 were: Elizabethtown, North Carolina - 0.90 ppm (1969); Summertown, South Carolina - 1.5 ppm (1969); Savannah,

32/ Admission No. 1, supra.

Georgia - 0.57 ppm (1969); Uniontown, Florida - 1.11 ppm (1969); Jim Woodruff Dam, Florida - 0.75 (1969); McIntosh, Alabama - 7.5 ppm (1969), 3.88 ppm (1970); New Orleans, Louisiana - 0.44 ppm (1970); Brownsville, Texas - 2.5 ppm (1969), 5.42 ppm (1970); Pine Bluff, Arkansas - 2.73 ppm (1970). (Exh. R-51; Exh. R-52.) Studies made in the Laguna Madre estuary near heavy application of DDT showed decline from 30 juvenile trout per acre to less than 0.2. Samples showed 1 - 2 ppm of DDT residue in the trout. Moreover, Respondent argues, particularly damaging is the potential damage of DDT in estuaries which are susceptible to deposit through run-off of DDT. Estuaries are important in the maturing of fish. 55% of commercially valuable fish depend on estuaries. In addition Blue Crabs mature in coastal water, but depend on estuaries for early growth. Clams and oysters and many shrimp spend their entire life cycle in estuaries (Tr. 31:3701). In laboratory experiments, shrimp were killed at 0.1 ppb's in the water (Tr. 31:3713).

An example of the unbalancing of the estuary ecosystem is the tendency for DDT to cause increased reproduction of snails in experiments. Other experiments showed 50% of fish used in an experiment were killed in 96 hours with water containing 10 ppb's of DDT (Tr. 45:5343); .6 ppb's for shrimp; 6 ppb's for hermit crabs (Tr. 45:5348). A sophisticated experiment with salmon, showed that 50% less fish treated with DDT than controls return to spawn, thus indicating that DDT affected the "learning" process of the

salmon (Tr. 46:5542-47). On the other hand, an experiment with trout indicated the learning process or reaction to escaping predators was not affected by DDT. Laboratory experiments indicated that DDT can cause fish to seek higher temperature, where they often die; this was explained as a "temperature selection process." (Tr. 46:5526-5531.)

Testimony was given that DDT residues in fish in cotton areas in the South, were directly related to run-off from fields (Tr. 27:3182). In ditches where DDT was trapped, mosquito fish would die or lose equilibrium after heavy rainfalls. Two lakes in Mississippi near cotton areas where DDT was sprayed, had been closed to all fishing, because residues in the fish were above the 5 ppm's level permitted.

On the other hand, Group-Petitioners' arguments which were introduced primarily through cross-examination of the witnesses presented by Respondent, were that the amount of DDT in the water does not constitute a hazard to fishes. Residue levels in the Rio Grande and Anazaldus Rivers averaged .01 - .02 ppb's (Tr. 34:4327), an amount insufficient to cause damage. Moreover, experiments in the laboratory cannot be extrapolated to nature, since the disadvantages of DDT are not as consistent as in the laboratory, and the complexities of nature cannot be adequately represented. Furthermore, DDT is not alone in detrimental effects on aquatic life. Other additions to the environment that affect marine fishes are heavy metals (zinc, cadmium) synthetic detergents, compounds with high biological

oxygen demands, heated effluents from steam electric stations, effluents from pulp and paper mill waste, spills as a result of crude oil and their attempt to clean up mixtures with chemical oil dispersants.

Group-Petitioners argue further that the theory of biomagnification has not been sufficiently analyzed. Additionally, even if some hazard exists from the magnification in the residues of fish as one progresses up the fish food chain line, the number of fishes remaining in the environment is the important factor rather than the sublethal effects or even lethal effects to fishes. Cross-examination 33/ of Respondent's witness revealed that only 2% of fish kills were caused by all pesticides combined. Fish harvests have been generally higher each year. Moreover, what problems may exist with respect to DDT's effect on aquatic life is due to abuse rather than use of DDT, as well as past accumulations from uses not presently at issue.

