U.S. EXPORT OF BANNED PRODUCTS

HEARINGS

BEFORE A

SUBCOMMITTEE OF THE COMMITTEE ON GOVERNMENT OPERATIONS HOUSE OF REPRESENTATIVES

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U.S. EXPORT OF BANNED PRODUCTS

TUESDAY, JULY 11, 1978

HOUSE OF REPRESENTATIVES,
COMMERCE, CONSUMER,
AND MONETARY AFFAIRS SUBCOMMITTEE
OF THE COMMITTEE ON GOVERNMENT OPERATIONS,
Washington, D.C.

The subcommittee met, pursuant to notice, at 10:05 a.m., in room 2247, Rayburn House Office Building, Hon. Benjamin S. Rosenthal (chairman of the subcommittee) presiding.

Present: Representatives Benjamin S. Rosenthal, Robert F. Drinan, Henry A. Waxman, Garry Brown, and Tom Corcoran.

Also present: Jean S. Perwin, counsel; Eleanor M. Vanyo, assistant clerk; and Henry C. Ruempler, minority professional staff, Committee on Government Operations.

OPENING STATEMENT OF CHAIRMAN ROSENTHAL

Mr. ROSENTHAL. The subcommittee will be in order.

Last spring, this subcommittee held hearings on the Consumer Product Safety Commission's decision to ban Tris-treated children's sleepwear from the domestic market because of mounting evidence that the flame retardant would cause cancer in children exposed to it.

Since the ban required sleepwear manufacturers to repurchase distributed garments, questions were raised about the disposition of sleepwear inventories which no longer could be sold in the United States.

Following the ban, the Consumer Product Safety Commission assured the subcommittee that little, if any, Tris-treated sleepwear was being exported. Subsequently, the subcommittee learned that at least $5 million worth of Tris-treated sleepwear was being exported, and that until recently no action was taken to prevent it.

Following 8 months of subcommittee investigation, it became clear that the export problem was not confined alone to the Consumer Product Safety Commission's experience with Tris.

The Environmental Protection Agency and the Food and Drug Administration also faced similar difficulties regarding the export of banned pesticides and drugs.

The subcommittee's investigation revealed serious problems in export policy affecting banned products.

First, that in addition to Tris-treated sleepwear, other consumer products, pesticides, chemicals, and drugs banned by U.S. regulatory agencies are exported all over the world.

Second, that there is no recognizable, uniform approach to export policy in this area. Each agency acts under different and often conflicting statutory mandates.

EPA's statutes require notification to foreign governments; FDA's and CPSC's do not. EPA can collect data regarding export volume; the others cannot. The Commerce Department cannot impose export controls without a State Department determination.

Third, that the amount of exports of banned products, although difficult to pinpoint precisely, is significant. For example, over 6 million pounds of canceled or suspended pesticides were exported in 1976. In addition, 25 million gallons of DDT were exported last year.

Consumer products which were banned by CPSC were exported both after the ban was proposed and after it became effective.

For example, the CPSC proposed a ban on June 30, 1977, on baby pacifiers which caused choking deaths in infants. Following that proposal, over 500,000 of these pacifiers were exported.

While most manufacturers had redesigned their pacifiers by the February 26, 1978, effective date, at least one manufacturer continued to export banned pacifiers.

There exists a remaining inventory of at least 40,000 banned pacifiers which could legally be exported under the current Federal Hazardous Substances Act provisions.

Fourth, that notification where required to foreign governments of agency actions by the State Department and the agencies, has been inadequate. At the present time, notification is haphazard at best—and nonexistent at worst.

Fifth, we are faced with the question of what U.S. policy in this area should be. If a product is too hazardous for Americans to use, should we permit its export? How do we handle the problem of risks assessed differently by other countries?

These hearings will attempt to focus on these problems and consider appropriate solutions.

Our first witness is Esther Peterson, the very distinguished Special Assistant to the President for Consumer Affairs.

We are very pleased and honored that you could be with us this morning, and we are delighted you have shown such a very serious and real concern with this subject matter.

We will be pleased to hear your testimony.

STATEMENT OF ESTHER PETERSON, SPECIAL ASSISTANT TO THE PRESIDENT FOR CONSUMER AFFAIRS; ACCOMPANIED BY EDWARD COHEN, SPECIAL COUNSEL; AND EDWARD HEIDEN, PROJECT COORDINATOR

Ms. PETERSON. Thank you, Mr. Chairman.

I am very pleased to be with you.

I must say that I think you outlined in your introductory remarks the seriousness and the dimension of this problem.

Therefore, I am more than pleased to be supportive of your efforts in this regard.

I view this issue—which may be of interest to you and Father Drinan—as part of my enlarged authority at the White House. I think it shows a growing concern of the consumer effect and the impact on many of the decisions that are being made today.

So it really pleases me to be able to be with you and to testify on the exportation of hazardous products—those that have been banned or whose distribution is limited by the U.S. Government.

I commend the subcommittee for convening hearings on this timely issue.

I have recently returned from a trip to Japan. On numerous occasions, representatives of various consumer organizations have expressed concern to me about potential hazards of products exported from the United States and other countries.

I should say that although my most recent trip abroad was to Japan, we have been receiving visitors from other countries. It is interesting to me that in almost every delegation that comes to us, this is an issue that is raised that is of growing concern.

The export of hazardous products was first raised as a prominent public issue, as you stated—when the Consumer Product Safety Commission in 1977 banned the domestic sale of children's garments treated with Tris, a flame-retardant chemical strongly suspected of causing cancer.

Many other exported products, having even more substantial economic significance, also raise the problem—either actually or potentially.

Export is currently permitted for several categories of hazardous products banned in the United States, such as certain food dyes—Red No. 2, cyclamate food sweeteners, pesticides, and certain foods, cosmetics, drugs, and other consumer products.

Several factors suggest that this problem will grow in dimension over the next several years because of the following things:

Substantial growth in world population, which can be expected to generate enormous demands for food, drugs, and new potentially hazardous pesticides carrying with them the danger of potential residual contamination of foods, milk, meats, and other products.

Acceleration of demand in developing countries for new U.S. technologies and manufactured consumer goods.

Mounting economic pressures for U.S. firms to increase exports.

And last—and perhaps most important in the long run—the National Cancer Institute and others predict that the discovery of new suspect carcinogenic substances likely to be present in consumer products will increase significantly.

It was based on these past experiences, as well as the anticipated future trends and this subcommittee's concern, which prompted the formation of an interagency working group in May on the exportation of hazardous materials.

The purpose of this working group is to assess the current state of the law with respect to these exports, determine whether a new policy to deal with the issue more uniformly and consistently is needed, and develop such a policy if a need is found to exist.

Included in the working group are the Departments of State, Agriculture, Commerce, Energy, Health, Education, and Welfare's Food and Drug Administration, Justice, and Treasury; as well as the Environmental Protection Agency, the Consumer Product Safety Commission, the Export-Import Bank, the Overseas Private Investment Corporation, and several executive offices.

We have taken, as the focal point of our concern, products which constitute a hazard to the health, safety, or ecosystem of the United

States or of foreign countries, based on consumer usage rather than worker or workplace exposure.

We are also interested in financing, loan, or guarantee arrangements abroad involving the production or marketing of hazardous products.

Certain activities are not part of our inquiry because of their special legislative history or because of unique problems that they raise, such as alcohol, tobacco, firearms, and products or processes whose primary purpose or use is national defense.

Also not included in this effort are products which are certified safe for use in the United States but which may be subject to unsafe consumption circumstances for those same uses abroad, such as infant formula.

We have completed the first phase of our work, which was to define the state of the law with respect to the export of hazardous products.

We found that of the laws that we have reviewed, eight are generally permissive in allowing the export of products banned in the United States. Three require some form of notification to the foreign government. Three require approval by a foreign government prior to export. Two authorize discretionary banning authority by the U.S. regulatory agency. And two impose an outright ban on the export of products not permitted for distribution in the United States.

In addition, we found that some agencies have systematic procedures for dealing with exports, while others treat each case on an ad hoc basis.

In addition, there are currently amendments pending to six statutes to modify existing provisions relating to the exportation of hazardous products. Most of the proposed amendments would tighten export controls on hazardous products.

For the subcommittee's convenience, I have attached a series of charts which summarize the export provisions of the statutes which we studied. That is attachment A. I think you can see from the list how complicated it is.

In addition, I am attaching a chart which categorizes each statute based upon the type of export control provisions it contains. This is attachment B. In that one, statutes are listed there in relation to the export restrictions they contain.

This uneven treatment of exports has created ironic situations where foreign governments pressure the United States for products which are banned in the United States.

Depo Provera, for example, is an injectable contraceptive. Tests of this drug have found that it causes breast tumors in dogs.

For this and other scientific reasons, the U.S. Government has refused to approve the use of the drug as a contraceptive in the United States. It is in strong demand, however, for family planning purposes in many developing countries.

Only a few weeks ago, several foreign government representatives testified before the House Select Committee on Population, expressing their desire to change the U.S. Government's attitude and policy toward export of Depo Provera which, although unacceptable for the United States, would be important in their nations' efforts to reduce population growth rates and thereby help strengthen their own nations' economy and productivity.

At the opposite end of the policy spectrum, other drugs, such as antibiotics, insulin, and drugs classified by the FDA as "old drugs"—those prior to 1938—may generally be exported for any use, even if prohibited for the U.S. use because of adulteration or misbranding.

All agencies in the working group agree that there is a need for more uniformity of policy governing the exportation of products banned in the United States.

Development of a uniform policy to meet the varying circumstances that may arise is no simple task. It will require a careful balancing of a variety of complex factors, many of which cannot be easily quantified.

The working group is now exploring the major issues which must be taken into consideration in developing a responsible policy.

First, a moral responsibility to limit the exportation of hazardous products must be balanced with the right and willingness of a foreign government to protect the health and safety of its citizens.

While President Carter has stressed human rights as a major theme of his foreign policy, foreign governments have a sovereign right to determine the health and safety standards and needs of their own people.

Should the U.S. Government dictate to foreign citizens what products they may or may not have? Does the United States have a special responsibility when the administrative mechanisms of other countries for deciding health and safety issues are inferior to ours, or even nonexistent?

Second, we must protect the health and safety of U.S. citizens. Assume, for example, that we adopt a nonrestrictive policy on exports of hazardous products, such as a pesticide banned in this country. How are we to control the reimportation of those products with a pesticide residue into the United States?

If we allow the export of sleepwear treated with Tris, can we guarantee that those products will not be sent back to the United States with a new label?

Third, differing economic, social, and cultural conditions in a foreign country may suggest that a product whose use is banned or severely restricted in the United States may be justifiable for use in that country.

One possible example of this that I have already cited is the injectable contraceptive Depo Provera.

Another more graphic example is the antibiotic chloromycetin. Its use is severely restricted in the United States to a few serious diseases; because for other infections which are prevalent in the United States, the FDA believes its risks greatly outweighs its benefits.

In many other countries, however, the drug is widely used to combat a variety of serious infectious diseases which are uncommon in the United States.

Fourth, an export policy must take into account economic burdens that the policy may impose.

In 1978, the U.S. balance-of-trade deficit for the first 5 months of the year totaled $17 billion—the worst of any year on record.

A restrictive policy would exacerbate this problem through lost sales. Such a policy could also adversely impact domestic manufactur-

ing output, jobs, and costs. It could result in burdensome cost disadvantages placed on U.S. firms attempting to compete in foreign markets.

The question naturally arises as to whether these costs should be borne and who should bear them—particularly if U.S. multinationals or foreign firms could undermine a restrictive policy by serving as an alternate supplier under less burdensome conditions.

This latter possibility points to the fifth issue: Recognition of the need to coordinate and cooperate with relevant international agencies, organizations, and governments in data analysis, information sharing, and the development of consistent, uniform policy approaches.

Sixth, an export policy must take into account the feasibility and practicability of administering and enforcing the policy. Substantial compliance and administrative costs could arise in attempting to assure that correct procedures were followed for each shipment.

We have identified the state of the law and concluded that a uniform policy should be developed. Certainly the bandaid approach of pairing a law to regulate a specific product has proven insufficient.

The working group is now turning its attention to the questions of what that policy should be, what additional data are needed to develop it, and whether new legislative or administrative mechanisms are necessary to carry out that new policy. We anticipate the work of the Interagency working group will be concluded by September.

The key interest of the executive branch in this area is in assuring that problems are dealt with in a manner that truly reflects a sound and consistent set of priorities and which balances the interests of all concerned parties.

The problem is a very crucial one, and it is time now to act.

We look forward to working closely with the subcommittee in developing a responsible Federal policy in this area.

Mr. ROSENTHAL. Thank you, Ms. Peterson, for a very thoughtful, precise, and articulate statement.

In terms of a timetable, what do you see as a final development of export policy?

Ms. PETERSON. I would hope that we would have our committee report and recommendations early in September.

Mr. ROSENTHAL. You mean the working group?

Ms. PETERSON. Yes. We hope that by then, we can have a negotiated policy that is acceptable. If not, we have to take it up to higher authorities, of course. But we are hoping to work this out.

Mr. ROSENTHAL. Do you think that the administration will be making legislative recommendations in this area?

Ms. PETERSON. I think it depends on what we recommend. If legislation is necessary, then we certainly will.

It is a little difficult for me at this stage of our study to prejudge how that will be. But we will be ready in our working committee to make what recommendations the working group puts forward. It is a good working group, and it is working vigorously.

I am very pleased that the common denominator from all of these agencies is that we must do something. That, I think, is a very, very solid beginning.

Mr. ROSENTHAL. Congressman Drinan?

Mr. DRINAN. Thank you, Mr. Chairman, and thank you, Ms. Peterson.

If the Congress enacted the statute that applies to the FDA, would any great worldshaking problem occur?

In your attachment A, you state that the United States Code specifies that there shall be no exportation of products which cannot be sold in the United States.

If we made a simple blanket rule like that, would any great tragedy result?

Ms. PETERSON. It is difficult for me to say "great tragedy." I tried to point out some of those obligations that we have to look at, because it could be that there are many countries that need some of these drugs.

I have talked to a lot of Peace Corps people.

Mr. DRINAN. We could put in there some type of an exemption, I suppose, that somebody at the FDA—or someone somewhere—could, in certain circumstances, make an exception.

Wouldn't that be a good, moral policy to put in? That if we say they cannot be sold in the United States, by what——

Ms. PETERSON. For myself, I would agree with you, that we need to do something but that we have to be terribly careful about this.

Mr. DRINAN. You should bring the President to agree with you.

You can make the President agree with you—you are so charming.

Ms. PETERSON. I want to be sure that it is the right thing to do.

Mr. DRINAN. Give me one reason why it isn't.

Ms. PETERSON. Let me give you an example.

Take bicycles with reflectors. We do not want bicycles sold in this country without reflectors. For all the countries in the world, I am not sure that is a necessary regulation.

Mr. DRINAN. Some administrator would have that.

But I was thinking much more of the health area.

Ms. PETERSON. If the country itself really feels that the advantages are for them——

I am thinking, again, of some of my Peace Corps children who have told me about drugs that are very necessary for the kinds of infestations that are present in some countries that we just never have in this country.

So I do think that we have to work out a——

Mr. DRINAN. There is no reason why the pesticides won't get on the fruit that will come back here. There is no reason to believe that the Tris-treated garments won't come back here under another label.

So we are really protecting ourselves.

Ms. PETERSON. This is exactly why I raised that as one of the issues in the question.

I assure you that we want to protect ourselves, and we want to protect foreign consumers.

Mr. DRINAN. Could an Executive order from the White House at least require every agency to give notice to a foreign government? Could it also make every agency collect data regarding the volume and the nature of the exports?

Ms. PETERSON. Yes. I think it could, but it wouldn't cover the independent agencies.

These are the kinds of things that we want to come up with, and we want to work with you on that.

Mr. DRINAN. What do you mean by independent? It couldn't reach FDA?

Ms. PETERSON. By Executive order, we don't have the authority to reach the independent agencies.

The Consumer Product Safety Commission would be one example. I will have to ask my counsel.

Mr. COHEN. There has been a raging dispute, which has been going on since the first independent agency—the ICC—was created as to the ability of the executive branch, through an Executive order, to reach these agencies, such as the CPSC.

Mr. DRINAN. What about the Commerce Department?

Mr. COHEN. FDA or EPA are executive branch agencies and could be reached.

Mr. DRINAN. Can't the Commerce Department at least pick up information as to how many exports are sold to what nations? They do it now. So why can't we have at least——

We don't even know how much is being exported.

Mr. COHEN. My understanding is that the Export Administration Act has been interpreted in such a way as not to give authority to Commerce to prohibit the exportation of banned products.

Mr. DRINAN. Can't the President say to his nominee, the Secretary of Commerce, you do this? In the name of public policy, you do this. Which he or she will do.

Mr. COHEN. It would depend upon the authority within each of the statutes.

If you are talking about under the Export Administration Act, I suppose it may be possible. You may want to ask the Department of Commerce, because they know the act better than we do, whether they could require reporting.

I would point out that some of the regulatory agencies have general authority in their statutes to require reporting, pursuant to rules that the particular agency may promulgate.

I suppose it might be possible for an agency, such as CPSC which has general reporting requirements, to require by rule the reporting of the exportation of any product which has been banned in the United States or which is not subject to a standard.

Mr. DRINAN. I hear all of this technical material, but my impression of this series of hearing is this.

But for Mr. Rosenthal and this subcommittee, nothing would have happened. Then all of a sudden Ralph Nader and this subcommittee are giving some heat to the executive. They formed this group that is going to study the matter.

I am just afraid that there is not enough initiative at the executive level to carry forward.

This subcommittee is busy. The Congress will adjourn and then September comes. If these things are unsatisfactory and very vague and ambiguous, as I am afraid they are going to be, then this matter could drift until next year.

Ms. PETERSON. Let me assure you that that is not my intention.

Mr. DRINAN. I know that you have very good intentions.

Ms. PETERSON. But intention is nothing if you don't carry it out. You know that, and I know that.

Mr. DRINAN. One last point.

Can't the executive, at least require notification to foreign governments that this substance has been banned in the United States?

Ms. PETERSON. That could likely be one of the recommendations that will come up.