Group-Petitioners agree that DDT can have a lethal effect in high dosages on certain species of fish. However, in attacking the testimony concerning fish kills in cotton areas, Group-Petitioners pointed out that drainage ditches from cotton fields are specifically and purposely established to retain pesticides - to act as pesticide sumps - so that they will degrade within the ditches, and to permit only a minimum be carried to other waterways.

33/ Tr. 2743214. David L. Stalling, Ph.D., Research Chemist, Chief Chemist, Fish-Pesticide Research Laboratory, Bureau of Sport Fisheries and Wildlife, Department of the Interior.

The theory of biomagnification would seem to be adequately demonstrated in the case of fish, giving rise to concern over use of pesticides with a persistence such as DDT. And it seems hardly enough to say that the amounts of DDT residue will remain in fish for a substantial period of time even if DDT were entirely banned. The marine system, although it covers a huge area and diffuses the amount of DDT to a very low extent, is somewhat a closed system. Although even non-degradable residues on soil would seem to harm little else than perhaps insects and earthworms traveling in that vicinity, DDT in the water is constantly filtered through and to an extent retained by aquatic organisms such as fish.

Although it is not part of this hearing, I am constrained to note that encouragement should be given to a development of more sophisticated methods to further prevent DDT residues from entering water systems, whether they be municiple sewers, drainage ditches leading to streams, or direct run-off from application of DDT in the fields to lakes and the ocean.

While it is necessary to maintain a vigilant concern over the possibility of serious damage to our important aquatic life, it is questionable whether the evidence presented in this case supports a finding that, at present and foreseeable future levels, the use of DDT would cause damage to aquatic life sufficient to justify complete cancellation.

5. Effect on Birds in the Wild

A considerable amount of testimony concerned itself with what effect DDT may have on birds. Respondent sought to show that the build-up of DDT in the food chain resulted in large amounts being stored in birds, causing a consequent thinning of the shells of eggs and reproductive failures. The argument is that experiments in the laboratory which showed such effects could properly be extrapolated to birds in the wild. It was alleged that the viability of certain bird species populations is endangered, either through poisoning or through the effect of reproductive failure.

An enumeration of some examples offered will be helpful.

Cowbirds maintained on laboratory experimental low-diets of DDT or exposed to higher dosages for short periods of time, were found either to eliminate the DDT or to store it in tissues where, apparently, it causes no poisonous effects. However, when fat reserves are utilized, the DDT may be released to the brain with lethal effect.

An experiment with Black Ducks being fed on 10 ppm DDE (dry weight) in the feed showed 24% shell-thinning.

There was a lot of testimony in regard to eggshells in-the-wild. Perhaps the best summary of such data from the point of view of the extremely adverse effect of DDT was posed by Dr. Joseph J. Hickey et al, 34/ in the article "Eggshell Changes in Certain North American Birds." (Exh. R-34, Hickey et al, 1970.)

34/ Ph.D., Professor, Wildlife Ecology, College of Agriculture, University of Wisconsin.

Analysis of eggshell thickness-index changes on a decade basis, carried out with 2,088 eggs representing that many individual females of 11 species and 14 geographical areas, disclosed an apparent decrease in Golden Eagles in the 1890s in western North America; this represented 1 significant decade-change (a decrease) out of 91 decades compared. Comparisons in the other 13 analyses disclosed no significant changes. When this comparison was enlarged to include a total of 2,804 eggs through 1969, significant decade differences were apparent in 12 of the 14 cases, 9 of these at the 0.005 level of probability. In this arbitrarily selected group of species, we conclude that eggshell changes were rare before 1939 and common sometime thereafter.

Expansion of this sample to 20,654 eggshells taken prior to 1946 and to 3,004 taken since then reveals that 9 out of 25 species have sustained shell-thickness and shell-weight decreases of 20 or more percent, at least for brief periods: The Peregrine Falcon in at least three regions, the Marsh Hawk and Brown Pelican in two regions and the Prairie Falcon, Cooper's Hawk, Double-crested Cormorant, Black-crowned Night Heron, Bald Eagle and Osprey in at least one region each. In eight of these, regional declines are known; and in some cases, these declines continue.