Mr. DRINAN. But that seems so self-evident. Why can't the President today put forth an order saying that we are going to tell all our friends out there about the fact that this particular substance is banned?

It seems so elementary.

If we want to say that all the nations of the Earth are our friends, we can hardly go around selling poison to them.

Ms. PETERSON. We might want to do much more than that.

Mr. DRINAN. In September, you can do all that you want. I am saying: Let's do something this afternoon.

You could write this Executive order yourself, and the President could sign it.

My 5 minutes have expired. Thank you very much.

Mr. ROSENTHAL. Congressman Brown?

Mr. GARRY BROWN. Thank you, Mr. Chairman.

How many foreign governments do you think are aware of the hazards of products used in their countries that are banned in this country?

I am inclined to think that they are well aware.

Ms. PETERSON. I think that they are well aware, but the level of awareness in the lesser developed countries is another question.

We have been working in our working group with representatives of the State Department, who are in touch with these countries.

Mr. GARRY BROWN. I thought your statement was very good. This is a very complex issue.

Ms. PETERSON. It is very complex.

Mr. GARRY BROWN. Lets' look at the pesticides and insecticides and the food additives, for instance, for livestock.

To permit those things to be used in foreign nations and then to permit those products to be imported into this country and to compete with American agriculture just seems very unfair.

If foreign producers of livestock can feed DES to their cattle, and if the President lifts the beef import quota,* * * It seems to me this is quite a double standard.

Yet I think we would have to agree that there are special circumstances in foreign nations—special climate problems, insect problems, and disease problems. When you start evaluating the use of some of these pesticides and insecticides and comparing the hazards of their use in these countries as compared to the hazard in this country where the disease and insect problem is not as great, we have to say they should be able to use them in those countries.

Wouldn't you agree that it is not a simple matter to just come up with an across-the-board ban?

Ms. PETERSON. That is what I am trying to say—that it is very complicated.

There are a couple of points I would like to make on that.

Many of these countries have not the facilities for even evaluating and testing. I am sure in your experience, you have known that.

So that gives us an additional moral responsibility, which I think is part of what Father Drinan is aware of. That is the part that bothers me, because there is a moral responsibility there for a lot of these countries that do not have the technical capabilities for evaluation.

I think the other problem is in relation to a product being reimported. Rather than prohibit beef imports, perhaps the way to assure safety is to tighten the export of the pesticides in the first place.

We have to weigh those issues, and that we are doing.

I completely subscribe to you that it is terribly complicated, and we are trying to evaluate it in a balanced way.

We have to, as I said in my testimony, protect our people here on the reimportation, which is very important, as well as carry out our moral responsibilities.

Mr. GARRY BROWN. It seems to me that the reimportation is the point in the course of the product that we ought to look at, instead of banning the exports, for the reasons I mentioned earlier.

Situations exist in some of these countries where alternative antidotes will not be effective. Therefore, when you look at the hazard of using a pesticide or insecticide that has been banned in this country, in that country we may say that there it is almost essential that the product be used.

Ms. PETERSON. We are at the stage of our technological development where we need much more. We have to work with the international health organizations on what alternatives are available.

We know that there are many multinational corporations that could be producing these products in other places and then sell them while we do not.

Mr. GARRY BROWN. In your statement, I think you probably came up with one of the best examples of all—Depo Provera.

FDA bans Depo Provera in this country on the basis of its efficacy hazard equation.

When you look at it from a domestic standpoint, the instance of maternal mortality in childbirth in this country is almost insignificant compared to the instance of mortality in childbirth in some of the lesser developed countries.

Therefore, if you are truly evaluating the utilization of a drug on its efficacy hazard equation, it seems to me you have to look at the efficacy hazard of the use of this drug in the nation where it is going to be used—not applying our standards to that situation.

Ms. PETERSON. That is what I tried to put in my statement.

Mr. GARRY BROWN. You did. That's why I say I think that is a very good example.

I would respectfully suggest that when you define the health benefits of Depo Provera in a foreign country where there is a high instance of mortality from childbirth, it comes out a lot better than when you treat it in a country where there isn't that high instance.

Ms. PETERSON. That is why we are looking at that very carefully.

I think you would be pleased if you sat in on the meetings of these responsible Government people who are really struggling with that moral, as well as practical economic, question.

Mr. GARRY BROWN. I am sure my time has expired. I thank you very much.

Mr. ROSENTHAL. On that particular issue, Dr. Kennedy, I am sure, will be willing and anxious to address himself to that tomorrow morning.

Mr. GARRY BROWN. Mr. Chairman, I don't think that Dr. Kennedy really wants to address it in that direction. I think he is looking at it from the standpoint of what is his analysis and determination from a domestic standpoint.

The question is whether all drugs banned in this country are banned automatically for use elsewhere.

Ms. PETERSON. Look at our chart here. We only have two areas where they are banned.

I think actually that you will be able to discuss that with Mr. Kennedy.

Mr. GARRY BROWN. But I think FDA is the one that does have greater authority to ban exports than other agencies.

Ms. PETERSON. You will see that on our attachment B—that is, for post-1938 drugs.

Mr. ROSENTHAL. Mr. Corcoran?

Mr. CORCORAN. Thank you, Mr. Chairman.

When was the so-called working group formed?

Ms. PETERSON. Actually, a stimulation came originally from your committee. A letter came from your committee to the President.

Mr. CORCORAN. What was the date of that letter?

Mr. ROSENTHAL. February 8, 1978.

[The letter referred to can be found on p. 29.]

Mr. CORCORAN. How many meetings has the working group had?

Mr. COHEN. The task force, or working group, has met once to outline the scope of the study. From that point, it has been based principally on an information exchange by paper or through meetings with individual agencies.

Esther's staff—myself and Mr. Heiden—have put together the working papers.

Mr. CORCORAN. Am I mistaken in drawing the conclusion that you have, in effect, simply prepared for this hearing?

Ms. PETERSON. Yes; you are mistaken. In fact, we didn't know about these hearings when our work began.

I was hoping that the hearings could be delayed so that we would have a real policy to come up with and have you react to it.

On the other hand, just as with Ralph Nader's letter, all of these things have come after the fact.

Mr. CORCORAN. Are you suggesting that the problems we are talking about, whether to ban these exported products which are undesirable for consumption in the United States, is a new problem?

Ms. PETERSON. No; it isn't. But it has increased remarkably over the last few years.

Mr. CORCORAN. Maybe your awareness has increased remarkably over the recent past.

Ms. PETERSON. I think it has come with the increase in technology.

Mr. CORCORAN. I would suggest parenthetically that perhaps if you had been devoting your attention to this problem in the last 18 months, rather than the formation of a losing proposition like the Consumer Protection Agency, possibly we would be much further along.

Ms. PETERSON. Maybe in hindsight, or maybe one could have done both.

On the other hand, I would like to say that our concern with this is part of a large authority to make sure that consumer awareness is possible.

Mr. CORCORAN. I understand your concern for it, and I agree with your conclusion that "we have identified the state of the law and concluded that a uniform policy should be developed. Certainly the bandaid approach of pairing a law to regulate a specific product has proven insufficient."

Let's go back to your timetable. You got the letter in February, had one meeting in May, and you expect to have this new, coherent, comprehensive policy in September; is that correct?

Ms. PETERSON. I should have introduced the staff here, which is Mr. Cohen the counsel and Mr. Heiden who is the project director.

Mr. CORCORAN. And they are terrific.

Ms. PETERSON. There have been a lot of consultations on this issue. These people, plus some assistants, have been working full time on interviewing and talking and examining and researching the law and researching the difficulty. We already have our working areas that we are involved in.

I don't feel that we are ready to come out with those, because we have to get them all together.

I am a great believer in before going public with these things to get a consensus and to get the people who are concerned together to work out what policy we will come up with from the administration.

That is not easy. I wish we could have done it earlier.

Mr. CORCORAN. And it takes time.

Do you expect that between now and the beginning of the 96th Congress that you would be in a position, as Chair of the working group, to recommend to the President a coherent policy on this issue for delivery to the Congress?

Ms. PETERSON. I hope our timetable is such that we can do that in September, if we live up to our timetable.

Mr. CORCORAN. Good.

One other area I want to question a bit is the cooperation of the State Department in this whole matter up to now.

It is my understanding that the State Department, particular with respect to the Tris question, was asked by the Consumer Product Safety Commission, through the Commerce Department, to control exports of Tris and materials treated with Tris.

We have a communication signed by the Secretary of Commerce, Juanita Kreps, that the State Department said that it would not further the foreign policy objectives of this Government for us to control the export of Tris.

You have talked with the State Department. They have attended your one meeting. Are they cooperating, and what explanation have they given?

Ms. PETERSON. Let me say that they are cooperating. I think it would be very well for you to talk with the State Department when they testify on this issue.

Mr. CORCORAN. I intend to. They will be here on Thursday.

Ms. PETERSON. They will be here, and I think it is better for you to speak with them.

Mr. CORCORAN. But what have you found? They are the fly in the ointment at this point.

Ms. PETERSON. They are working with us, and I must not prejudge their final decision on these matters.

Mr. CORCORAN. But at this point, in other words, you are taking no position one way or another with respect to what they did regarding Tris?

Ms. PETERSON. At this moment, we are not; because we are in the formulative period of our decision.

Mr. CORCORAN. That doesn't sound like the woman I thought was going to head the new Consumer Protection Agency.

Ms. PETERSON. Then you never knew this woman, because this woman was never going to speak unless she knew what she was talking about.

And I did know what I was talking about on the consumer bill.

Mr. CORCORAN. Except that it didn't pass.

Ms. PETERSON. I know; that is your fault. [Laughter.]

Mr. CORCORAN. Perhaps it is not my fault; perhaps it is my success.

Ms. PETERSON. I am sorry; we all look at it differently.

Mr. CORCORAN. And perhaps, in view of the fact that it did not succeed and in view of the fact that no progress was made despite the extensive time and your meetings with the President, that now we are getting down to something of tangible, concrete difficulty.

Ms. PETERSON. Probably if we hadn't had all that problem, we would have done this much earlier.

Mr. CORCORAN. I doubt it.

Mr. GARRY BROWN. Would the gentleman yield?

Mr. CORCORAN. Certainly.

Mr. GARRY BROWN. I would just say that I could just as well view the position you took on the Consumer Protection Agency as the exception to the rule that you are always right. [Laughter.]

Ms. PETERSON. Thank you.

We could meet and discuss this some other time.

Mr. CORCORAN. It is the form of the thing that bothers me.

We have substantial problems which have been identified for many, many years and nothing has been done about them.

Ms. PETERSON. Let me say one final thing on this.

I think if we had not had to drag this out all these years and had established a legitimate place within the Government to take care of all these, it could have happened a lot faster. We would have been on our toes much quicker.

Mr. CORCORAN. Thank you.

Mr. ROSENTHAL. Thank you very much.

We do want to acknowledge that you have an extraordinarily important assignment ahead. We know you will proceed with due diligence and with the dedication that you are well known for.

[The attachments to Ms. Peterson's statement follow:]

32-427 O - 78 - 2

ATTACHMENT A

Food and Drug Administration

	(A)
	Biological Products — 42 USC 262
PRODUCTS OR FINANCING ARRANGEMENT	Biological Products 42 USC 262(a)
REGULATORY AUTHORITY FOR DOMESTIC USE	HEW Secretary licenses establishments which propagate or manufacture and prepare biological products 42 USC 262(a)
REGULATORY AUTHORITY FOR EXPORTS	No exportation of products which cannot be sold in U.S. 42 USC 262(a)
PENDING AMENDMENTS	None

	Consumer Product Safety Commission
	Federal Hazardous Substances Act 15 USC 1261
PRODUCTS OR FINANCING ARRANGEMENT	Substances which are (1) toxic, corrosive, an irritant, a strong sensitizer, flammable, combustible, or which generates pressure and which may cause substantial personal injury or illness, and (2) toys. 15 USC 1261
REGULATORY AUTHORITY FOR DOMESTIC USE	CPSC may ban hazardous substances, require labeling, and seek a court order to seize noncomplying products 15 USC 1262; 1265
REGULATORY AUTHORITY FOR EXPORTS	All products can be exported if it (1) Is in a package branded in accordance with the specifications of the foreign purchaser. (2) Is labeled in accordance with the laws of the foreign country. (3) Is labeled on the shipping package as intended for export. (4) Is so exported. 15 USC 1265(a)
PENDING AMENDMENTS	Before exporting any substance which is misbranded; banned, or for which a regulation has been proposed, the exporter must notify the CPSC 30 days (or less if CPSC approves) prior to export. CPSC notifies the foreign country of such exportation and the fact that such substance is considered misbranded, has been banned, or is the subject of a proposed regulation. CPSC also files a notice in the Federal Register. If CPSC determines that exportation of such substance presents an unreasonable risk of injury to persons in the U.S., penalties apply for exporting such substances. HR 12442, Sec. 7

	Food and Drug Administration
	Food, Drug & Cosmetic Act — 21 USC 321
PRODUCTS OR FINANCING ARRANGEMENT	Cosmetics
REGULATORY AUTHORITY FOR DOMESTIC USE	Secretary may establish standards of adulteration and misbranding 21 USC 361-362
REGULATORY AUTHORITY FOR EXPORTS	May be exported, (no permit required) if-- (1) Accords to specification of foreign purchasers (2) Is not in conflict with laws of foreign country (3) Is labeled for export (4) Is not offered for domestic sale 21 USC 381(d)
PENDING AMENDMENTS	None

	Food and Drug Administration
	Food, Drug and Cosmetic Act — 21 USC 321
PRODUCTS OR FINANCING ARRANGEMENT	New drugs 21 USC 321(p)
REGULATORY AUTHORITY FOR DOMESTIC USE	No introduction of new drugs in interstate commerce without approval by FDA. ("Interstate commerce" between any State or territory and any place outside thereof) 21 USC 355(a)
REGULATORY AUTHORITY FOR EXPORTS	No exportation for commercial use under any circumstance 21 USC 355(a) Exportation authorized for investigational use only if FDA receives, through the State Department a formal request from the foreign government. The request must specify that such government has adequate information about the drug and the proposed investigational use. 21 CFR 312.1
PENDING AMENDMENTS	New drugs not yet approved in U.S. may be exported if exporting firm applies to the HEW Secretary for an export permit. The Secretary shall issue the permi unless he finds (1) Drug does not accord to specifications of foreign purchaser (2) Drug is not labeled for export (3) The foreign government has not been informed of the legal status of the drug in the U.S. and it does not disapprove of importation of the drug (4) Export of the drug is contrary to the public health (presumably of the U.S. or the foreign country) HR 11611 and S. 2755 Sec. 134-135

	Food and Drug Administration
	Food, Drug & Costmetic ACt — 21 USC 321
PRODUCTS OR FINANCING ARRANGEMENT	Drugs approved for U.S. use
REGULATORY AUTHORITY FOR DOMESTIC USE	Drug must previously have been approved by FDA
REGULATORY AUTHORITY FOR EXPORTS	May be exported, (no permit required) if-- (1) Accords to specifications of foreign purchasers (2) Is not in conflict with laws of foreign country (3) Is labeled for export (4) Is not offered for domestic sale 21 USC 381(d)
PENDING AMENDMENTS	May be exported (no permit required) so long as drug meets manufacture and quality standards required for domestic products (outlined in subparts 3 and 4 of HR 11611 and S. 2755) HR 11611 and S. 2755 Sec. 134

	Food and Drug Administration
	Food, Drug and Cosmetic Act — 21 USC 321
PRODUCTS OR FINANCING ARRANGEMENT	Foods
REGULATORY AUTHORITY FOR DOMESTIC USE	Secretary may establish standards of identity, levels of adulteration, and standards of misbranding 21 USC 341-343
REGULATORY AUTHORITY FOR EXPORTS	May be exported, (no permit required) if-- (1) Accords to specifications of foreign purchasers (2) Is not in conflict with laws of foreign country (3) Is labeled for export (4) Is not offered for domestic sale 21 USC 381(d)
PENDING AMENDMENTS	None

	Food and Drug Administration
	Food, Drug & Cosmetic Act — 21 USC 321
PRODUCTS OR FINANCING ARRANGEMENT	Medical devices
REGULATORY AUTHORITY FOR DOMESTIC USE	Depending upon the type of device, the Secretary may (1) establish performance standards, (2) require premarket approval, (3) ban devices which present unreasonable deception or an unreasonable and substantive risk of illness or injury, and (4) require recall 21 USC 360d, 360e, 360f, 360h
REGULATORY AUTHORITY FOR EXPORTS	Generally, may be exported (no permit required) if (1) Accords to specifications of foreign purchasers (2) Is not in conflict with the laws of foreign country (3) Is labeled for export (4) Is not offered for sale in domestic commerce In addition to the above, devices which do not comply with performance standards, have not received premarket clearance, or have been banned cannot be exported unless the Secretary has determined (1) That exportation is not contrary to the public health and safety, and (2) That the foreign country approves 21 USC 381(d)(1) and (d)(2) Similar requirements for investigational devices (proposed 43 FR 20749 to 21 CFR 812.19(b))
PENDING AMENDMENTS	None

PRODUCTS OR FINANCING ARRANGEMENT	Food and Drug Administration Radiation Control for Health and Safety Act of 1968 42 USC 2636 Electronic products 42 USC 263c(2)
REGULATORY AUTHORITY FOR DOMESTIC USE	Secretary of HEW may establish performance standards to control emission of electronic product radiation and require notification for defects or non-compliance 42 USC 263f(a);263g
REGULATORY AUTHORITY FOR EXPORTS	Products for export need not conform to standards if- (1) Labeled for export (2) Product meets all applicable requirements of the foreign country 42 USC 263f(a)(3)
PENDING AMENDMENTS	None

	Consumer Product Safety Commission
	Consumer Product Safety Act — 15 USC 2051
PRODUCTS OR FINANCING ARRANGEMENT	Consumer products--articles used in and around the residence, school, or in recreation for the personal use, consumption, or enjoyment of a consumer except tobacco, motor vehicles, pesticides, boats, ammunition, aircraft, foods, drugs, cosmetics, or medical devices. 15 USC 2052(a)(1)
REGULATORY AUTHORITY FOR DOMESTIC USE	CPSC can (1) set mandatory federal standards for products which pose an unreasonable risk of injury; (2) ban products which pose such risk and no standard can adequately protect the public, (3) seek a court order to seize products which contain an imminent hazard; (4) order pre-market notice of new products; (5) mandate labeling requirements; and (6) order recall. 15 USC 2056; 2057; 2061; 2062; 2063; and 2064
REGULATORY AUTHORITY FOR EXPORTS	Any product can be exported (except to U.S. installation outside the U.S.) if it (1) Is manufactured or sold for export purposes and not distributed in the U.S., and (2) Is labeled for export 15 USC 2067
PENDING AMENDMENTS	Before exporting any product which does not comply with an existing or proposed standard or ban, the exporter must notify the CPSC 30 days (or less if CPSC approves) prior to export. CPSC notifies foreign country of the exportation and the existing or proposed standard or ban. CPSC also files a statement in the Federal Register. If the CPSC determines that exportation of products presents an unreasonable risk of injury to U.S. consumers, than Consumer Product Safety Act applies to exports of that product. HR 12442, Sec. 5

	Consumer Product Safety Commission
	Flammable Fabrics Act — 15 USC 1191
PRODUCTS OR FINANCING ARRANGEMENT	Wearing apparel, fabric or related materials 15 USC 1191
REGULATORY AUTHORITY FOR DOMESTIC USE	CPSC can set standards; issue cease and desist orders, and seek court order to seize noncomplying products. 15 USC 1193; 1195
REGULATORY AUTHORITY FOR EXPORTS	Any product can be exported (except to U.S. installations outside the U.S.) if it is labeled for export. 15 USC 1202 CPSC interprets this provision so as to require the manufacturers of noncomplying goods to have the intention to export goods at the time of original manufacture. 16 CFR 1602.2
PENDING AMENDMENTS	Before exporting any product which does not comply with an existing or proposed standard, the exporter must notify the CPSC 30 days (or less if CPSC approves) prior to export. CPSC notifies foreign country of the exportation and the existing or proposed standard. CPSC also files a statement in the Federal Register. If CPSC determines that exportation of a product presents an unreasonable risk or injury to persons in the U.S., then the Flammable Fabrics Act applies to exports of that product. HR 12442, Sec. 8

	Department of Commerce Export Administration Act of 1969 50 USC App. 2401
PRODUCTS OR FINANCING ARRANGEMENT	Articles, materials, or supplies, including technical data or any other information. (Agricultural commodities included with the approval of the Secretary of Agriculture). 50 USC App 2403
REGULATORY AUTHORITY FOR DOMESTIC USE	None
REGULATORY AUTHORITY FOR EXPORTS	Department of Commerce can limit exports to the extent necessary to-- (1) Protect the domestic economy from the excessive drain of scarce materials and to reduce the serious inflationary impact of foreign demand. (2) Further significantly the foreign policy of the U.S. and to fulfill its international responsibilities (3) Exercise the necessary vigilance over exports from the standpoint of their significance to the national security of the U.S. 50 USC App 2402
PENDING AMENDMENTS	None

	Drug Enforcement Administration Controlled Substances Import and Export 21 USC 881
PRODUCTS OR FINANCING ARRANGEMENT	Narcotics and Dangerous Drugs
REGULATORY AUTHORITY FOR DOMESTIC USE	Controls are provided for the transshipment of controlled substances through the United States to other countries and for their in transit shipment within the U.S. for immediate export, and for the possession of controlled substances on board any vessel, aircraft or other vehicle arriv-in or departing from the United States.
REGULATORY AUTHORITY FOR EXPORTS	Regulates the importation and exportation of all controlled substances - narcotics, marijuana, depressants, stimulants and other dangerous drugs. No controlled substance can be exported except in compliance with specified procedures which vary according to the schedule of the substance. Registration of importers and exporters of substances classified in schedule I or II would be based on the Attorney General's determination that this would be consistent with the public interest and certain treaty obligations.
PENDING AMENDMENTS	None

PRODUCTS OR FINANCING ARRANGEMENT	Environmental Protection Agency Federal Insecticide, Fungicide, and Rodenticide Act — 7 USC 136 Substance or mixture of substances intended for preventing, destroying, repelling, or mitigating any pest, or for use as a plant regulator, defoliant or desiccant. 7 USC 136
REGULATORY AUTHORITY FOR DOMESTIC USE	Registration of pesticides with a finding by EPA of no "unreasonable adverse effect on the environment" required before registration; EPA registration of pesticide producers; EPA can issue "stop sale, use, or removal" orders and seek court orders for seizure of non-complying pesticides. 7 USC 136a; 136e;176k
REGULATORY AUTHORITY FOR EXPORTS	Pesticides to be exported are not subject to regulation when intended solely for export and prepared or packed according to specifications or directions of the foreign purchaser. EPA notifies State Department whenever a registra- is cancelled or suspended. State Department notifies foreign governments and appropriate international agencies. EPA, in cooperation with State and other appropriate federal agencies are to participate and cooperate in international efforts to develop improved pesticide research and regulation. 7 USC 1360
PENDING AMENDMENTS	Pesticides which are not registered for U.S. use can be exported if prominently labeled as follows: "Not registered for use in the United States of America" S. 1678, Sec. 17 Pesticides which are not registered for U.S. use can be exported if foreign purchaser has signed a statement acknowledging that he understands that the pesticide cannot be sold in U.S. and a copy of the statement shall be transmitted to the appropriate official of the foreign government. HR 8681; Sec 18

	Environmental Protection Agency Toxic Substances Control Act 15 USC2601
PRODUCTS OR FINANCING ARRANGEMENT	Chemical substances or mixtures except pesticides, tobacco, nuclear materials, firearms, etc. 15 USC 2602
REGULATORY AUTHORITY FOR DOMESTIC USE	EPA may require testing, impose pre-market notice requirements, require labeling, limit or prohibit sale if tests show a reasonable basis to conclude an unreasonable risk of injury to health or the environment, or obtain a court order to seize a substance or mixture posing an imminent hazard 15 USC 2603-2606
REGULATORY AUTHORITY FOR EXPORTS	Statute does not apply if substance, mixture or article is manufactured for export and is labeled as such except as follows: 1. If EPA finds the substance, mixture or article will present "an unreasonable risk of injury to health within the United States or to the environment of the United States", it may prohibit export. Administrator may order testing to make such a determination 2. If a person intends to export a substance which has been subject to a regulatory action, such person shall notify EPA and EPA shall furnish foreign government notice of the rule, order, action, or relief. 15 U.S.C. 2611
PENDING AMENDMENTS	NONE

ATTACHMENT B

SAFETY STATUTES AND AMENDMENTS CONTAINING EXPORT REQUIREMENTS,

BY NATURE OF REQUIREMENT

Exports Allowed	Export Notification	Export Approval	Discretionary Banning Authority	Ban of All Exports
Foods (FDCA)	Pesticides and Fungicides (FIFRA)	Medical Devices (FDCA)	Medical Devices (FDCA)	New, Unapproved U.S. Drugs (FDCA)
Approved U.S. Drugs (FDCA)	Toxic Substances (TSCA)	Investigational Drugs (FDCA)	Toxic Substances (TSCA)	Biological Products (FDA)
Electronic Products (RCHSA)	Narcotics and Dangerous Drugs (CSA)	Narcotics and Dangerous Drugs (CSA)	Proposed Drug Amendments (FDCA)	
Cosmetics (FDCA)	Proposed FIFRA Amendments	Proposed Drug Amendments (FDCA)	Proposed FHSA Amendments	
General (Export Administration Act)	Proposed HSA Amendments		Proposed CPSA Amendments	
Consumer Products (CPSA)	Proposed FFA Amendments		Proposed FFA Amendments	
Flammable Fabrics (FFA)	Proposed CPSA Amendments			
Hazardous Substances (FHSA)				

[The subcommittee letter to the President regarding export of Tris-treated children's sleepwear and White House responses follow:]

February 8, 1978

The President
The White House
Washington, D. C. 20500

Dear Mr. President:

In recent months, there has been considerable controversy surrounding the Consumer Product Safety Commission's decision to ban the chemical flame retardant - Tris. One aspect of the problem, which has been particularly troublesome, has been the inability of the Consumer Product Safety Commission to stop the export of Tris-treated children's sleepwear. It appears that the Commission has determined that it does not have the statutory authority to prevent the export of a product which it has found to cause cancer in children. When CPSC Chairman Byington attempted to enlist the aid of the Department of Commerce, he was told by the Secretary that since the Export Administration Act does not specifically authorize the Department to stop the export of items banned in this country, the State Department would have to determine whether or not such exports significantly affected the foreign policy objectives of the United States. The Commerce Department was informed by the State Department that it did not.

The Commerce, Consumer and Monetary Affairs Subcommittee of which we are members has been conducting a study of the problem of the export of banned substances to determine whether items banned by other government agencies in addition to the CPSC were being routinely exported. In response to a letter from the subcommittee, Secretary Kreps indicated that the Commerce Department was unable to act without direct policy guidance from the Department of State regarding the relationship between the export of banned substances and U.S. foreign policy.

We are writing to ask your help in addressing this serious problem. Tomorrow the CPSC may vote to affirm its position that it cannot prevent the export of Tris-treated sleepwear, paving the way for the export of garments that will cause cancer in the foreign children who wear them. It is inconceivable to us that the United States could condone such action in

this case and in other cases where the export of an item banned here would result in serious harm to the users abroad. We would be happy to work with the Administration to develop legislation which would define U.S. policy regarding the export of banned items. This situation as it current exists is unacceptable. Neither the agency which bans an item nor the Department of Commerce have the ability to stop the export of those products whose export cannot be justified on any reasonable grounds.

The subcommittee will be holding hearings this spring with the various agencies involved in this problem. We hope that the State Department can be convinced of the foreign policy merits of an export policy which takes into consideration the harmful nature of what is being sent abroad by this country. In the meantime, however, large quantities of Tris-treated sleepwear will begin leaving the United States soon unless its manufacturers know that such action will not be allowed in the future.

We urgently request that all efforts be made to identify potential exporters and recipient countries and that all means be exhausted to discourage those who would exploit foreign markets at the expense of innocent children. We strongly believe that Tris should not be exported. We need your help to stop it.

Sincerely,

Benjamin S. Rosenthal
Chairman

Henry A. Waxman

THE WHITE HOUSE

WASHINGTON

February 17, 1978

Dear Congressman Rosenthal:

The President has asked me to acknowledge his receipt of your letter of February 8 regarding continued export of tris-treated children's sleepwear. The President appreciates your comments and has the matter under consideration.

Sincerely,

Frank Moore

Frank Moore
Assistant to the President
for Congressional Liaison

The Honorable Benjamin Rosenthal
U.S. House of Representatives
Washington, D.C. 20515

THE WHITE HOUSE

WASHINGTON

May 26, 1978

Dear Congressman Rosenthal:

This is in further reply to your letter of February 8, 1978, regarding your concern surrounding the controversy with respect to the Consumer Product Safety Commission's decision to ban the chemical flame retardant Tris.

We agree that a careful survey of agency responsibilities with respect to the export of banned substances subject to regulation by federal agencies is necessary and useful. Therefore, we have convened an ad hoc interagency working group on this subject. This will be a step in developing a clear understanding of what federal agency policies are in this area and how the application of existing statutes governing exports of banned items are meeting present needs.

We appreciate your concern and your efforts to protect consumers.

Sincerely,

Esther Peterson
Special Assistant to the President
for Consumer Affairs

The Honorable Benjamin S. Rosenthal
U. S. House of Representatives
Washington, D.C. 20515

Mr. ROSENTHAL. Our next witness is Mr. Jacob Scherr, representing the Natural Resources Defense Council.

I notice that you have a 34-page statement, Without objection, we shall include your statement in the record; and perhaps you can give a synopsis of your statement.

STATEMENT OF S. JACOB SCHERR, ATTORNEY, NATURAL RESOURCES DEFENSE COUNCIL; ACCOMPANIED BY FRANCINE SCHULBERG, LAW STUDENT, HARVARD LAW SCHOOL

Mr. SCHERR. That was my intention. Thank you, Mr. Chairman.

I am Jacob Scherr. I am an attorney with the Natural Resources Defense Council. NRDC is a public-interest environmental organization with a membership of over 38,000 persons in the United States and in 21 foreign countries. We have been actively concerned about the protection of the international environment for about 5 years. I am a member of the staff of the NRDC international project. One of the objectives of this project is to monitor and participate in the development of U.S. Government decisions which have an effect upon the global environment. I have been particularly concerned about the ecological problems associated with the transfer of technology to developing nations through U.S. foreign aid and trade. Last May, I served as a member of the U.S. delegation to the sixth session of the Governing Council of the United Nations Environment Program—UNEP—in Nairobi, Kenya. Through my work I have become familiar with the environmental attitudes and policies of developing country governments.

I appreciate this opportunity to discuss, on behalf of NRDC, the policy of the United States with regard to exports of regulated products. It is our view that existing legislation creates, for the most part, an unjustifiable double standard on exports. Most products considered too dangerous or too little studied for use at home are, nonetheless, allowed to be freely sold abroad. The failure of the U.S. Government to recognize its responsibility for the control of potentially dangerous exported goods has led to significant damage to health and the environment, both here and overseas, and has injured our Nation's image in the international community.

We want to stress at the outset that we do not advocate prohibition of the export of all products that are banned for domestic use, nor do we propose to force U.S. environmental and health standards on other countries. We recognize that each nation, as a sovereign, has the primary duty to protect the health and safety of its people. We realize that there may be products that would not be appropriate for use in the United States but could provide overriding benefits to other countries with different problems and priorities.

Instead, the obligation of the United States as an exporter is to provide to the governments of the importing countries an opportunity to make their own informed judgments as to the risks and benefits involved with the purchase and use of products which are banned or restricted in the United States. The need for notification, full information, and technical assistance is particularly acute in developing countries, many of which lack adequate administrative and tech-

nical capabilities. Through cooperation with importing countries and minimal regulation, the United States can mitigate the hazards posed by exports of banned or restricted products.

The sales abroad of products not permitted for use at home has become a matter of international concern over the last few years as a result of incidents of widespread poisoning and severe environmental harm. There is a sense of outrage on the part of many poor countries whose citizens are the most vulnerable to exports of hazardous drugs, pesticides, and food products. At the 1977 meeting of the UNEP Governing Council, Dr. Kiano, the Kenyan Minister for Water Development, warned that developing countries will no longer tolerate being used as dumping grounds for products that have not been adequately tested. And that their people should not be used as "guinea pigs" for determining the safety of chemicals. He urged that "unless a product has been fully tested and certified and widely used in the countries of origin, it should not be used for export."

The views of Dr. Kiano were incorporated in a decision passed by the 58-nation Governing Council. This decision acknowledged that there "have been unethical practices concerning the distribution of chemicals, drugs, cosmetics, and food unfit for human consumption and that there is a need for harmonious cooperation between exporting and importing countries." The Governing Council urged:

> Governments should take steps to insure that potentially harmful chemicals, in whatever form or commodity, which are unacceptable for domestic purposes in the exporting country, should not be permitted to be exported without the knowledge and consent of appropriate authorities in the importing countries.

The control of toxic chemicals clearly is no longer a problem only for industrialized nations. Production, distribution, and consumption of chemical products is increasing worldwide. It is estimated that some 30,000 different chemicals are produced commercially and are utilized as ingredients in probably more than a million products. Several hundred new chemicals are introduced into the market each year. As is true of many advanced technologies, the use of chemicals has spread throughout the developing world much faster than the capability to assure their safe use. Some developing countries have enacted virtually no legislation to govern the importation, domestic use, and disposal of potentially toxic chemicals. Few maintain any facilities for monitoring the effects of the products on the health or the environment. Even where decent laws are on the books, many governments lack the technical and administrative capacity to implement them.

By permitting the uncontrolled export of hazardous chemical products, the United States and other producing nations demonstrate a lack of sensitivity to the challenges faced by health and environmental officials in developing countries.

Of all the hazardous chemical exports, pesticides perhaps have the greatest potential for widespread injury. According to the World Health Organization, pesticide poisoning of farmworkers has become a major health problem in many poor countries. It is the rural poor in these nations who are the most likely victims, because of their inexperience in handling modern chemicals in the absence of instructions and safety warnings in local and understandable language. The risks of pesticide use are further compounded by the lack of expertise on the part of officials of importing countries who must rely

on pesticide salesmen more interested in promoting their products than in sharing information on known dangers.

The extent of human suffering and environmental harm resulting from trade in banned or restricted pesticides cannot be fully documented. Most incidents do not receive any international attention. Only a few major catastrophes have been reported. One involved the pesticide Leptophos, which was never registered by the Environmental Protection Agency for domestic use. In 1975 alone, Velsicol, a Texas-based corporation, exported over 3 million pounds of Leptophos to 30 countries. Over half of that was shipped to Egypt, a country at that time with no procedures for pesticide regulation or tolerance setting.

In December 1976, the Washington Post reported that Leptophos use in Egypt resulted in the death of a number of farmers and illness in rural communities. In addition, over 1,000 water buffalos died from Leptophos poisoning. Egypt stopped its purchases of the pesticide in 1976, but despite the accumulation of data on Leptophos' severe neurotoxicity, Velsicol continued to market the product abroad for use on grain and vegetable crops, while proclaiming the pesticide's safety.

The hazards posed by the production and sale of products prohibited for domestic use is not limited to harm in the importing nation. It can have a direct effect on U.S. public health and the environment. In the Texas plant that manufactured Leptophos, many of the workers became severely ill as a result of exposure to the pesticide. One worker described his condition as: "My spine is deteriorating; it is dissolving." A Senate subcommittee revealed that since 1972 American imports of a number of vegetable products from Mexico contained residues of the highly toxic pesticide.

U.S. drug sales abroad illustrate another element of the hazardous export problem. Under current law, new drugs not licensed for use in the United States cannot be exported. However, the law exempts approved drugs sold abroad from the limitations placed upon their domestic distribution.

Thus, prescription drugs can be sold over the counter; adulterated, contaminated, and misbranded drugs can be exported; and there is no effort by the United States to curb misleading advertising or deceptive marketing practices by U.S. companies selling to developing countries.