These eggshell changes appear to be absent in Whooping Cranes, Broad-winged Hawks and Rough-legged Hawks. They have reached 15-19% in Ontario Common Loons, 14-16% in some White Pelicans, 7-9% in some Great Blue Herons, 8-12% in California Goshawks, 9-13% in some Sharp-shinned Hawks and 10% in Great Lakes Herring Gulls. Changes generally under 10% (with some local exceptions) were observed in Red-tailed Hawks, Red-shouldered Hawks, Golden Eagles, Gyrfalcons, American Sparrow Hawks, Great Horned Owls and Common Crows. The species we reviewed are not regarded as a representative cross-section of North American birdlife, and the population significances of the data are restricted by small samples and time spans, often representing only a few years in a given region.

The shell-change data seem to characterize regional differences in chemical fallout, compatible

> tion that varies with diet and phylogenetic differences in sensitivity to pollutants. DDE is the pollutant most often associated with these physiological changes and population decreases. The importance of additional chlorinated hydrocarbons, including PCBs, as well as mercury remains to be worked out. The threat to North American species is geographically widespread and not limited to the site of pesticide application. It probably involves a small fraction of the continent's species and often only some geographic fraction of a species population; but it seems to be mounting, and its occurrence in the tropical parts of North and South America remains to be worked out.

On the other hand, the counter-argument appears to be that the phenomenon of eggshell thinning is simply an example of correlation rather than of cause and effect; and that simply because some eggshells have been found to be thinner than those collected prior to the advent of DDT, does not prove that, on the average, eggshells are not thinner than they were before. As an example, reference is made to the use of museum eggs for comparison purposes. The argument is that museum eggs were of the highest caliber and not a random selection; so, therefore, a comparison of experimental eggs with museum eggs does not represent a true appraisal.

Dr. Kenneth L. Davison, 35/ a witness presented by Int.-USDA reviewed certain studies that had been conducted on the question of eggshell thickness; and compared the results with those of certain of his own experiments (Tr. 22:2700-2767). He concluded that mean thickness or the weight of eggshells is not significantly affected by DDT, nor is that percentage of calcium in the eggshells affected,

35/ Ph.D., Research Physiologist, Animal Science Research Division, Metabolism and Radiation Research Laboratory, Fargo, North Dakota.

He said that it would be very difficult to obtain in the wild a result of what effect DDT has on eggshell thinning in the wild.

The evidence was clearly conflicting as to whether or not extrapolation could be had in this matter.

It appears that the ultimate injury to be condemned is the adverse effect on the reproductive ability of each species of birds. There was quite a bit of testimony as to whether or not the bird populations presently are thriving or not thriving; and the validity of such bird counts as the Hawk Mountain Survey and the National Audubon Christmas Count received considerable attention. The position taken by Group Petitioners and USDA posed the question as to whether or not these tests as to eggshell thinning were valid insofar as the protocol and methodology were concerned. Likewise an attack was made on the conclusions because of inability to interpret the results.

There was no evidence that DDT was the only factor in a decline of bird populations and examples given included pollutants, other pesticides than DDT, the advances of urbanization which brought human population changes and noise factors, and also disruption of the normal bird life by unnecessary intrusion.

In this particular facet of my discussion of the effect of DDT on wildlife it seemed natural to raise the question as to what would happen if a certain species become eliminated. I am of the impression that in answer to my question in that regard Dr. Hickey stated that insofar as the Peregrine Falcon is concerned, man could get

along without it even though it would be a sentimental and esthetic loss that would be very great; but as a predator it would be replaced more or less through a readjustment by nature itself. In other words, I think he was telling me that some other predator would simply take over the work that was being done by the Peregrine Falcon.

I don't find any evidence that focused its direct thrust on damage to birds by the uses of DDT that are permitted under the registrations in question. It can be seen that some of the former uses could have placed the DDT in areas where birds would have access to it. For example, the extensive use of DDT for spraying against the Spruce budworm and also for spraying against the spread of gypsy moth and likewise the direct spraying of some waterways.

The evidence adequately shows that there should be a continued and extended experimentation and observation of the effect of DDT, as well as any other pesticide, on the bird populations in the wildlife; in the event that such studies might reveal more serious damage to the birds in the wild than has heretofore been shown.