It is not uncommon for U.S. drug companies to provide foreign customers with different information than domestic purchasers. One example involved Winstrol, a synthetic male sex hormone manufactured by a subsidiary of Sterling Drug, which causes several known side effects, including the stunting of growth in children and baldness. The Food and Drug Administration has stated that these side effects are virtually irreversible. While Winstrol is drastically limited for domestic use, it is available in virtually every pharmacy in Brazil. A 2-page advertisement in a Brazilian medical journal pictured a healthy boy and recommended the drug to combat poor appetite, fatigue, and weight loss.

We have been unable to obtain trade statistics on the export of particular products which have been banned or restricted by U.S. agencies.

Since products manufactured for export only are generally exempt from reporting requirements of U.S. laws, U.S. regulatory agencies at best carry out limited monitoring of exports of unregistered or unlicensed products. Those records which are maintained are often regarded as trade secrets and, therefore, they are not disclosed. The Department of Commerce does compile records of all exports along with the country of destination, but these figures are grouped by categories from which it is virtually impossible to determine a figure for a particular product that is banned or unregistered in the United States.

We do have some data from EPA on pesticide exports, which suggests that the variety and volume of exports of unregistered or restricted pesticides are significant. An estimated 15 percent of the 588 million pounds of pesticides exported from the United States in 1975 were comprised of products never registered by EPA, or canceled or suspended by EPA. In that year, pesticides produced for export, whose use was banned or severely restricted in the United States, included aldrin, strobane, DDT, toxaphene, and endrin. There were also several pesticides exported in 1977 for which EPA registration never had been granted. In regard to some of these pesticides, EPA has no information even as to their ingredients.

We have reviewed in my written statement six U.S. product control statutes which are administered by the EPA, the CPSC, and the FDA. All of these statutes contain provisions concerning the export of products within their purview. Each takes a slightly different approach on exports of banned or unlicensed products but each in some way poses a double standard.

In total, they reflect the current attitude of the U.S. Government toward export of hazardous products, as that of caveat emptor—let the buyer beware. Yet we believe that this view is inconsistent with the commitment of the United States to the protection of human rights and well-being. Further, it can undermine efforts to protect the health and safety of members of the U.S. public and the quality of our own environment.

The sales abroad of banned or restricted chemical products was, again, a matter of extensive discussion at the UNEP Governing Council meeting in May of 1978. The Kenyan delegation which had first raised the issue at the 1977 session, was joined by representatives from Bangladesh, Ghana, Iran, Jamaica, Nigeria, Pakistan, and the Philippines in expressing concern about hazardous exports.

Also, a number of industrialized nations, including Belgium, Canada, the Federal Republic of Germany, Sweden, and the United States were in agreement that existing means for providing full information to chemical-purchasing nations were inadequate.

The Governing Council adopted another decision, which reaffirmed its decision of 1977 which I mentioned earlier. The Governing Council called upon governments of both exporting and importing countries to institute adequate monitoring and evaluative and protective measures in regard to international commerce and chemical products. The decision appealed to exporting countries to prevent the export of items which are restricted or not registered for domestic use until it has been ascertained that designated officials in the importing government have obtained information on environmental health tests and their results

and detailed instructions in mutually agreed languages for the safe use of these products, so as to permit these officials to make fully informed decisions on the import and utilization of the products. A corresponding appeal was directed to importing governments to improve their own capabilities to make such decisions.

What emerged from the UNEP discussions was a sense that both exporting and importing countries share a responsibility in regard to trade in potentially toxic chemicals.

It is also in our Nation's own immediate interest to more effectively monitor and control such hazardous exports. First, tighter regulation of the export of hazardous products would mitigate the direct health hazards posed to those Americans involved in the products' manufacture and distribution. The Leptophos tragedy is not unique. Another example involved Kepone, which in 1974 and 1975, 99 percent of the American production was exported. In 1975, the Life Science Products Co., which had a small chemical plant in Hopewell, Va., ceased its production of Kepone after 70 persons connected with the plant, including 10 wives and children of employees, became seriously ill from Kepone exposure. Kepone discharges from the plant were also responsible for the contamination of the James River and the Chesapeake Bay.

The Senate Subcommittee on Agricultural Research and General Legislation determined in 1976, after examining the Kepone incident, that plants manufacturing pesticides solely for export did not have to comply with the Federal Insecticide, Fungicide, and Rodenticide Act provision requiring the registration of establishments. Thus, under existing law, it appears to be perfectly legal to begin the large-scale manufacture and worldwide distribution of a pesticide without even notifying the Environmental Protection Agency. The manufacture of a banned pesticide for export may pose an additional risk to the health of the U.S. public as residues on imported foods.

I believe in addition to furthering our efforts to protect domestic health and the environment, the acceptance by the United States of an obligation to cooperate closely with environmental and health officials in countries importing U.S. products also serves our Nation's diplomatic and commercial interests. Incidents, such as those involving Leptophos, do damage to the reputation of U.S.-produced goods and increase resentment toward our Nation. As awareness of product dangers countinues to grow in developing countries, an enlightened U.S. policy on hazardous exports could provide a competitive advantage over other exporting countries.

We believe that the objectives of a U.S. policy on hazardous exports should be:

First, close monitoring of production and export of hazardous products.

Second, assurance that all available information concerning the risks and benefits associated with the prohibited or restricted product has been made available to the designated health or environmental official in the importing country prior to the export of the product.

Third, requirement that all exports of regulated products meet U.S. quality control and labeling standards.

Fourth, notification to the importing countries and international organizations of all appropriate U.S. regulations. We believe that

through the closer monitoring of trade, the U.S. Government can insure that other nations can receive an early warning of newly discovered hazards.

Fifth, provision of technical aid and training to governments of developing countries importing U.S. products.

Sixth, the authority to prohibit exports where products pose unreasonable risks to health and safety of the U.S. public or to the global commons.

In my written statement, I have set out in detail the elements of a program which we believe would implement these objectives.

We believe that these policy objectives can be achieved only through change in the legislative mandate of each of the regulatory agencies that administers a product control statute.

It is our view that the individual agencies should have the primary responsibility to administer the export controls, because they have the expertise in handling and regulating the particular products. The direct relationship between the U.S. agencies and their counterparts in other countries would also provide the most effective and efficient means of communication. We feel, however, that State Department involvement is critical in assisting the agencies to establish relationships with their foreign counterparts.

Insuring that importers know the nature of their purchases will not, by itself, end the abuse of chemical products in poor countries. Only the development of effective regulatory systems in third world countries can do that. However, the U.S. policy we have suggested would at least reduce the chances that the most dangerous chemicals would not be imported or used by people totally unaware of the risks involved.

The proposed program would not significantly burden either the exporters or the agencies. Yet these minor requirements would provide an important measure of protection for the health of the public and the environment, both home and abroad.

Thank you.

Mr. ROSENTHAL. Congressman Drinan?

Mr. DRINAN. Thank you, Mr. Chairman.

I want to commend you, sir, upon this very fine statement.

On page 19 and following, you speak about the bill concerning FIFRA which presumably will be passed. Would that correct much of the abuse in the area of the pesticides?

Mr. SCHERR. I do believe that it would clear up most of the problem. I feel that the provisions might have been better had it required a direct certification from the environmental officials in the importing government that they had examined the risks and benefits involved in the use of a banned pesticide.

Mr. DRINAN. It is not certain that we cannot do that. But now it requires that they sign a statement acknowledging that they know they are buying a product which cannot be sold.

Mr. SCHERR. The proposed amendment would require only the actual purchaser to sign such a statement.

In the proposed policy we recommended at the end of our statement we would actually have such a certification signed not by the purchaser but by an official of the importing government.

Mr. DRINAN. Would you talk about the bill on which Congressman Paul Rogers' subcommittee had hearings lately? This concerns the drugs and the pharmaceuticals.

Mr. SCHERR. We recognize that there might be certain circumstances in which a particular drug would not be approved in the United States but for which another country might have a serious need. Therefore, we would not oppose an end to the current prohibition on exports of all unapproved drugs. Our concern, however, is that the removal of a prohibition on exports of unapproved drugs could lead to abuse, unless very strenuous safeguards were applied to insure that health officials in the importing government have an opportunity to examine all the available data and to make up their minds as to the risks and benefits associated with the proposed export.

Mr. DRINAN. In most, or in many, cases there would be no officials in the receiving country who would be qualified to make that type of judgment. I suppose it comes back to this.

It is my understanding that in Paul Rogers' subcommittee, only the pharmaceutical companies supported the particular legislation that was proposed.

Would you feel that the United States has the power and should exercise that power to force the American pharmaceutical companies to live up to standards when they sell abroad—standards that are, in fact, acceptable to the FDA or other agencies? Would that be a possible route?

Mr. SCHERR. I would agree with that in regard to the labeling of drugs and insuring that drugs are manufactured in accordance with good manufacturing practices. The most difficult problem is whether or not we might permit the manufacture and sale abroad of a drug in our own country which we don't approve for use here. I am aware of the concern of a lot of people that such exports should be totally banned. But it is our feeling that other countries have to make their own decisions, to some degree, on the risks and benefits. I believe the U.S. obligation is to insure that they have full information and perhaps even to go a little further to provide them with technical assistance in evaluating those risks and benefits.

Mr. DRINAN. That is not really the approach that Congress is taking on FIFRA though; is it?

Under the bill that is now in conference—and that presumably will become law—they have to stamp them—not register them for use. But they still, in fact, can sell them.

Mr. SCHERR. Yes.

Mr. DRINAN. On another point, is EPA as lax—after the GAO report—as they were before?

It sounds incredible that they should have failed to do all of these things.

Mr. SCHERR. I assume that Barbara Blum from the EPA will address this tomorrow. But it is my understanding that there hasn't been a significant change in their notification practices.

Mr. DRINAN. I commend you on a very comprehensive and very helpful statement.

Thank you.

Mr. ROSENTHAL. Mr. Corcoran?

Mr. CORCORAN. Thank you, Mr. Chairman.

I also want to echo the comments of my colleague, Congressman Drinan, regarding the quality of your testimony. I appreciate it very much.

As I understand it, your testimony recommends notice to foreign recipients of the hazard rather than a recommendation for banning of exports altogether. And in this way we would avoid the United States making the risk assessment judgment, except in cases of possible reimportation or global environmental hazard. Is that a correct description of your overall position?

Mr. SCHERR. Yes; but I would say that we are calling for more than just notification. We are proposing that data on all environmental tests on a particular chemical be provided to the importing government. And technical assistance should be given to other countries so that they can make fully informed decisions on imports.

Mr. CORCORAN. One of the other elements of your recommendations has to do with the possibility that perhaps the exporter ought to give notification to the receiving government, or to the government in which another company might be receiving this hazardous product. That is an added suggestion—at least to my knowledge of the subject—over and above what exists in the law today.

I find it an intriguing suggestion, but I would also want your opinion, having made that recommendation, as to whether or not it would also be very important for the State Department to give official communication to that receiving government.

Mr. SCHERR. I would agree with that. On the issue of notification, I see the State Department essentially acting as a conduit for information provided by the various regulatory agencies. The State Department does not have personnel on its staff with the necessary technical ability.

I think basically that the State Department should just provide a means for ensuring, for example, that the Consumer Product Safety Commission is in communication with its counterpart in the developing countries.

Mr. CORCORAN. Up to now, they have not been a conduit. In fact, they have been a stopping point.

Mr. SCHERR. The problem is that it appears that there is both a flood of imported goods going into other nations and a flood of messages going from the State Department to our various embassies. It seems like there has been a problem of sorting out what products are really dangerous and require immediate notification. So the job is not being done.

Mr. CORCORAN. Thank you.

Mr. ROSENTHAL. Thank you very much for a very useful and very important presentation.

Father Drinan?

Mr. DRINAN. I wonder, Mr. Scherr, if the World Health Organization, or some similar group, would be in a position to take this information and put it in a simplified form so that the Government, for example, of El Salvador and the nations of Central America could have some standard by which they know what they are doing. Has that been thought of?

Mr. SCHERR. International organizations, such as the World Health Organization or the United Nations environment program, do have

a role to play. But it appears that a lot of importing countries are looking to the exporting government directly for information. I am very concerned about the suggestion that we should solve this problem by giving some international organization the responsibility. I think it is kind of an elegant way of saying we are going to pass the buck. The record of the international organizations in this area has been that they have not been terribly effective in disseminating information on health hazards. I would prefer to see it being done directly by the exporting countries.

Mr. DRINAN. I would assume that certain highly developed nations have the same problem on the export of pharmaceuticals, nations such as Sweden, England, France, and maybe Italy.

What legislation has developed in that area, so that the multinationals there, or local corporations, are not exporting things that are banned in Sweden?

Mr. SCHERR. I am not familiar with that.

We are in the process of doing a study on toxic chemical laws in various other countries. One of the issues we will be looking at is the control of exports of banned products. But at the present time, I do not have information on the laws of other countries.

Mr. DRINAN. I would assume that Japan, too, is a major exporter too of pharmaceuticals.

Mr. SCHERR. I believe that the United Kingdom, Germany, and Switzerland are all major exporters of chemical products. I would not be surprised if their laws contained similar exemptions for exported products.

Mr. DRINAN. So we are not the only offender.

Mr. SCHERR. By no means.

Mr. DRINAN. I don't know whether that makes our behavior better or worse.

Thank you very much.

Mr. ROSENTHAL. Thank you, Mr. Scherr.

[Mr. Scherr's prepared statement follows:]

STATEMENT OF S. JACOB SCHERR, ATTORNEY, NATURAL RESOURCES DEFENSE COUNCIL

I am S. Jacob Scherr, an attorney with the Natural Resources Defense Council ("NRDC"). NRDC is a public-interest environmental organization, with a membership of over 38,000 persons in the United States and in twenty-one foreign countries.[1/] NRDC has for five years been actively concerned about the protection of the international environment. I am a member of the staff of the NRDC International Project, one of the objectives of which is to monitor and participate in the development of U.S. Government decisions that have an effect upon the global environment. I have been particularly concerned with the ecological problems associated with the transfer of technology to developing nations through U.S. foreign aid and trade. Last May, I served as a member of the United States delegation to the sixth session of the Governing Council of the United Nations Environment Program ("UNEP") in Nairobi, Kenya. Through my work, I have become familiar with the environmental attitudes and policies of developing country governments.

1/ NRDC's principal place of business is 122 E. 42nd Street, New York, New York 10017, with additional offices in Washington, D.C. and Palo Alto, California

I appreciate the opportunity to discuss, on behalf of NRDC, the policy of the U.S. regarding exports of regulated products. It is our view that existing legislation creates an unjustifiable double standard. Most products considered too dangerous or too little studied for use at home are, nonetheless, allowed to be freely sold abroad. The failure of the U.S. Government to recognize its responsibility for the control of potentially dangerous exported goods has led to significant damage to health and the environment both here and overseas and has injured our nation's image in the international community.

We want to stress at the outset that we do not advocate a prohibition of the export of all products that are banned for domestic use, nor do we propose to force U.S. environmental and health standards on other countries. We recognize that each nation, as sovereign, has the primary duty to protect the health and safety of its people and we realize that there may be products that would not be appropriate for use in the U.S., but could provide overriding benefits to other countries with different problems and priorities.

Instead, we believe the obligation of the United States, as an exporter, is to provide to the governments of the importing countries an opportunity to make their own informed judgments as to the risks and benefits involved with the purchase and use of products which are banned or restricted in the U.S. The

need for notification, full information, and technical assistance is particularly acute in developing countries many of which lack adequate administrative and technical capabilities. Through cooperation with importing countries and minimal regulation, the U.S. can mitigate the hazards posed by exports of banned or restricted products.

I. The Nature of the Problem

The sales abroad of products not permitted at home have become a matter of international concern over the last few years as a result of incidents of widespread poisoning and severe environmental harm. There is a sense of outrage on the part of many poor countries whose citizens are the most vulnerable to exports of hazardous drugs, pesticides, and food products. At the 1977 meeting of the UNEP Governing Council, Dr. J. C. Kiano, the Kenyan Minister for Water Development, warned that developing nations will no longer tolerate being used as "dumping grounds for products that had not been adequately tested" and that their peoples should not be used as "guinea pigs" for determining the safety of chemicals. He urged that "Unless a product has been fully tested and certified, and widely used in the countries of origin, it should not be used for export."[2/]

2/ The Standard, Nairobi, Kenya, May 11, 1977 at 3.

The views of Dr. Kiano were incorporated in a decision passed by the 58-nation Governing Council. Decision 85(V) adopted on 25 May 1977 and entitled Human and Environmental Health, acknowledged that "there have been unethical practices concerning the distribution of chemicals, drugs, cosmetics, and food unfit for human consumption" and that "there is a need for harmonious cooperation . . . between exporting and importing countries." The Governing Council urged:

> "Governments to take steps to ensure that potentially harmful chemicals, in whatever form or commodity, which are unacceptable for domestic purposes in the exporting country, are not permitted to be exported without the knowledge and consent of appropriate authorities in the importing countries." 3/

The control of toxic chemicals clearly is no longer a problem only for industrialized nations. The production, distribution, and consumption of chemical products is increasing worldwide. It is estimated that some 30,000 different chemicals are produced commercially and are utilized as ingredients in probably more than a million products. Several hundred new chemicals are introduced into the market each year. 4/ As is true of many advanced technologies, the use of chemicals has

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3/ A copy of the full text of the decision is included in an appendix to this testimony.

4/ UNEP, "The State of the World Environment 1978," at 2 (May 1978).

spread throughout the developing world much faster than the capability to assure their safe use. Some developing countries have enacted virtually no legislation to govern the importation, domestic use and disposal of potentially toxic chemicals, and few maintain any facilities for monitoring the effects of the products on health or the environment. Even where decent laws are on the books, many governments lack the technical and administrative capacity to implement them. The communications between officials of the ministeries who manage importation and distribution and officials of health ministeries, who are at least likely to appreciate the significance of potential hazards may be minimal. By permitting the uncontrolled export of hazardous chemical products, the U.S. and other producing nations demonstrate a lack of sensitivity to the challenges faced by health and environmental officials in developing countries.