6. Effect on Other Animals

The usual experiments concerning the toxicity of DDT have been with rodents, testing for carcinogenicity. Of course, DDT purposefully is used to kill rats and bats by attacking the nervous systems of those targets.

One of the significant studies involving DDT and animals was conducted by Dr. Alice Ottoboni 36/ with the use of beagle dogs. as to the results, Dr. Ottoboni testified (Tr. 33:4122):

> We have examined every dog in the study that has finished its role in the project. As I mentioned earlier, we have autopsied approximately 500 dogs. There have been no tumors related to dose of DDT. I have seen no liver tumors.

The scientist also noted that DDT has caused no detrimental reproductive effect in beagles; although menopause was delayed, thereby sometimes permitting an additional litter of pups.

As far as the effect on domestic animals is concerned, the record reflecting the action taken because of the use of DDT on and around livestock was noted with approval. When, during the early 1950's, those responsible for the monitoring of pesticide residues noticed that an increase of DDT in cow's milk had reached a level higher than acceptable, appropriate investigations were instituted, and the results of the experiments showed that DDT was absorbed easily through the skin of cows; and that alfalfa containing high residues of DDT led to the transfer of DDT to the milk. Prompt action in cancelling the use of DDT on livestock and limiting DDT

36/ Ph.D., Biochemist, California Department of Public Health, Berkley, California.

residues on feed, plus the necessary cooperation of those concerned with the program, virtually eliminated that problem. The evidence indicated that it has not reoccurred significantly.

Other experiments show that cows were affected by dizziness and disequilibrium when fed massive doses of DDT. However, there are no reports of significant damage to livestock or domestic animals from DDT through the uses at issue in this hearing.

The evidence indicates that continued experimentation should be conducted on animals to determine whether hitherto undetected damage may be taking place in domestic animals at reasonably expected exposure levels from present and future use.

7. Transport, Persistence and Biomagnification

In enumerating the reasons for partial and complete banning of the uses of DDT, Respondent and Int.-EDF et als frequently alluded to the persistence, transport, and bioconcentration (or biomagnification) as well as the toxicity of DDT. Basically, their argument runs like this: the nature of DDT is such that it is an inherently uncontrollable chemical that cannot be confined to its site of application; so, as a result, DDT and its metabolites are available to, and concentrated in, non-target organisms including fish and wildfowl.

There was testimony that DDT has been discovered in the Adelie penguin in the Antarctic 37/, in a pilot whale off Faroe Islands 38/, and in dust particles over the Island of Barbados 39/, even though no DDT has been known to be applied at or near any of those areas.

Vehicles of the natural mobility of DDT from the site of application are: drift from the point of application; volatilization (or evaporation) from soil and plants after application; and run-off from the fields. DDT is also transported by "abusive" methods such as waste from formulating plants and the disposal of containers or the cleaning of spraying equipment in streams and lakes. The transport of DDT is very difficult clearly to analyze and understand. Although traces of DDT have been discovered in far-ranging areas, the problem remains as to how, exactly, they arrived there. The

37/ Exh. Int.-EDF-18, Risebrough, et al, 1972.
38/ Dr. Peterle, Tr. 28,929.
39/ Exh. Int.-EDF-16, Risebrough, et al, 1968.

answers are not only necessarily incomplete, but they are not well documented.

The problem of avoiding drift is nothing more than the age-old struggle to get a chemical to end up where it should. Wind velocity and temperature inversion, as well as techniques of application 40/, are primary factors in attempting to prevent excessive drift.

Huge strides have been made in refining the techniques for the application of pesticides, particularly by aerial application, since the days of the late 1940's when crop-dusters, perhaps romantically, sprayed DDT over the proposed target area and sometimes half of the immediate environment surrounding it. Inventions such as the cutoff nozzle, and reduced caliber of the nozzle openings have raised substantially the percentage of accuracy in the application of pesticides.