Of all the hazardous chemical exports, pesticides perhaps have the greatest potential for widespread injury. According to the World Health Organization, pesticide poisonings of farm workers have become a major health problem in many nations.[5/] It is the rural poor in developing countries who are the most

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5/ World Health Organization, "Occupational Health Programme," Report by the Director General (April 9, 1978).

likely victims because of their inexperience in handling modern chemicals and the absence of instructions and safety warnings in local and understandable language. The risks of pesticide use are further compounded by the lack of expertise on the part of officials of importing countries who rely on pesticide salesmen more interested in promoting their products than in sharing information on known dangers.[6/]

The extent of human suffering and environmental harm resulting from trade in banned or restricted pesticides cannot be fully documented. Most incidents do not receive any international attention. Only a few major catastrophes have been reported. One involved the pesticide Leptophos which was never registered by the Environmental Protection Agency ("EPA") for domestic use. In 1975 alone, Velsicol, a Texas-based corporation, exported 3,092,842 pounds of Leptophos to thirty countries. Over half of that was shipped to Egypt, a country with no procedures for pesticide regulation or tolerance setting.[7/] In December 1976, the Washington Post reported that Leptophos use in Egypt resulted in the death of a number of farmers and

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6/ E. Eckholm, The Picture of Health: Environmental Sources of Disease 166 (1977)

7/ Response of Jim Kaminsky, General Accounting Office to a letter of Representative George E. Brown, Jr. (June 21, 1977)

illness in rural communities.[8/] Symptoms included convulsions, speech impairments and loss of bladder control. In addition, over 1,000 water buffalo died from Leptophos poisoning. Egypt stopped its purchases of the pesticide in 1976. But despite the accumulation of data on Leptophos's severe neurotoxicity, Velsicol continued to market the product abroad for use on grain and vegetable crops while proclaiming the pesticide's safety.[9/]

The hazards posed by the production and sale of products prohibited for domestic use is not limited to harm in the importing nation, but can have a direct effect on U.S. public health and environment. In the Texas plant that manufactured Leptophos, many of the workers became severely ill as a result of exposure to the pesticide. Symptoms included partial paralysis, blurred vision, dizziness and for one worker spastic paralysis of the lower extremities. One worker described his condition: "My spine is deteriorating. Its dissolving."[10/] And a Senate Subcommittee revealed that since 1972 American imports of

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8/ Washington Post, December 10, 1976, at 1.

9/ Eckholm, supra note 6 at 166

10/ Washington Post, December.1, 1976, at 1

tomatoes, beans, peppers, cucumbers, peas, cantaloupe, eggplants and squash from Mexico contained residues of the highly toxic pesticide.[11/]

Other reported international incidents involve organic mercury fungicides and the herbicide 2,4,5-T. In 1972, Iraq imported 8,000 tons of wheat and barley coated with an organic mercury fungicide, whose use had been banned in the U.S. and other developed countries. At least 400 Iraquis died and up to another 5,000 were admitted to hospitals after consuming the grain.[12/] U.S. companies continued to sell 2,4,5-T in South America even after its EPA registration for most domestic uses was cancelled in 1970. In Columbia, a rash of miscarriages and deformed babies during the early 1970's has been possibly linked to exposure to 2,4,5-T, a pesticide similar in make-up to Agent Orange, the defoliant used by the U.S. military in Vietnam and later found to cause birth defects and death.[13/]

U.S. drug sales abroad illustrate another element of the hazardous export problem. Under current law, new drugs not licensed for use in the U.S. cannot be exported. However, the

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11/ San Francisco Banner, June 24, 1977. The residue tolerance for Leptophos was finally revoked by EPA in November 1976.

12/ T. Farvar, "The Interaction of Ecological Social Systems," Outer Limits and Human Needs 70 (1976).

13/ Weir, "For Export Only: Poisons, Dangerous Drugs," Rolling Stone, February 10, 1977 at 31.

law exempts approved drugs sold abroad from the limitations placed on their domestic distribution. Thus, prescription drugs can be sold over-the-counter; adulterated, contaminated and misbranded drugs can be exported; and there is no effort by the U.S. to curb misleading advertising, marketing and deceptive practices by U.S. companies selling to developing countries.

It is not uncommon for U.S. drug companies to provide foreign customers with different information than domestic purchasers.[14/] Winstrol, a synthetic male sex hormone manufactured by a subsidiary of Sterling Drug Inc, causes several known side-effects including the stunting of growth in children and baldness, deepening of voices and clitoral enlargements in girls. The Food and Drug Administration ("FDA") has stated that these side effects are "virtually irreversible." While Winstrol is drastically limited for domestic use, the Brazilian magazine Opiniao reported that it is available in virtually every pharmacy in Brazil. And a two page advertisement in a Brazilian medical

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14/ See Hearings before the Subcommittee on Monopoly of the Senate Small Business Committee, May 26 and 27, 1976.

Naturally, United States law can not affect unscrupulous practices by foreign distributors of U.S. manufactured products. But to the extent that inadequate or inaccurate information is provided to purchasers or importing governments by American companies, it is our responsibility to regulate such activities.

journal pictured a healthy boy and recommended the drug to combat poor appetite, fatigue and weight loss. The same company also exports the painkiller dipyrone known to cause a fatal blood disease. The American Medical Association warns that dipyrone be used only as "a last resort." But marketed in the Dominican Republic as Novaldin, dipyrone is advertised with pictures of a contented child smiling about the "agreeable flavor" of the Novaldin drops.15/

Chloramphenical, an antibiotic marketed in Latin America by several American firms, is active against many different infections, takes effect quickly and is relatively inexpensive to produce. However, chloramphenical use has serious side-effects causing, in some patients, aplastic anemia with a mortality rate of between 30 and 60 percent. The FDA has required that chloramphenical be recommended only for life-threatening infections such as typhoid fever, Rocky Mountain spotted fever and hemophilus influenzal meningitis. In the United States, promotional materials have to carry a warning that the drug must not be used for trivial infections. In Latin America, however, the same drug was promoted for tonsillitis, bronchitis, whooping cough, soft tissue abscesses and other "life-threatening"

15/ Weir, supra note 13 at 31

diseases. It was even pushed for the treatment of influenza and the common cold.[16/]

Lomotil, produced by the American-based G.D. Searle Co. is an effective drug for relieving the symptoms of diarrhea associated with mild stomach disorders. However, in developing countries where diarrhea is generally associated with faecally transmitted, often water borne infections, Lomotil use only masks indications of a more serious potentially fatal disease.[17/] With children, Lomotil use is especially hazardous because the difference between the recommended dose and fatal dose is very small. In the United States Lomotil can only be purchased by prescription and is not recommended for use by children. But in many developing countries Lomotil is sold over the counter and is promoted as suitable for serious cases of diarrhea. In fact, in the Sudan, Lomotil was sold in packages proclaiming the

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16/ Hearings on the Drug Regulation Reform Act (H.R. 12611), Before the Subcommittee on Health and the Environment of the House Committee on Interstate and Foreign Commerce, June 12, 1978 (Statement of Milton Silverman)

17/ The World Bank's Health Vector Policy Paper for 1975 reported that ". . .bacillary dysentery and amoebiasis, enteritis and other diarrheal diseases was the leading cause of death in Paraguay (1971) Guatemala (1970) and El Salvador (1971). . . In a case study on the Punjab, a death rate of 3,446 per 100,000 infants from acute diarrhoeal diseases were reported."

drug was "used by astronauts during Gemini and Apollo space flights" and recommending use by children even as young as 12 months.[18/]

Recently, much attention has been focused upon tris-treated baby clothes. Tris, used as a fire retardant in children's sleepwear was found to be carcinogenic and was subsequently banned for sale or distribution in the U.S. by the Consumer Product Safety Commission ("CPSC") on April 8, 1977.[19/] Many U.S. manufacturers of tris-treated sleepwear reacted to the CPSC action by exporting their inventories of such products to countries without tris bans, primarily third world nations. The CPSC finally banned the export of tris-treated products on June 14, 1978.[20/] However, the ban did not take effect until several million dollars' worth of the product found its way into foreign markets.[21/]

18/ M. Muller, "Lomotil A Case of Moral Incontinence" New Scientist, 31 March 1977, p. 786.

19/ 42 Fed. Reg. 18849 (1977)

20/ 43 Fed. Reg. 25711 (1978)
The CPSC took this action pursuant to the Federal Hazardous Substances Act. While this Act exempts all products manufactured for export from the requirements of the Act, CPSC claims it was within its power to ban the export of tris-treated sleepwear since the sleepwear had originally been manufactured for domestic sale.

21/ Washington Post, May 5, 1978 at C-1

We have been unable to obtain trade statistics on the export of particular products which have been banned or restricted by U.S. agencies. Since products manufactured for export only are generally exempt from reporting requirements of U.S. laws, U.S. regulatory agencies at best carry out limited monitoring of exports of unregistered or unlicensed products. Those records which are maintained are often regarded as trade secret and therefore not disclosed. The Department of Commerce does compile records of all exports, along with the country of destination, but these figures are grouped by categories from which it is impossible to determine a figure for a particular product that is banned or registered in the U.S.

We do have some basic data from EPA on pesticide exports, which suggest that the variety and volume of exports of unregistered or restricted pesticides are significant. An estimated 15% of the 588 million pounds of pesticides exported in 1975 were comprised of products never registered or cancelled or suspended by EPA. In that year, pesticides produced for export whose use was banned or severely restricted in the U.S. included aldrin, strobane, DDT, 2,4-D, toxaphene, heptachlor, lindane, 2,4,5-T and endrin.[22/]

22/ Kaminsky response, supra note 7.

The U.S. status of these pesticides is:

Aldrin: All registrations except three minor non-food uses cancelled because of suspected carcinogenicity and possible toxicological effects including birth defects, reproductive effects and danger posed to endangered species.

Among the pesticides exported in 1977 for which an EPA registration had never been granted were Chemviron, Orchex, Korvar, Finaven, Zeniofol, Reldan, Machete, Nemophos, Cyolane (Cylan), and Simetryn. In regard to some of these pesticides, EPA has no information even as to their ingredients.

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Strobane: All registrations voluntarily cancelled because of suspected carcinogenicity.

DDT: All registrations except four health related uses cancelled because of evidence of carcinogenicity and adverse environmental effects.

2,4-D: Referred to EPA's Office of Special Pesticide Review ("OSPR") because of conflicting analysis of carcinogenicity tests.

toxaphene: Undergoing review by OSPR to determine whether to cancel registration (known as Rebuttal Presumption Against Registration or RPAR process) triggered by evidence of oncogenicity, other chronic effects and reductions in non-target aquatic, avian and mammalian species.

heptachlor: Pursuant to a settlement plan, all uses except two minor non-food uses will be phased out.

lindane: undergoing RPAR process triggered by evidence of oncogenicity, fetotoxicity and reproductive effects and acute toxicity in aquatic and avian species. Final decision on RPAR due at end of this year.

2,4,5-T: all registrations for food uses and for uses in or near bodies of water cancelled. Remaining uses (primarily forest) undergoing RPAR process triggered by possible oncogenicity and teratogenic and fetotoxic effects due to dioxin contaminants.

II. Current Legislation Regarding Hazardous Exports

The six U.S. product control statutes contain provisions concerning the export of products within their purview. Each takes a slightly different approach on exports of banned or unlicensed products, but each in some way imposes a double standard. That is, one standard is used for those products manufactured for sale abroad and another standard is used for products manufactured for sale in the U.S.

Federal Insecticide, Fungicide and Rodenticide Act ("FIFRA")[23/]

FIFRA, as amended in 1972, is administered by the EPA. Under the Act, all pesticides sold or distributed in interstate commerce must be registered and must meet labelling, packaging and other standards. However under §17(a) "pesticides . . . intended solely for export to any foreign country and prepared or packed according to the specifications or directions of the purchaser of the foreign purchaser" are exempted from the other provisions of the Act except for Section 8. Section 8 permits

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continued from page 13
endrin: registration for use on tobacco cancelled. Undergoing RPAR process triggered by evidence of oncogenicity, teratogenicity, reductions in endangered species and reductions in non-target aquatic pests. Currently designated restricted (can only be applied under the direct supervision of an applicator determined to be competent in the handling of pesticides).

EPA, Suspended and Cancelled Pesticides, Revised May 1978; OSPR Status Report April 17, 1978; and personal conversations with EPA staff.

23/ 7 U.S.C. §§136-136y

the Administrator to require whatever record keeping he determines are necessary for effective enforcement of FIFRA.

Section 17(b) also states that "whenever a registration or a cancellation or suspension of the registration of a pesticide becomes effective, or ceases to be effective, the Administrator shall transmit through the State Department notification thereof to the governments of other countries and to appropriate international agencies."[24/]

The following criteria were established by EPA for determining which registration actions should be transmitted to foreign officials and international organizations:

> "The Agency will make available for transmittal to foreign governments notices of all registrations. . . . Foreign governments and appropriate international organizations expressing interest will be notified of any cancellation or suspension action which has become effective and which is determined to have national or international significance."[25/]

24/ The FIFRA amendment requiring notification was passed in 1972, yet EPA did not publish operating procedures until July 1, 1975.

Section 17(d) of FIFRA also requires the Administrator to participate and cooperate in any international efforts to develop improved pesticide research and regulations.

25/ Response of Jim Kaminsky, supra, note 7.

EPA's past efforts to notify foreign governments of registration changes were recently reviewed by the General Accounting Office ("GAO") and were found to be less than adequate.[26] The GAO surveyed EPA's and the Department of State's policies, practices, and relevant legislation; reviewed documents, records and reports on notification; and interviewed responsible officials at the two agencies and ten foreign countries.[27]

Since 1972, when the notification provision became effective, EPA has cancelled, suspended or significantly restricted use of fourteen pesticides, yet the records surveyed revealed that EPA requested the State Department to notify foreign nations about only five of the regulatory actions taken.

No attempt was made to inform foreign governments about regulatory actions on the following pesticides: chlordane, quaternary ammonium compounds, aramite, chloranil, safrole, heptachlor, kepone, OMPA, strobane.[28] EPA officials stated

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26/ Letter from Henry Eschwege, Director, Community and Economic Development Division GAO, to Douglas M. Castle, Administrator, EPA, (April 20, 1978).

27/ The ten nations were: Costa Rica, West Germany, Guatemala, Indonesia, Mexico, New Zealand, the Philippines, Sri Lanka, Surinam, and Thailand. The FIFRA amendment requiring notification was passed in 1972, yet EPA did not publish operating procedures until July 1, 1975.

28/ EPA (or its predecessor agency) had cancelled the registration of six other pesticides prior to the 1972 notification requirement: bithionol, endrin, lindane, polychlorinated biphenyls. No notices of these cancellations were transmitted.

that the reasons EPA decided against notification were either that the registrants initiated the cancellations or because all product uses were not cancelled.

However the GAO determined that the actions taken on the above listed chemicals:

> "have both national and international implications, and notifications should have been made. For example, registrations of chlordane and heptachlor were suspended and strobane was cancelled for most uses because of their suspected potential in causing tumors in animals. Chlordane and heptachlor were two of the most widely used pesticides in the world. The strobane action canceled 34 product registrations."

In the cases where the regulatory action was deemed significant, notification was sent to U.S. embassies overseas leaving the responsibility for assuring that the appropriate offical of the foreign government received notification on Embassy personnel. The GAO reported that "in talking with cognizant foreign officials, we found that few had actually received the notifications. It appears that notifications were not distributed to cognizant officials because neither EPA nor State had procedures for assuring that notifications reach their proper destinations."

The GAO also found that foreign officials received "little, if any, information through official channels regarding the U.S. regulatory status of pesticides" and that:

> "Representatives from less developed nations were particularly anxious to receive such timely data because they did not have funds or qualified people to perform hazard evaluations equivalent to EPA's; therefore, they rely heavily on U.S. registration as a guide for

allowing use in their country."

A House-Senate Conference committee is currently considering amendments to FIFRA which would tighten up regulation of exports.[29/] Both the House and Senate versions would require exporting firms to supply to EPA annual production and sales data. Both bills also provide that all pesticides not registered by the EPA carry prominent labels stating "Not Registered For Use In The United States Of America." The House amendments would require all foreign purchasers of unregistered pesticides to sign a statement acknowledging that they know they are buying a product that cannot be sold in the U.S. Copies of the statements would be sent by EPA to the importing government. In addition, the Senate version would mandate that pesticides sold abroad meet the same packaging and labelling standards as products sold domestically.

Toxic Substances Control Act ("TOSCA")[30/]

TOSCA was passed in 1976 to assure that adequate data is developed as to effects of chemical substances on health and the environment and to provide EPA with the authority to regulate

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29/ H.R. 8681, 95th Cong., 1st Sess., §18 (1977)
S. 1678, 15th Cong., 1st Sess., §17 (1977)

30/ 15 U.S.C. §§2601 et seq.

those substances that present an unreasonable risk of injury. Section 12(a) exempts those chemical substances that are manufactured and labelled for export from all domestic regulations of the Act except Section 8 (Reporting and Retention of Information). The export exemption does not apply only if the Administrator finds that the chemical will present an unreasonable risk of injury to health or to the environment of the United States.

TOSCA also contains a notification provision, Section 12(b), which states that any person intending to export a chemical for which submission of data is required under the Act must notify the Administrator of that intention, the Administrator will then furnish to the importing government notice of the availability of the data. Similarly, if a person intends to export a chemical for which rule, order, action or relief has been granted or is pending, the exporter must notify the Administrator who in turn will furnish the importing government notice of such regulatory action. It is too soon to determine whether EPA will be more successful in implementing TOSCA's notification requirement than it has been with the FIFRA provision.

Consumer Product Safety Act ("CPSA")[31/]
Federal Hazardous Substances Act ("FHSA")[32/]
Flammable Fabrics Act ("FFA")[33/]

All three laws are administered by the Consumer Product

31/ 15 U.S.C. §§ 2051 et seq.

32/ 15 U.S.C. §§ 1261 et seq.

33/ 15 U.S.C. §§ 1191 et seq.

Safety Commission. The CPSA, passed in 1972, seeks to protect the public against unreasonable risks of injury associated with consumer products and enpowers the CPSC to promulgate consumer product safety standards and to ban unreasonably dangerous products. Section 18 of the CPSA states that the requirements of the Act do not apply to any consumer product if (1) the product was manufactured or sold for export and (2) the product is labelled that it is intended for export.

The FHSA, as amended, provides for the ban or precautionary labelling of hazardous substances (other than pesticides, food, drugs and cosmetics). Under Sections 5 and 6 a person is not subject to the criminal penalties of the Act for shipping a hazardous substance to a foreign country if the substance is marked for export and labelled in accordance with the specifications of the foreign purchaser and in accordance with the laws of the foreign country.

The FFA, as amended, permits CPSC to set Fabric Flammability Standards or regulations to protect the public against unreasonable risk of the occurence of fire. Section 15 states that the Act does not apply to any fabric which is to be exported provided the fabric is labelled for export.

H.R. 12442, currently pending before the House of Representatives, would amend the export provisions of these three acts administered by the CPSC to give the Commission greater authority over the export of hazardous products. These proposed amendments would:

(1) eliminate a product's exemption from the respective Act if the CPSC determines that the exportation would present an unreasonable risk of injury to persons in the United States.

(2) require that in specified circumstances the exporter must give the CPSC 30 days advance notice of the exportation during which the CPSC would be required to notify the involved foreign government of the exportation and the status of the product in the U.S. The CPSC must also publish a notice in the Federal Register that they have been notified of the intended export. The notification requirement would be triggered under the CPSA if the product intended for export is not in conformity with an applicable or proposed consumer product safety standard. Notification under the FHSA would be required when the product intended for export is a misbranded hazardous substance, a banned hazardous substance, or a substance subject to a proposed rulemaking to classify the substance as banned. And notification would be required under the FFA when the intended export fails to conform to an applicable flammability standard or regulation in effect or proposed under the Act.

Federal Food, Drug, and Cosmetic Act ("FFDCA")[33/]

The FFDCA, as amended, is administered by the Food and Drug Administration ("FDA"). It was broadly designed to "keep interstate

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33/ 21 U.S.C. §§301 et. seq.

channels from deleterious adulterated and misbranded articles of specified types to the end that public health and safety might be advanced."[34/]

The export provisions of the FFDCA differentiate between three catagories of medical products:

(1) new drugs, new animal drugs and animal feeds containing new animal drugs which cannot be exported unless they are licensed for domestic use;

(2) other drugs (e.g. antibiotics, insulin, "grandfather drugs") which may be exported if they meet four criteria: (i) they accord to the specifications of the purchaser, (ii) they are not in conflict with the laws of the importing nation, (iii) they are labelled for export, and (iv) they are not offered for domestic sale.[35/]

34/ U.S. v. Walsh, 331 U.S. 432, 67 S. Ct. 1283, 91 L. Ed. 1585 (1947)

35/ Drugs, other than new drugs, that meet the four conditions can be exported even if they are adulterated and misbranded.

(3) medical devices, which may be exported if they meet the four criteria stated in (2) and the Secretary of the Department of Health, Education and Welfare ("HEW") determines that the device is not contrary to public health and safety and that it has the approval of the importing country.[36/]

The House and Senate are both considering a FDA-sponsored bill which would lift the export ban on new drugs.[37/] Unlicensed drugs could be exported under the Bill if the exporter obtains a permit from the Secretary of HEW. Prior to the issuance of a permit, the exporter must provide the Secretary with: evidence that the drug accords to the specifications of the foreign purchaser; certification from the government of the country of destination that it has been informed of the legal status of the drug in the United States and that it does not disapprove of the importation and distribution of the drug; and other specified information. The Secretary is required to issue the permit unless he determines that (i) the product does not meet the purchaser's specifications, (ii) the product is not clearly labelled for export, (iii) the applicant has failed to supply the required certification from the foreign government, (iv) based on the available evidence, the export is contrary to public health, or (v) the application contains an untrue state-

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36/ Section 801(d)

37/ H.R. 12611, 95th Cong., 2nd Sess., §§ 134-136
S. 2755, 95th Cong., 2nd Sess., §§ 134-136

ment of material fact. The bill would also require that all exports comply with U.S. manufacturing and quality control and labelling standards. Under the Act the exporter must also assure that the product reaches its destination and establish and maintain records to enable the Secretary to determine whether the conditions of the permit are being met. Finally the Bill provides the Secretary with the authority to exchange information with health officials of foreign governments and international organizations and to provide training for employees of foreign governments.

While we do not oppose amendments to the FFDCA which would permit the export of certain drugs unlicensed for domestic use, we feel that the FDA bill does not sufficiently protect the interests of the U.S. or the foreign purchaser. Our suggestions for what we believe would be a more effective approach are presented at the end of this testimony.

III. The Scope of U.S. Responsibility

The current attitude of the United States toward exports of hazardous products might be characterized for the most part as caveat emptor or "let the buyer beware."[38/] Yet this view is inconsistent with the commitment of the United States to

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38/ The doctrine of caveat emptor has all but been abandoned in the United States. It is now well established in U.S. law that the seller has a duty to exercise the care expected of a reasonable person of ordinary prudence to see the goods do no harm to the buyers.

the protection of human rights and well-being. Further, it can undermine efforts to protect the health and safety of members of the U.S. public and the quality of our environment.

The sales abroad of banned or restricted chemical products was again a matter of extensive discussion at the UNEP Governing Council meeting in May 1978. The Kenyan delegation, which had first raised the issue at the 1977 session, was joined by representatives from Bangladesh, Ghana, Iran, Jamaica, Nigeria, Pakistan, and the Philippines, in expressing concern about hazardous exports. Also, a number of industrialized nations, including Belgium, Canada, the Federal Republic of Germany, Sweden, and the U.S., were in agreement that existing means for providing full information to chemical-purchasing countries were inadequate. The Governing Council adopted a decision reaffirming the 1977 decision discussed earlier, which noted "the repeated occurrence of harmful effects to the health of people and of the environment caused by lack of awareness of the risks associated with potentially harmful chemicals" and "the need for strong and effective measures in all countries to ensure protection against such risks." The decision called upon Governments of both exporting and importing countries to institute adequate monitoring, evaluative and protective measures in regard to international commerce in chemical products. The Governing Council appealed to exporting

countries to prevent the export of items which are restricted or not registered for domestic use until it has been ascertained that designated officials in the importing country have obtained (1) information on environmental health tests and their results and (2) detailed instructions in mutually agreed languages for the safe use of these products, so as to permit these officials to make fully informed decisions on the import and utilization of the products. A corresponding appeal was directed to importing countries to improve their own capabilities to make such decisions.[39/]

What emerged from the UNEP discussions was a sense that both exporting and importing countries shared a responsibility in regard to trade in potentially toxic chemicals. It is also in our nation's own immediate interests to more effectively monitor and control hazardous exports. First, tighter regulation of the export of hazardous products would mitigate the direct health hazards posed to those Americans involved in the products' manufacture and distribution. The Leptophos tragedy described earlier is not unique. Another example involved the now infamous kepone, 99% of which was exported in 1974-75. In 1975, Life Science Products, a small chemical plant in Hopewell, Virginia ceased its production of Kepone, after 70 persons

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39/ The decision was initially introduced by Belgium, Canada, Iran, Kenya, the U.S.S.R., and the United Republic of the Cameroon. A copy of the full text of the decision is included in the appendix to this testimony.

connected with the Life Science plant, including ten wives and children of employees, became seriously ill from Kepone exposure. In 1977, the Congressional Research Service investigated the incident and reported that the symptoms exhibited by those affected included,

> "slurred speech, nervousness, tremors, twitching eyeballs, liver damage, loss of memory, and sterility. A total of 29 Life Science employees have been hospitalized for treatment. According to Virginia health officials, between 15 and 20 former Kepone workers still have a significant disability and about 12 probably will never be able to hold a job again."40/

Kepone discharges from the Hopewell plant were also responsible for contamination of the James River and Chesapeake Bay. As a result the river had to be closed to fishing.

The Senate Subcommittee on Agricultural Research and General Legislation in 1976, after holding oversight hearings concerning the Kepone incident, determined that manufacturing plants producing pesticide technical materials and pesticides produced exclusively for export did not have to comply with the FIFRA provision requiring registration of establishments.41/ Under existing law, it appears to be perfectly legal to begin

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40/ Musgrove, Connie, Kepone Pollution: A Summary Review (Issue Brief Number IB76062) The Library of Congress, Congressional Research Service, Major Issues System, Environment and Natural Resources Policy Division, May 27, 1977 p. 1.

41/ S. Rep. No. 95-334, 15th Cong. 1st Sess. 1977 p. 13

the large-scale manufacture and worldwide distribution of a pesticide without even notifying the EPA.

The manufacture of a banned pesticide for export may pose an additional risk to the health of the U.S. public as residues on imported food. A study conducted by FDA last year revealed that 45% of the 55 imported green coffee bean tested by the Agency contained illegal residues of pesticides that have been banned or restricted for use in the United States. The pesticides detected included DDT, BHC, DDE, lindane, malthion, dieldrin and heptachlor.[42/]

There is one further pathway for exported pesticides to return to the U.S. Toxic chemicals introduced into the environment in Canada, Mexico, or even overseas can by travelling by water or air, cause harm in the U.S. Traces of DDT have been found in the most remote corners of the world. In fact, it is impossible to find any population that has not been exposed to DDT.[43/]

42/ Press Release, Senator Gaylord Nelson, January 30, 1978

43/ These domestic impacts establish the need for closer monitoring of unregistered or severely restricted pesticides. Only with complete information concerning the life cycle of exported chemicals, from production to disposal, can the EPA, FDA, and the Occupational Health and Safety Administration establish enforcement priorities so as to avoid injury to U.S. health and the environment.

In addition to furthering our efforts to protect domestic health and the environment, the acceptance of an obligation to cooperate closely with environmental and health officials in countries importing U.S. products also serves our nation's diplomatic and commercial interests. Incidents, such as those involving Leptophos, do damage to the reputation of U.S.-produced goods and increase resentment towards our nation. As awareness of product dangers continues to grow in developing countries, an enlightened U.S. policy on hazardous exports could provide a competitive advantage over other exporting countries.

IV. Proposal for a Uniform Policy on Hazardous Exports

We believe that the objectives of a U.S. policy on hazardous exports should be:

(1) Close monitoring of production and export of hazardous products. In our view, the availability of these statistics is a necessary starting point for effective control of trade in banned or restricted products.

(2) Assurance that all available information concerning the risks and benefits associated with the prohibited or restricted product has been made available to the designated health or environmental official in the importing country prior to the export of the product.

(3) Requirement that all exports of regulated products meet U.S. quality control and labelling (including promotion) standards.

(4) Notification to the importing countries and international organizations of all appropriate U.S. regulatory actions. Through closer monitoring of trade, the U.S. government can insure that other nations can receive an early warning of newly discovered hazards.

(5) Provision of technical aid and training to governments of developing countries importing U.S. products.

(6) Authority to prohibit exports where products pose unreasonable risks to health and safety of the U.S. public or to the global commons.

To attain these goals, we believe that the U.S. export policy should contain the following program elements:

(a) A permit system whereby prior to the export of any product not approved for domestic use, the exporter must obtain a permit from the appropriate federal agency. Permit applications would consist of supplying the agency with information easily obtainable by the exporter, including, but not limited to:

(i) name and address of the establishment where the product is manufactured;

(ii) name and address of purchaser or consignee;

(iii) evidence that the product accords to the specifications of the purchaser;

(iv) samples of labelling and promotional materials;

(v) description of tests made on the product, if any known to the exporter; and

(vi) certification from a designated health or environmental official of the country of destination that he has examined all available information, that he understands that the product is not available for sale or use in the United States and that he approves of the importation.

(b) Requirement that labelling of the product be in the language of the country of destination and that it contains the following information: generic name, directions for use, storage instructions, warnings of known side-effects, and expiration date. The label shall also clearly state, as appropriate, that the product is prohibited or restricted for use in the United States.

(c) Requirement that any promotional or labelling materials not be false or misleading.

(d) Requirement that manufacturing, holding, and distribution of the product comply with U.S. standards for good manufacturing practice.

(e) Requirement that the product meets all internationally prescribed standards.

(f) Requirement that the product is not adulterated, contaminated or misbranded.

(g) Requirement that each regulatory agency establish a program to provide for the exchange of information with the appropriate officials of the foreign governments and international organizations. The agencies should make available data concerning the risks and benefits associated with the

products' use, the handling and storage of the product, instructions for proper application and any additional appropriate information. In addition, the agencies should establish programs to train officials or employees of developing country governments to enable those officers or employees to make appropriate regulatory decisions.

(h) Notification system which would inform every importing nation of any action taken by a U.S. agency to revoke, amend, or limit a permit, license, or registration to sell or use a product in the U.S. and any action taken to ban a product from the U.S. market.

We believe that the policy objectives can be achieved only by changing the legislative mandate of each regulatory agency that administers a product control statute. It is our view that the individual agencies should have the primary responsibility to administer the export controls because they have the expertise in handling and regulating the particular products. In addition, regulation of exports by the individual agencies, rather than Department of Commerce or Department of State, will minimize any duplication of effort. The direct relationship between the U.S. agencies and their counterparts in other countries would also provide the most effective and efficient channel of communication.

We feel that State Department involvement is critical in assisting the agencies to institute their international programs and establish relationships with foreign governments. Finally the program should include an effort to create greater coordination between all agencies involved in the prevention of injury caused by the manufacture, handling, distribution, use and disposal of hazardous products.

Ensuring that importers know the nature of their purchases will not, by itself, end the abuse of chemical products in poor countries. Only the development of effective national regulatory sytems in third world countries can do that.[44/] However, the U.S. policy we have suggested would at least reduce the chances that the most dangerous chemicals would not be imported or used by people totally unaware of the risks involved. The proposed program would not significantly burden either the exporter or the agencies. Yet, these minor requirements would provide an important measure of protection for the health of the public and the environment at home and abroad.

I thank you.

44/ Improvements in Third World regulatory capabilities are essential to deal with the related problem of the movement to developing countries of manufacturing plants producing dangerous goods or involving hazards to worker's health. See B. Castleman, "The Export of Hazardous Factories to Developing Nations" (March 7, 1978.

Appendix
Testimony of J. Scheer

UNITED NATIONS ENVIRONMENT PROGRAMME
GOVERNING COUNCIL DECISION
5th Session, May 1977

85 (V). Human and environmental health

The Governing Council,

Having considered the report of the Executive Director, in particular the section dealing with human health, 23/

Recognizing that health is a basic human need and an integral part of the quality of life,

Noting the progress accomplished, in co-operation with the World Health Organization, in the programme for human and environmental health,

Aware that there have been unethical practices concerning the distribution of chemicals, drugs, cosmetics and food unfit for human consumption,

Conscious that there exists an urgent need for all countries to develop measures to protect themselves,

Further aware that there is need for harmonious co-operation between manufacturers and exporters of chemicals, foods, drugs and cosmetics, as well as between exporting and importing countries,

1. Requests the Executive Director to continue to give high priority to the protection of human and environmental health and to co-operate closely with United Nations bodies, especially the World Health Organization, the Food and Agriculture Organization of the United Nations and the International Labour Organisation, in this field, paying special attention to the problems, in both developed and developing countries, of contaminants, both chemical and biological, of food, and to epidemiology and the control of chronic diseases of all kinds (especially parasitic diseases) as far as they relate to environmental factors;

2. Urges Governments to take steps to ensure that potentially harmful chemicals, in whatever form or commodity, which are unacceptable for domestic purposes in the exporting country, are not permitted to be exported without the knowledge and consent of appropriate authorities in the importing country;

3. Requests the Executive Director, in co-operation with the competent organizations of the United Nations system, especially the Codex Alimentarius Commission, to assist developing countries in developing and strengthening their capabilities for evaluating chemicals, foods, drugs and cosmetics being distributed within their countries.

23/ UNEP/GC/90 and Corr.1, paras. 198-229.

Appendix
Testimony of J. Scheer

UNITED NATIONS ENVIRONMENT PROGRAMME
GOVERNING COUNCIL DECISION
6th Session, May 1978

B. Health of people and the environment

Strongly reaffirming the provisions of decisions 53 (IV) of 13 April 1976 and 85 (V) of 25 May 1977, and in particular those contained in its paragraph 2 of the latter,

Noting the repeated occurrence of harmful effects to the health of people and of the environment caused by lack of awareness of the risks associated with potentially harmful chemicals,

Noting further the need for strong and effective measures in all countries to ensure protection against such risks,

1. Appeals to the countries exporting potentially harmful chemicals, in whatever form or commodity, to prevent the export of items which are restricted, or not registered for use, in the countries of origin until the exporting countries have ascertained that the results of tests and evaluations on the effects of these chemicals on the health of people and the environment (as well as detailed instructions in mutually agreed languages for the safe use of these products) have been provided to the designated authorities in the recipient countries, so as to make it possible for these authorities to make fully informed decision on the import and utilization of the products;

2. Further appeals to the Governments of recipient countries to take appropriate measures to strengthen the capabilities of the authorities designated to make the decisions referred to in paragraph 1 above;

3. Calls upon the Governments of both exporting and recipient countries to institute adequate monitoring, evaluative and protective measures in this regard;

4. Requests the Executive Director to explore ways and means of assisting recipient countries in instituting the measures referred to in paragraph 3 above, and in finding solutions to problems involving potentially harmful chemicals including the provision of information on alternatives to their use.

UNEP/GC.6/L.8/Add.3

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Mr. ROSENTHAL. Our next witness is Henry Eschwege, Director of the Community and Economic Development Division of the General Accounting Office.

We appreciate your being here, Mr. Eschwege, and you may proceed.

STATEMENT OF HENRY ESCHWEGE, DIRECTOR, COMMUNITY AND ECONOMIC DEVELOPMENT DIVISION, GENERAL ACCOUNTING OFFICE; ACCOMPANIED BY ROBERT G. CHAMBERS, AUDIT MANAGER

Mr. ESCHWEGE. Thank you, Mr. Chairman.

I would like to introduce my colleague, Mr. Robert Chambers, who is an audit supervisor in our office and who has been in charge of our work done on pesticides.

We appear before you today to discuss the effectiveness of Federal efforts to notify foreign nations regarding U.S. pesticide suspension and cancellation actions.