In the words of Norman B. Akesson 41/:

> * * * there is no doubt that we were causing a great deal of difficulty in the 1950's, but this has certainly been very considerably controlled and that in the present instances we have means and methods by which we are keeping this application on the site to a very significant degree; that we have in the offing equipment and methods, application techniques which will keep this very nearly 100 percent on the field we want to treat * * *

This was confirmed by Farrell Higbee 42/ who stated:

> Cutoff of the machines after they had left the field was an early problem. However, with the

40/ In an attempt to reduce the problem of drift, many states have enacted laws regulating application of pesticides. See Exh. GP-40, EPA, Digest of State Pesticide Use and Application Laws.
41/ Professor of Agricultural Engineering, University of California at Davis.
42/ Executive Director, National Agricultural Aviation, Washington, D.C. and Loveland, Colorado.

development of sprays and nozzles and orifices that made the sprays more concentrated, the problem of drift has been minimized through the years.

He believed that, at the present time, aerial application has reached a range of 93% accuracy.

Nevertheless, there is testimony that a not-insignificant amount of DDT does end up not precisely on the intended area.

A second phenomenon, less controllable and perhaps less measurable, is that of the volatilization of DDT.

A prime factor effecting the rate of volatilization is that of temperature. Exactly how much of the DDT that is sprayed on a field and lies on top of plants and the soil, and later is volatilized is not exactly known, although estimates have been made of 5 - 10% during the first 24 - 48 hours after application, much less thereafter 43/ (Tr. 6:741). Whether this DDT is then lost in the ionesphere or comes down in the Antarctic or Barbados, or wherever, is a speculation of too exotic proportions to produce any meaningful conclusions based on the tenuous testimony presented at this hearing.

The soil performance of DDT was discussed by Dr. Philip C. Kearney 44/ who said (Tr. 30:3522 - 23):

> It is very difficult to come up with a precise time for DDT to disappear from soils. A large number of factors influence DDT disappearance. Degradation

43/ Virgil H. Freed, Ph.D., Professor of Chemistry, Head of the Department of Agricultural Chemistry, and Director of the Environmental Health Science Institute at Oregon State University.

44/ Ph.D., Leader, Pesticide Investigations Group dealing with behavior of pesticides in soils, ARS, USDA, Beltsville, Maryland

> is just one mechanism by which DDT disappears in soils. Volatilization, lateral movement, chemical reaction, photodecomposition, are all involved in the disappearance of DDT from soils, and they have to be taken into account.
>
> * * * I think a time encompassing as little as six months to a period greater than 10 years would be a reasonable range to give for the persistence of DDT in the soils.

Apparently, a number of factors affect the soil persistence, e.g. rate of application; depth of incorporation in the soil; soil type; soil temperature; cultivation; type of formulation; soil acidity; plant cover; microbes; topography; wind movements; inter-reactions with other pesticides and soil chemicals; and recycling by organisms.

A third method of transport is run-off. Because of the persistence of DDT, it has been argued that DDT is more available than most other pesticides to be carried away by water run-off into adjoining ditches and eventually to rivers, estuaries, and even into the ocean, where it can affect the various ecosystems. There was testimony to the effect that in some cotton areas sluiceways are purposely dug to cause DDT run-off into ditches, thus endangering all aquatic areas and permitting the survival of only such marine organisms and animals that can withstand the exceptional degree of the pesticide.

There was testimony 45/ that two lakes in Mississippi were closed because of the high concentration of DDT, said to be due partly to run-off from cotton spraying. However, the deposition evidence tends

45/ See deposition of Billy Joe Cross, Tr. 67:7587 and Exh. R-127.

to support an argument that the lakes in question, not having any flushing ability, were in themselves a pesticide sump. In my opinion, this deposition evidence is the only forceful demonstration of any alleged direct injury due to any uses of DDT permitted under the registrations involved here.

I would like to discuss for a moment the testimony regarding DDT residues in the soil.