This matter was addressed in our April 20, 1978, report to the Administrator, Environmental Protection Agency—CED–78–103.

Our review is still going on on the broad subject of exporting and importing of pesticides. But we came across this weakness, I would say, in the notification process; so we sent this rather short report to the Administrator back in April of 1978.

There is considerable room for improvement in EPA's and the Department of State's joint implementation of the pesticide notification program in identifying regulatory actions to be reported; in improving procedures to insure that data provided in notifications is complete, concise, and understandable; and in insuring that responsible U.S. embassies abroad and foreign officials receive all notifications in a timely manner.

EPA regulates pesticides under the Federal Insecticide, Fungicide, and Rodenticide Act of 1947, as amended.

Section 17(b) of the act requires EPA to notify foreign governments and appropriate international agencies "whenever a registration or a cancellation or a suspension of the registration of a pesticide becomes effective or ceases to be effective."

Notification of the U.S. suspension and cancellation actions are beneficial to both the United States and foreign nations.

The latter benefits because they are alerted to unreasonable hazards associated with using particular pesticides and can act to lessen exposure of their workers and citizens.

The United States benefits when a nation restricts using these pesticides on food and fiber products imported into the United States.

EPA prepares pesticide suspension and cancellation notifications in the form of an airgram. The airgrams provide brief statements of the regulatory action and request that certain documents—usually Federal Register notices—be provided to foreign governments.

The airgram and attached material are then forwarded to the Department of State which, after review and approval, transmits them to its diplomatic and consular posts throughout the world for forwarding to appropriate host country officials.

EPA often does not make notifications on regulatory actions.

In our April 1978 report to EPA, we reported that, since the act was amended in 1972 requiring foreign nation notifications, EPA has canceled, suspended, or significantly restricted using 14 pesticides or pesticide product ingredients.

EPA and Department of State records show that EPA requested the Department to notify foreign nations regarding only five of the regulatory actions. These were aldrin/dieldrin, vinyl chloride, mirex, leptophos, and BHC.

In each case, the Department of State notified U.S. embassies. Agricultural and scientific attachés, or other embassy personnel, were responsible for assuring that foreign government officials received notification.

During the same period, however, EPA did not request foreign nation notifications on the other nine regulatory actions involving quarternary ammonium compounds in 1973; chlordane, heptachlor, kepone, OMPA, and strobane in 1976; and aramite, chloranil, and safrole in 1977.

Mr. ROSENTHAL. Can you tell us why they didn't do that?

You said EPA did not consider it necessary. Why didn't they consider it necessary?

Mr. ESCHWEGE. This is because they are talking only about making such notifications when they themselves have initiated the cancellation or the suspension. When the actions were not final or when all product uses were not canceled, they would not notify foreign nations.

Mr. ROSENTHAL. Were there safety factors involved in the nine pesticides that were not referred on?

Mr. CHAMBERS. In most cases, there were.

Mr. ESCHWEGE. We think so; yes.

We think in all nine cases they should have notified the foreign countries.

Mr. ROSENTHAL. And in those nine cases—and I haven't followed this through—but is there a likelihood that food products they were used on could be reimported into the United States? Is that a possibility?

Mr. ESCHWEGE. I am not sure we know about all nine cases.

Mr. CHAMBERS. We have cases where food products that have been imported contain some of these banned chemicals.

Mr. ROSENTHAL. So there was not only a danger to foreign nationals but a danger to U.S. citizens.

Mr. ESCHWEGE. Yes, sir. I think that is an important thing to stress.

Mr. ROSENTHAL. How does EPA justify not doing this—on technical grounds or a judgment call or what?

Mr. ESCHWEGE. Since we made our review EPA has—as I point out later in my statement—notified other countries about three additional of these pesticides.

Mr. ROSENTHAL. But then there were six that still were not.

Mr. ESCHWEGE. That is correct.

Mr. ROSENTHAL. I am sorry for interrupting.

Mr. ESCHWEGE. Since our review, EPA has made notifications on three of these pesticides, which are heptachlor, chlordane, and kepone. There is one other pesticide, DBCP, which EPA canceled and made notice on during 1978.

Mr. ROSENTHAL. EPA didn't make notification on kepone, which is deadly.

Mr. CHAMBERS. Until 1978.

Mr. ROSENTHAL. When did they take their first action?

Mr. CHAMBERS. Kepone action was in 1976.

Mr. ROSENTHAL. For 2 years, kepone exportation went on without notification.

Mr. ESCHWEGE. That is correct.

Mr. ROSENTHAL. That is almost unbelievable.

Mr. ESCHWEGE. EPA did not consider it necessary to request the Department of State to notify foreign nations about the nine pesticides.

EPA's criteria for reporting suspension and cancellation actions limit foreign government notifications to those actions, and I quote "determined to have national or international significance."

EPA officials said that only EPA-initiated cancellations and suspensions of basic pesticide-active ingredients registered for use in several products are considered actions of national or international significance. Actions on individual pesticide products are not.

EPA decided that notifications on these pesticides were not required because the actions were not final, registrants voluntarily requested the cancellations, or all product used were not canceled.

We believe, however, that all of these regulatory actions have both national and international implications, and notifications should have been made.

For example, registrations of chlordane and heptachlor were suspended, and strobane was canceled for most uses because of their suspected potential for causing tumors in animals.

Chlordane and heptachlor were two of the most widely used pesticides in the world.

The strobane action canceled 34 individual product registrations.

EPA, or its predecessor, also canceled major uses of 12 pesticides, such as DDT, mercury, PCB, and 2,4,5-T prior to the act's 1972 amendment.

Although the 1972 amendment did not require foreign nation notifications of these prior cancellations, EPA requested notifications on 6 of the 12.

EPA should have requested notifications on the other six pesticides, as they were of equal interest to other nations as those that were reported.

EPA has not consistently applied its criteria for foreign nation notifications. For example, EPA notified nations of its action on 2,4,5-T although significant uses—uses on rangeland, forests, and transportation rights-of-way—were retained.

Further, EPA notified foreign nations on its revocation of leptophos tolerances—the maximum residue that can remain on food—even though there were no pesticide registrations suspended or canceled because leptophos was never registered for use in the United States.

Regarding the latter, EPA said that although notification of tolerance revocations is not covered by the act, it felt that this action was within the spirit of the act and that there was sufficient worldwide interest to warrant notice.

We believe EPA's rationale in the leptophos notification should be extended to all significant pesticide regulatory actions.

A further limitation in the program is that EPA cannot readily determine the international significance of pesticide regulatory actions.

Actions on relatively minor pesticide uses in the United States may involve significant uses in one or more foreign nations because of differences in climate, crops, and pests.

Accurate, up-to-date, worldwide pesticide usage data is not generally available. This lack of information and the inherent problems in predicting changes in significant worldwide pesticide usage patterns underscores the very real need to notify foreign nations of virtually all pesticide suspension and cancellation actions.

At the time our work was performed overseas, EPA had initiated 3 notifications covering 11 pesticides.

Officials of 20 foreign nations told us that generally their countries had received very little, if any, information through official channels regarding the U.S. regulatory status of pesticides.

Of the 20 foreign nations, only West Germany and Sri Lanka acknowledged receiving all three notifications. Five others acknowledged receiving one or two notices. Eight said no notifications were received, and the remaining five did not comment on this matter.

The statistics on notifications received by foreign nations may not be entirely accurate, because officials may not recall notifications that were received. Or officials who were notified may have moved on to other assignments.

The lack of foreign nation notifications stemmed, in part, from some embassies not receiving the notifications.

For example, the American Embassy in Costa Rica told us that it had received no notifications. Four other embassy officials stated that they had received only one of the three notifications.

A further complication is that forwarding pesticide notifications may conflict with other duties of some embassy officials.

For example, an official at one embassy told us that he did not routinely forward notifications on chemicals not registered in the host country because it may adversely affect U.S. exporting.

Mr. ROSENTHAL. He or she was making up his or her own judgment.

Mr. ESCHWEGE. I would say so. It is an isolated case.

Mr. ROSENTHAL. That person should be disciplined; don't you think? Do you have the name of that person?

Mr. ESCHWEGE. I don't think we have it readily, but we can supply it.

Mr. ROSENTHAL. Will you foward the name of the person and the assignment to the subcommittee please?

Mr. ESCHWEGE. Yes, sir.

[The material referred to follows:]

The official was a local agricultural specialist in an American Embassy. However, as Mr. Chambers points out later in testimony on pages 74 and 75, we believe that the instructions supplied to Embassy officials may be ambiguous, leading them to believe that pesticide notifications are discretionary. The record is not sufficiently clear to warrant disciplinary action. Rather, we believe that it would be more constructive for the Department of State to transmit clear, unequivocal instructions requiring Embassy personnel to transmit all pesticide notifications to foreign nations in a timely manner.

Mr. ESCHWEGE. Foreign officials in 14 countries expressly told us that they wanted to receive timely notifications on U.S. pesticide regulatory actions. None said that they did not want to receive notifications.

Representatives from less developed nations were particularly anxious to receive such timely data, because they did not have funds or the expertise to perform the types of hazard evaluations being done by EPA.

They rely heavily on U.S. registration as a guide for allowing use in their country.

For example, one official wrote to us that Leptophos—Phosvel—was still being imported and used in Surinam, because he had received no information on adverse health or environmental effects as a result of its use.

The official requested information on Leptophos and asked to receive notifications on all future actions.

Had Surinam received EPA's March 3, 1977, notification on the revocation of Leptophos tolerances, it would have been aware of the nerve damage associated with Leptophos use 14 months before it requested this information from the GAO.

In cases where foreign officials did receive notifications, some commented that the Federal Register notices provided were unclear and hard to understand, effective dates of regulatory actions could not be ascertained, and some copies of notices that were received were illegible.

We provided several foreign officials with copies of the EPA booklet, "Suspended and Cancelled Pesticides," which summarizes EPA actions on pesticide suspensions, cancellations, and other restrictions.

Many of the officials believed that the type of information in the booklet alerted them sufficiently to initiate actions or to request additional data from which to judge whether use of the pesticide should be curtailed or discontinued.

We concluded that foreign nations want to receive timely and concise notifications on U.S. actions to aid them in their regulatory functions. It is apparent, however, that foreign nations are not receiving all EPA notifications and that when notifications are received, they may be illegible or unclear in meaning.

EPA and the State Department could improve their joint implementation of the pesticide law's notification provision.

In our report, we recommended that EPA:

Review all pesticide suspensions and cancellations—both agency and registrant-initiated—to identify those of national and international significance.

Compile information on these actions in concise publications for distribution to appropriate foreign nations. Publications should include effective dates and synopses of the regulatory actions in language that can be understood by officials whose primary language may not be English.

And, finally, we recommended that EPA develop an appropriate system with the State Department for timely and efficient dissemination of this and similar data to foreign officials. A most effective way might be to have EPA provide direct notifications to appropriate foreign officials, concurrent with notification to the Department of State.

This concludes my statement.

Mr. ROSENTHAL. I want to say that the GAO has done its usual first-rate job in this matter, and I commend both of you and your colleagues and associates for doing that.

We are deeply thankful and grateful for your efforts.

Congressman Drinan?

Mr. DRINAN. Thank you, Mr. Chairman.

I echo those sentiments about the thoroughness of the study.

Why did the GAO choose the EPA first? Is this the beginning of a series—going to the FDA and so on?

Mr. ESCHWEGE. We have done some work—I was not personally involved with it—in the FDA area as well. It was concerned with imported meat.

Mr. DRINAN. I take it that the GAO on its own initiative started this?

Mr. ESCHWEGE. Yes, sir. We have done this on our own initiative.

Like most agencies, we have to spread our forces rather thinly, but we thought it was about time to get into this area.

Mr. DRINAN. I assume that some judgment was made that the EPA should be surveyed before other agencies, since as you have found they have been quite derelict in their duties.

Mr. ESCHWEGE. The judgment that we usually make in such cases has to do with the coverage that is given to various programs by the agencies' internal review mechanisms themselves, as well as the interest that the Congress expresses in these areas.

We thought this would be a timely subject for review.

Mr. DRINAN. On the choice of nations, only two developed nations are there, and only two major developed nations—West Germany and New Zealand.

I take it that your results are the same—that the EPA failed to communicate, even with highly developed nations and even with a nation like New Zealand where English is spoken.

Mr. ESCHWEGE. We have some statistics on that.

Mr. CHAMBERS. That is an accurate statement.

We had varying responses from all countries.

As we indicated in our testimony, only Sri Lanka and West Germany had received all three notifications.

Countries like Spain had received none.

Mr. DRINAN. It may be that we could fault the Embassy in Madrid, for never translating this document or communicating it.

Mr. CHAMBERS. That's right.

Mr. DRINAN. May I ask this also?

You wrote on May 12 a very good letter to Mr. Costle, the Administrator of EPA. You made recommendations, and then you reminded him of his duty to communicate after 60 days from this report with the Government Operations Committee. I wonder if that report has come in; 2 months have elapsed.

Mr. ESCHWEGE. That was April 20. The reply was due by about June 20.

I am not aware that they have officially responded.

Mr. CHAMBERS. The response has not officially been made as of this morning.

Mr. DRINAN. But that response is due.

Mr. ESCHWEGE. You are correct, Mr. Drinan. That would have been due by June 20. It is overdue.

Mr. DRINAN. They don't inform the foreign nations, and they don't even comply with the statutory duty to inform the Congress.

What is the next phase of your study on EPA, or would you go on to some other agency?

Mr. ESCHWEGE. We are actually continuing in this review to try to get a better handle on the import side of pesticides to see whether there are any residues of some of these prohibited pesticides appearing on foods that get imported into this country.

We have a constant presence at EPA. We have staff there all the time looking at the different programs—just as we have at FDA and other agencies of the Government. So we are getting into many facets of EPA's work.

Mr. DRINAN. Let me ask you the question that I asked previous witnesses.

If the new bill on FIFRA becomes law, will that rectify the negligent conduct that you have pointed out on the part of EPA?

Mr. ESCHWEGE. It will rectify a good deal, but I still feel there are a number of things that that particular provision can't really fully address.

One was mentioned by a previous witness—having to do with making sure that if we manufacture pesticides just for export which are banned in this country, that the workers are protected in the plant.

The other one is that if even with those restrictions, these pesticides are exported, that they don't come back to us in the form of imported foods. So those are the two main areas, I think, where you are not going to be able to cover it under FIFRA.

Mr. DRINAN. Could American law really cover that?

If pesticides are, in fact, exported, assuming someone gives the power to do that, is there any way to monitor these things if they come back on vegetables from Mexico?

Mr. ESCHWEGE. There is supposed to be some monitoring of that.

I might add to this that some of these pesticides being used overseas don't necessarily come from the United States. So even if we were to somehow fix that by a complete ban, it might not prevent some of the food from coming in with these residues on them.

Mr. DRINAN. Is there any way of detecting the residues on the foods?

Mr. ESCHWEGE. FDA has procedures for doing that. We are still looking at those.

We have had problems trying to get a handle on this. But as we see it, these procedures, I am sure, could be strengthened. That is our tentative conclusion on that. There are procedures.

Mr. DRINAN. Thank you.

I would ask the Chair if there is any way for the Congress or the Government Operations Committee to insist that the EPA, before they testify tomorrow, comply with their statutory duty, which they have not done, in commenting on the report of the GAO which they received on April 20?

Mr. ROSENTHAL. We are trying to deal with that.

Mr. DRINAN. Thank you very much; and thank you, sir, for a fine report.

Mr. ROSENTHAL. Mr. Corcoran?

Mr. CORCORAN. Thank you, Mr. Chairman.

Mr. ROSENTHAL. Did you want to say something first, Mr. Chambers?

Mr. CHAMBERS. Yes.

I want to go back to a point that you addressed about the notification that was not transmitted.

I think that may stem, in part, from the telegrams that went out from the State Department.

I think the message was ambiguous.

The reason we put this example in our testimony is that there may be other Embassy officials who may be misinterpreting their duty to notify foreign nations.

I want to quote from the telegram that went out in 1975.

It says:

> Foreign governments and appropriate international organizations expressing interest will be notified of any cancellation or suspension action which has become effective and which is determined to have national or international significance.

So the reason that these things may not be passed is, in part, due I think to the ambiguity in this 1975 telegram. The statement appears to make notifications optional.

Mr. ROSENTHAL. Mr. Corcoran?

Mr. CORCORAN. Thank you, Mr. Chairman.

I also want to associate myself with the remarks of the chairman and my colleague, Congressman Drinan, on our pleasure at your appearing here in the middle of an investigation and the quality of the report that you have given us. I have one specific question to begin.

Have you received a letter of reply to your April 20, 1978, letter to the Administrator of the EPA?

Mr. ESCHWEGE. No; we would get the same reply that the committee would.

Mr. CORCORAN. Second, in the course of your testimony, you point out that the EPA has as one of its standards for notification the effective date of a ban on, for instance, a pesticide.

There is a period of time between the notice that there is going to be, or there is possibly going to be, a ban for the hazardous characteristics of a particular pesticide and the actual effective date of the ban.

That is a very critical period. A lot of activity can take place during that period.

Would you agree with me that perhaps there should be an EPA notice at that point of the fact that there is a potential hazardous danger and then the indication to the foreign government that there will be a confirming communication of the final results?

Mr. CHAMBERS. We think that there are two additional types of information that should be forwarded by EPA to foreign nations.

These cover EPA's restricted-use list. In other words, those pesticides which can be applied only by certified applicators.

Second, the list of EPA's rebuttable presumption against registration list of pesticides.

This is a list of pesticides that are suspected of causing unreasonable adverse human health or environmental problems. A pesticide on this list will undergo extensive scientific review before EPA decides to allow the registration to be renewed.

I think what you are addressing would be covered if these lists were made available through the notification procedure.

Mr. CORCORAN. One other area I want to have you elaborate on a bit is this.

In the testimony, you talk about the lack of quality and lack of clarity and the general breakdown in communications to the foreign governments.

In the course of the coming weeks, during which you will be concluding your investigation, will you be focusing on this communications problem? And will you be making some specific recommendations to the Congress on that?

Mr. ESCHWEGE. Yes. This will be covered again in our final report.