Dr. Kearney, supra, testified that residues usually found in soils that have been treated with DDT are: From crop lands, o-p' DDT, 0.03 ppm; p-p' DDT, 0.16 ppm; o-p DDD, 0.01 ppm; p-p' DDD, 0.05 ppm; o-p DDE, at less than 0.01 ppm; and p-p' DDE, 0.06 ppm. He says that the concentrations that are found in run-off are extremely low, viz, less than 1 ppb. The National Soils Monitoring Program, 1969, shows the only states with residues of DDT in the soil greater than 1 ppm are: Michigan - 2.09 ppm; Mississippi - 2.06 ppm; California - 1.43 ppm; and Alabama - 1.13 ppm. In non-crop lands, such as cities, only Bakersfield, California showed a residue less than in a crop land. E.g., Camden, New Jersey - 1.36 ppm; Miami - 5.93 ppm; Milwaukee - 1.07 ppm. The witness said that there was no established cause for this. The witness concluded that there is a DDT level of equilibrium in soils that, when reached, will not continue to build up from that rate of application. (Dr. Kearney said that the finding of residues on non-crop land confounded him, giving as an example Maryland at 0.09 ppm on non-crop land and 0.01 ppm on crop land.)

Concerning residues in fresh water, Dr. H. Page Nicholson 46/ testified that in 1966, the results of a six and one-half-year residue study of an Alabama river system, draining 400 square miles of cotton-producing area, indicated maximum concentrations of DDT at 30 parts per trillion and DDE at 90 parts per trillion.

Testimony revealed a wide range of amounts of DDT found in coastal and estuarine ocean water; and, since the amounts were so minute, a problem of accuracy arose. A finding of 1 - 3 parts per trillion would seem to be typical (Tr. 68:7794 - 96) (See, also, Exh. R-26, and Exh. R-28).

Residues on food have been categorized in the "Market Basket Survey" by the Federal Drug Administration. This survey indicates that the daily dietary intake of DDT (and metabolites) in milligrams per kilogram body weight for the years 1965 through 1970 is as follows:

1965 - 0.0009	1968 - 0.0007
1966 - 0.0010	1969 - 0.0005
1967 - 0.0008	1970 - 0.0004

The FAO and WHO acceptable daily intake has been set at 0.005. 47/ It would appear, therefore, that the daily intake of DDT by the average person in the United States has been declining since 1966 and is presently well within an acceptable rate.

46/ Ph.D., Chief, Agriculture and Industrial Water Pollution Control Research Program, EPA, Southeast Water Laboratory, Athens, Georgia.

47/ See Admission No. 3, supra.

The level of DDT in adipose of the general population from 1967 through 1970 are as follows: 1967 - 6.22 ppm; 1968 - 7.60 ppm; 1969 - 6.26 ppm; and 1970 - 5.81 ppm. 48/

The problem of measuring residues of DDT, particularly in animals and in water, has been made much more difficult because of the problem of accurate chemical measurement. In addition, there has been widespread confusion, particularly prior to 1967, with the residues of the chemical polychlorinated biphenyls, commonly referred to as PCB's.

Earlier in our discussion I mentioned briefly the phenomenon of biological accumulation (also referred to in the literature as bioconcentration; biological concentration; and biomagnification). The evidence indicates that there is no clear and concise understanding of this phenomenon and likewise the evidence does not clearly satisfy the curiosity as to whether such a food-chain build-up actually has adverse effects (except in the situation where the concentration exceeds any promulgated tolerance levels).

In searching the statements of those who espouse more forcefully the theory of biomagnification, perhaps the most acceptable summary appears in the testimony of Dr. Nicholson 49/, who during cross-examination (Tr. 28:3268-69) reiterated an earlier published statement of his which read as follows:

> The implications for damage are great, but well defined examples are few, perhaps because biological accumulation is not as generally damaging as feared; but also perhaps because the ecological relationships involved are so extremely complex that they are difficult to unravel.

48/ Exh. CP-34, EPA, Human Monitoring Survey, Yobs, M.D. June 1971.

Perhaps the more reasonable way to conclude the discussion of biomagnification is to remember that the persistence which makes DDT a desirable compound for the elimination of pests is at the same time the persistence that holds a potential threat to species of wildlife; and should be used as a reminder that adequate vigilance must be maintained to prevent any threat from becoming a reality in our environment.

VII. USES

As mentioned earlier, this case is concerned only with those uses of DDT as to which the Department of Agriculture has issued a statement of essentiality and which statement appears here as Admission No. 2. The primary use is on cotton. The evidence indicates that it has been estimated that over one-half of the DDT, used in the United States, is used on cotton.

Although there is no concession on the record, I believe that, other than from Int.-EDF et als. 49/, there is little objection to limited uses of DDT, viz, for spraying the underside of vehicles to prevent the spread of gypsy moth infestations; for disinfecting airplanes and personnel carriers, for standby to be used in emergency health situations as determined by appropriate federal and state government officials; and for prescription uses. I say that because I think the evidence shows that the risk to the environment is minimal.

Rather than set out at this point a list of the essential uses, with a short discussion of each, I think it will suffice to concentrate on two specific uses, namely the use on cotton; and the use on sweet peppers. What I say as to those two uses adequately demonstrates my thinking on the other uses involved here as well.

49/ From the outset, Int.-EDF et als has maintained an incredibly implacable position that all uses of DDT should be banned, e.g., Tr. 30:9151.

1. Cotton

It has been estimated that two-thirds of the DDT that is used in the United States is used on agriculture, and that 75% of the DDT that is used on agricultural crops is used on cotton. Currently less than 38% of the cotton acreage in the United States is treated with DDT (Tr. 52:6171-72). Group-Petitioners presented testimony that indicated that DDT is essential for use on cotton.

On the other hand, Respondent takes the position that this widespread use of DDT is the extreme example of forcing hazard upon the environment; citing such things as damage to wildlife, fish and birds, and to beneficial insects such as bees, and predators of pest-targets. There was testimony that in many instances the primary pests of cotton, that is the boll weevil and the bollworm, have become resistant to DDT; and that, in addition, it is not an indication of effective and economical management to continue the use of DDT. The argument is that alternative chemical pesticides are more effective, being so partly because they permit a more immediate resurgence of beneficial insects after the pesticide spraying, whereas the use of DDT creates a resurgence of secondary pests because of its persistence against the beneficial insect predators.

The Respondent urges a more widespread use of alternative means which would be less damaging to the environment and at the same time, from present appearances, would be more effective than DDT.

The evidence as to the suggested alternatives to DDT for the control of cotton pests included the sterile male release method; the development of cultivation of crop varieties, such as Frego Bract, which purport to offer greater resistence to insects; pest attractants, which could be both chemical and physical; cultural and sanitation methods, such as stock-stripping; the use of natural predators and parasites for maximum control; the use of microbial agents or pathogens; and the, so-called, diapause program, which uses a combination of stock destruction together with a limited use of a pesticide. A very interesting pictorial display of the approach methods on the question of cotton pests is found in Exh. GP-41 which are the 80 individual prints of slides shown during the testimony of David F. Young, Jr. (See Tr. 1:98-152 and 2:158-208.) These methods were the subject of a considerable amount of testimony. However, it was the opinion of one expert in pest control 50/, who was a pioneeer in the area of developing alternative methods to insecticidal control of pests that:

> In spite of the diligent effort of entomologists and associated scientists to develop ways to control insects without using chemicals, the instances of success are very few. (Exh. Int.-USDA 2.)

Dr. Knipling was of the opinion that cancellation of all DDT uses would result in potentially more adverse materials being used as a pesticide. He said:

50/ E. F. Knipling, Ph.D., Science Advisor to the Administrator of the Agricultural Research Service, USDA.

> [illegible] information and experience, there are biological . . . not enough of the right kinds of biological agents in our natural environment to provide effective control for the boll weevil or the pink bollworm or the cotton flea hopper and certain other insects that affect cotton, for example. * * * Now, this leaves for the present, then, the only way to produce cotton productively * * * involves the use of chemicals * * *. (Tr. 3:402-03.)

> Of course, I have been weighing these things for years, but in my honest opinion, as things now stand, and my concern may be a little bit different than others, I would rather see DDT and Toxaphene be continually available to the cotton growers for the time being, waiting to see how our experiments are coming out rather than to deny them these materials at the present time. One reason, they are effective against the boll weevil, and at the same time they alleviate the bollworm problem. I am actually more concerned that if these are not used, that the alternatives that will be used are going to do more to upset the beneficial destructive insect complexes in the cotton fields in the South than to continue to use DDT and Toxaphene.

> * * * I am concerned about the potential hazard of DDT in the environment and what it may do to fish and wildlife. This is obviously important, I think, to all of us. * * * But for the uses for cotton, for the other uses in which the alternative may be more damaging, at least to the immediate environment, are more hazardous to people, I can't hardly . . . I can't justify in my mind that we should switch. (Tr. 3:419-421.)

There is an argument put forth that it is less expensive to apply a replacement for DDT. However, as I see it, the evidence was conflicting and there appeared to be some merit to the argument that DDT might be more economical to apply in view of the fact of its

persistence the number of applications required can be reduced (Tr. 3:343). There was also evidence that the yield of cotton was increased. The organophosphates appear to be the principal replacement for DDT. It is said that low initial application rates may well provide effective control. There appears to be no question but what the person applying the organophosphates could be subject to a greater hazard. This seems to be borne out by the label requirements as we have seen earlier. Also, the use of organophosphates appears to increase the likelihood of immediate harm to non-target animals and separate species located in the treated area. There was quite a bit of testimony in regard to the effect of pesticides on the very important beneficial invertebrate bees. There seemed to be a concensus that although bees are adversely affected if they are subject to DDT, the adverse effect is greater, in some instances, if they are subjected to a treatment of organophosphates.

Resistance to DDT by both the boll weevil and the bollworm was the subject of some of the testimony. Actually, I do not find it necessary for the purposes of this case to determine the degree of resistance, if any, in any particular geographical area. I think that what must be decided here is whether or not DDT is still effective as a pesticide against the primary pests on cotton. According to the evidence I heard, DDT is still so effective.

There was testimony also that an improvement in the management practices of cotton-growing would eliminate some of the need for the

use of DDT. I do not think that argument carries much weight. While the evidence convinces me that the use of DDT on cotton is declining and should be reduced as soon as effective replacement means of controlling pests are developed, I do not feel that the evidence to date permits any conclusion to the effect that DDT should be banned for use on cotton at this time.

2. Sweet Peppers

Although the use of DDT on sweet peppers in the Delmarva Peninsula is of a lesser significance in the overall consideration of the benefit-risk equation in this hearing, it appears to be economically illustrative of the benefit-risk problem as it applies to a specific use of DDT. I use this example even though it is not a specific issue since it is a matter concerning an intervenor who is not a Registrant.

Testimony revealed that only about 3% of the nation's sweet peppers are produced for canning in the Delmarva Peninsula. Admittedly, peppers are a secondary rather than a staple food product and appear to be a food that appeals only to certain segments of our society. However, the farming of sweet peppers is an important item in the Delmarva Peninsula. It is the sole livelihood of many workers. That area is low and flat and it is punctuated with estuaries and smaller peninsulas, all of which seem to be ideally susceptible to the concentration of DDT in the aquatic and marsh habitats; and, thereby, seem to be potentially injurious to the commercially important oyster, crab, and fish industries.

That DDT was the only efficient pesticide for use against the European corn borer, a pest with a great affinity for sweet peppers, was uncontradicted. The evidence indicated that where, as in the Commonwealth of Virginia, the pesticide carbary. (Sevin) has been recommended, its use resulted in a disastrous sweet pepper harvest.

Witnesses indicated that not only does the European corn borer attack with a rapid infestation, but also sweet peppers to be successfully marketed must display an extremely high degree of non-infestation. Apparently, the use of DDT provides the necessary marketability.

From a benefit-risk point of view, I think that the situation of sweet peppers in the Delmarva Peninsula provides a situation where adverse effects of the use of DDT could be traced quite easily. Whereas the extent of cotton production suggests, territorially, a tremendously large area from which to make detailed tracings of the adverse effects that follow the use of DDT, the relatively small area of sweet pepper cultivation in Delmarva, being near marshes and waterways, provides a more reasonable proving ground. In other words, if the run-off from those agricultural lands contaminated the waterways, it would appear that it might be subject to practical proof. There was no evidence that such adverse results would flow from the use of DDT on sweet peppers.