As we point out, there is a document now that is pretty good. Unfortunately, it does not get updated enough to be useful all the time. That is this booklet on "Suspended and Cancelled Pesticides," which has a lot of good information.

What they are getting now is copies of the Federal Register, and you know how difficult that is to read. And copies get to be pretty sloppy after awhile.

Mr. CORCORAN. Going to the star of the hearings so far—the State Department—could you tell us whether or not the State Department maintains any kind of a list of EPA actions in each embassy so that at each one of those embassies any inquiring foreign official or company or citizen in a foreign country could learn from our Embassy whether or not there has already been a determination by agencies of this Government about hazardous materials now in that country?

Mr. ESCHWEGE. The State Department told us that they don't have such a list. Some of the embassies in the foreign countries didn't even have the notifications. As far as we know, there is no list, unless somebody on their own initiative reads through the New York Times and other papers and finds it.

Mr. CORCORAN. At this point I realize you are still in the middle of your investigation, so I am not asking for a final recommendation. But is it possible, or perhaps probable, that one of your recommendations might be that the State Department would maintain such a list at each embassy?

Mr. ESCHWEGE. It is very possible. I think you have given us a good idea there.

Mr. CORCORAN. Lastly, your concluding recommendation is that: "EPA provide direct notification to appropriate foreign officials concurrent with notification to the Department of State."

I have been pretty rough on the Department of State. My colleagues have been pretty rough on the Department of State. You are pretty rough on the Department of State in that final comment.

Furthermore, based on the earlier testimony of the representative of the Carter administration who is chairing this working force, they are thinking at this point that there is going to be a coordinated and comprehensive approach to this. Now there is a conflict there. How do you think it should be resolved?

Mr. ESCHWEGE. We would like to think that our recommendation is a good one to consider, because it kind of shortcuts the process. Whether it is State Department or anyone else, we want to get that information over there as soon as possible.

We are not bypassing the State Department entirely. We are saying that they should be informed too. But this is an additional safety valve to make sure that this information gets over there.

Mr. CORCORAN. Thank you very much.

Mr. ROSENTHAL. I think both ideas are very good myself. Mr. Corcoran's proposal seems to me so elementary—that each embassy should have kept a roster on all the notifications they received and how they distributed them. It seems so elementary.

Do you have any information at all about what has happened in countries that have received notifications? What actions they have taken? Or have they taken any actions?

Mr. CHAMBERS. We asked that question in the various countries that we went to. We did get two positive responses on banning Leptophos.

When Guatemala and Costa Rica received the notification they did cancel the use of Leptophos in their countries.

So, in fact, this type of data is used and can be valuable to a country.

Mr. ROSENTHAL. Congressman Drinan?

Mr. DRINAN. Thank you, Mr. Chairman.

I wonder if you gentlemen could confirm the estimate that has been made by the Natural Resources Defense Council—namely, that 15 percent of the 588 million pounds of pesticides exported in 1975 were not registered for use in the United States?

Mr. ESCHWEGE. May we provide that for the record?

Mr. DRINAN. Yes.

[The material referred to follows:]

The figure provided by the Natural Resources Defense Council for total 1975 pesticide exports is essentially correct. The attached schedule shows total U.S. exports of approximately 588 million pounds for calendar year 1975.

EPA's records of pesticide exports for calendar year 1975 show the following categories of pesticides that are not registered or that are not fully registered:

	Gallons	Pounds
Unregistered	2,864,991	77,640,278
Undergoing Registration	10,530	5,165,484
Temporary Permit	2,100	2,012,508
	2,877,621	84,818,270

We did not convert total gallons of exports to pounds, however, it is obvious that total pounds and gallons in these categories would exceed 15 percent of the total 588 million pounds exported. We do not know if the Natural Resources Defense Council included all three categories in their computations.

It must be cautioned, however, that the active ingredient chemicals in export products are not necessarily suspended or canceled. Unregistered means only that the specific product is not registered by EPA; some of these products contain only active ingredients that are essentially unrestricted for use within the U.S. We do not have exact data on exports of pesticides for suspended or canceled uses. This data can only be obtained by obtaining and comparing labels of each export product to suspended and canceled U.S. uses.

U.S. Pesticide[1/] Exports by Destination-1975

AREA	QUANTITY (lbs)
Western Hemisphere	
Canada	92,662,126
20 Latin American Republics	158,109,833
Other Western Hemisphere	9,137,521
Sub-total	259,909,480
Western Europe	150,571,034
Communist Areas In Europe	10,369,973
Asia	117,062,052
Australia and Oceania	10,439,775
Africa	39,332,688
Sub-total	327,775,522
TOTAL	587,685,002

Source; U.S. Exports; Domestic Merchandise SIC-Based Products by World Areas; FT 610 Annual 1975; Issued January 1977; U.S. Department of Commerce; Bureau of the Census.

Mr. DRINAN. The cyclamates have not come up today. They were banned by the FDA some time ago.

It is my understanding that American companies are marketing them throughout Canada and Europe and elsewhere. Did you come across any evidence of that?

Mr. ESCHWEGE. No.

Mr. DRINAN. That would not be in EPA.

Mr. ESCHWEGE. Since this is not defined under pesticides, we didn't do that one; no.

Mr. DRINAN. One last point.

All these unregistered or banned items—do we sell them to Europe with the same frequency that we sell them to Latin America or to the developing world?

I wonder what is your experience with regard to West Germany? Do they see a lot of unregistered, or banned, chemicals or pesticides coming into West Germany?

Mr. ESCHWEGE. We have some statistics on that, I believe.

Mr. CHAMBERS. I think we should go back, for example, to leptophos.

We don't have individual statistics on the total amount of each chemical shipped to each country.

For leptophos, there was a total of 13,950,000 pounds shipped overseas in the period from 1971 to 1976.

The bulk of those shipments went to developing countries—countries like Egypt, the Ivory Coast, Colombia; and Germany imported almost no leptophos.

The developed countries produce their own pesticides. It is much cheaper. When you add the freight onto the cost of producing these pesticides, they can do it cheaper in their countries, for the most part. So they manufacture.

The major industrial countries in Western Europe are heavy exporters—France, Switzerland, the Netherlands, Great Britain, and Germany.

Mr. DRINAN. One last question: When will all the backup material from the GAO study be available?

Mr. ESCHWEGE. We hope to have our report to the Congress this fall, but I think it will be late this fall.

Mr. DRINAN. Thank you very much.

Mr. ROSENTHAL. Thank you both very, very much.

The subcommittee stands adjourned until 10 o'clock tomorrow morning.

[Whereupon, at 11:45 a.m., the subcommittee adjourned, to reconvene at 10 a.m., Wednesday, July 12, 1978.]

U.S. EXPORT OF BANNED PRODUCTS

WEDNESDAY, JULY 12, 1978

HOUSE OF REPRESENTATIVES,
COMMERCE, CONSUMER,
AND MONETARY AFFAIRS SUBCOMMITTEE
OF THE COMMITTEE ON GOVERNMENT OPERATIONS,
Washington, D.C.

The subcommittee met, pursuant to recess, at 10:05 a.m., in room 2247, Rayburn House Office Building, Hon. Benjamin S. Rosenthal (chairman of the subcommittee) presiding.

Present: Representatives Benjamin S. Rosenthal, Robert F. Drinan, Elliott H. Levitas, and Garry Brown.

Also present: Jean S. Perwin, counsel; Doris Faye Taylor, clerk; and Henry C. Ruempler, minority professional staff, Committee on Government Operations.

Mr. ROSENTHAL. The subcommittee will be in order.

Our first witness this morning is Donald Kennedy, Commissioner for the Food and Drug Administration.

We are very pleased to have you with us.

We know that you have a prepared statement, and we would be pleased to hear it.

STATEMENT OF DR. DONALD KENNEDY, COMMISSIONER, FOOD AND DRUG ADMINISTRATION, PUBLIC HEALTH SERVICE, DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE; ACCOMPANIED BY JOHN JENNINGS, M.D., OFFICE OF THE COMMISSIONER; AND RICHARD M. COOPER, CHIEF COUNSEL

Dr. KENNEDY. Thank you, Mr. Chairman.

The main question being examined at these hearings is whether the U.S. Government should allow the export of useful but potentially hazardous substances not approved for marketing in this country. It is one that evokes strong views on both sides.

On the one hand, there is concern that current export policy for some products results in the "dumping" of inferior or even dangerous substances in countries poorly equipped to evaluate the potential risks involved.

On the other hand, it is claimed that export restrictions deprive citizens of foreign countries the benefits of important products that, for often rather special reasons, have been deemed unsuitable for use by U.S. citizens.

Like other Federal agencies that regulate chemicals, the Food and Drug Administration sometimes finds itself at the center of controversy between representatives of these divergent, but equally legitimate, positions.

Over the years, through participation in a number of debates on this issue, we have reexamined the export provisions of our laws to determine if changes were in order.

For example, recently as part of an overall revision of our drug laws, we submitted to Congress significant amendments to the current export provisions regarding drugs.

Because of the importance of this change, I would like to discuss it here in some detail, with your permission, including the ways in which it would modify current law and why we believe it is necessary.

Then I will turn briefly to export rules for other FDA regulated products.

Under current law, a new drug may not be exported for commercial use unless it is approved for marketing domestically and complies with all the requirements of title V of the Federal Food, Drug and Cosmetic Act and the drug's new drug application.

An unapproved new drug may be exported only under an investigational new drug protocol approved by the Food and Drug Administration. That investigational study must comply with all the conditions and requirements that attend a clinical study conducted in this country.

But certain categories of drugs that are not classified as new drugs—like antibiotics, insulin, and pre-1938, or grandfather, drugs—may be exported without any prior notice to the Food and Drug Administration, even when these products may be adulterated or misbranded under domestic standards. These drugs must simply comply with the specifications of the foreign purchaser and the laws of the importing countries and be labeled for export only.

Our proposed new law—the Drug Regulation Reform Act of 1978—would revise the current export rules applicable to drugs. Under the act, two standards for export would apply to all drugs.

Approved drugs in compliance with domestic requirements could be freely exported. Unapproved drugs or approved drugs not in compliance with domestic requirements could be exported only after an export permit had been approved by the Secretary.

An export permit would be granted only when the exporter of an unapproved or noncomplying drug demonstrates that the importing government has assented to its importation after being informed of its legal status here and the basis for it.

The scientific and medical data concerning the drug's unapproved status would be made available to the importing government to assure an informed decision. The Secretary would have authority to deny an export permit where such export would be contrary to public health.

Currently, we provide information on the safety and efficacy of many drugs to the World Health Organization and to individual foreign countries.

For example, when a drug is withdrawn from the market for reasons of safety, we notify the World Health Organization and all those countries which have requested to receive information of this kind.

The World Health Organization, in turn, issues special bulletins to all its member governments.

Because we have limited authority and resources to provide technical assistance of this kind to foreign countries, we have included a provision in the Reform Act authorizing the Secretary to provide assistance to foreign governments that lack the resources to evaluate the medical and scientific information about a drug.

The Food and Drug Administration would expand its exchange of drug information with foreign health officials and international organizations, such as the World Health Organization, and would provide training for representatives of foreign government where it is needed.

We envision that training sessions would be held either in the foreign country or in the United States, as necessary.

This technical assistance would not only provide the foreign government with an informed decision as to the importation of a given noncomplying or unapproved drug but would also enhance the overall scientific and technical capabilities of those foreign governments which need such assistance.

In sum, our proposed change in the law would provide greater protection against the export of some drug products, such as adulterated and misbranded antibiotics, insulin, and pre-1938 drugs.

At the same time, it would make more drug products available to foreign countries that are needed in those countries.

This is essentially the same policy that Congress adopted in 1976 when it considered the export policy for medical devices in the medical device amendments.

A drug or device deemed unsuitable for distribution and use in the United States may nevertheless make substantial contributions to the health needs of another country.

In our view, the relative safety and efficacy of a drug or medical device is a composite judgment which must be made by each country based upon many factors, such as the status of the health care system in that country, patient compliance with dosage regimens, alternative therapies that may be available, and other health-related and social characteristics of that nation's population.

A number of diseases prevalent through the world—especially in the tropics where most of the developing nations are found—are rare or nonexistent in this country. A drug that is useful against such a disease may never receive adequate testing in this country to warrant its approval here.

Again, under the existing law, such a drug could not be exported from the United States for general use in other countries of the world—even if it had received approval in these other nations. Neither could a qualified drug company in this country contract to produce a drug for a foreign country.

Our recent decision not to approve the drug Depo Provera for use as an injectable contraceptive was a benefit/risk determination made in terms of the U.S. population for whom the drug was intended.

In announcing our decision, I made it clear that the drug, which is approved for use as a contraceptive in nearly 70 nations, may well have favorable benefit/risk ratios in those other countries.

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Animal studies have demonstrated that the drug may pose serious potential risks in long-term usage.

The availability in this country of many safe and effective alternative methods of contraception and sterilization precludes the need in the United States for a long-term, potentially high-risk injectable contraceptive.

However, in nations with serious overpopulation and related health problems, these potential risks could very well be acceptable when weighed against the potential benefits of the use of Depo Provera as one element in a comprehensive family planning program.

We are writing a letter to the foreign governments involved and the international health organizations to explain that our decision was made solely in terms of the U.S. population.

I would like to provide a copy of this letter for the record.

[The letter referred to follows:]

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION
ROCKVILLE, MARYLAND 20852

Monsieur le Ministre de la Sante
de la Republique populaire d'Angola
Luanda,
ANGOLA

Gentlemen:

On March 7, 1978 the United States Food and Drug Administration (FDA) notified the Upjohn Company that approval had been denied to market Depo-Provera (medroxyprogesterone acetate) Sterile Aqueous Suspension, 150 milligrams, for use as an intramuscular contraceptive for women in the United States. The decision was based on the grounds that the benefits of Depo-Provera for contraception in the United States do not justify the potential risks to the user.

For the information of World Health Organization members, and all other interested parties, the considerations on which FDA made this decision are as follows:

1. Safety questions raised by studies in beagle dogs showing an increased incidence of mammary tumors associated with the drug have not been resolved. Benign tumors in the dogs occurred at the human dose (on a mg/kg basis), and benign and malignant tumors occurred at 25 times the human dose over a period of three years. No intermediate doses were studied. Although the tumors at the human dose level were benign there were too few animals to ascertain the propensity for malignancy at doses lower than 25 times the human dose. Of the 4 dogs studied at this dose level only 2 survived for as long as 5 years.

   The U. S. manufacturer of Depo-Provera claims that there does not appear to be an increased incidence of mammary tumors in women exposed to Depo-Provera, but studies have been inadequate to make such a claim with any degree of confidence.

2. The availability in this country of many safe and effective alternative methods of contraception and sterilization lessens the need for a long-term, potential high-risk injectable contraceptive. No clear evidence has been submitted to show that a significant patient population in need of the drug exists in the United States. Since October 1974, when FDA stayed the order providing for patient labeling for Depo-Provera for contraception, to the present time, there has been no clear demand from the medical community for Depo-Provera for contraceptive use.

3. Irregular bleeding disturbances caused by the drug often result in the administration of estrogen, imposing an added risk factor and decreasing the benefits of a progestogen-only contraceptive. Although the usefulness of this approach has been debated, estrogen supplement for the control of bleeding has been reported in numerous studies, i.e., Powell, L.C., and Seymour, R.J., Am. J. Obstet. Gynecol. 110:36, 1971 Harnecker, J. et al., Proceedings of the Sixth World Congress on Fertility and Sterility, Tel Aviv, 1968, p. 27; and El-Habashy, M.A., Mishell, D.R. and Moyer, D.L., Obstet. Gynecol. 35:51, 1970. The use of estrogens in cases where there are severe bleeding disorders also has been reported by Dr. Edwin B. McDaniel in the McCormick Hospital program at Chiang Mai, Thailand.

4. Exposure of the fetus to medroxyprogesterone, if the drug fails and pregnancy occurs, poses a risk of congenital malformations. This risk is enhanced by the prolonged action of the drug.

We wish to emphasize that the benefit-risk judgment made for the United States is not necessarily appropriate for other countries, and the FDA's failure to approve a drug does not necessarily signify that it is unsafe for contraceptive use in other countries. The balancing of risks and benefits in deciding on a product's appropriateness should be undertaken by each nation in light of its own circumstances and needs. We recognize that the benefit-risk considerations may not be the same in other countries of the world as they are in the United States. Nations with a higher birth rate, lower physician-to-patient ratio, and less readily available or acceptable alternative contraceptive methods, would of course have different benefit-risk considerations.

The Administration recently submitted to Congress major new drug legislation that would, among other things, change the current law governing the export of drugs from the U.S. Under the proposed Act, a drug unapproved for use in this country could be exported provided that the drug meets the specification of the foreign purchaser, and that the Government of the country of destination has approved the importation and distribution of the drug. This is essentially the policy the Congress adopted in 1976 when it considered the export policy for medical devices in the Medical Device Amendments.

The proposed drug legislation also provides for assistance to foreign governments lacking the technical resources to evaluate the safety and efficacy of a drug offered to it. The bill authorizes the exchange of drug information in our possession with foreign health officials and international organizations such as the World Health Organization. The current law's export prohibitions deny potential benefits to both the health and scientific capabilities of foreign nations.

Even without the proposed new authorities, we are in a position to provide assistance to foreign governments in helping them to make decisions about drugs. In the case of Depo-Provera, for example, we recently met with a representative of the World Health Organization and offered to provide summaries of our evaluations of the safety and efficacy data of this drug, transcripts of advisory committee meetings during which benefit/risk considerations were weighed, and other data that might assist foreign countries in deciding whether to import it. To the extent we are able, we will continue to cooperate with the World Health Organization and other appropriate organizations by providing data on this or any other drug or device being considered for use in other nations.

Sincerely yours,

Donald Kennedy
Commissioner of Food and Drugs

Mail List for Depo-Provera

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Dr. KENNEDY. The subcommittee may be aware of a recent Washington Post editorial on Depo Provera.

The editorial states, in part, that:

> We do not believe on principle that drugs barred from certain uses in this country should necessarily be barred from export for foreign countries if the transactions follow guidelines proposed in the Carter administration's drug regulation bill now before Congress.

This editorial manages to express, for a change, almost exactly our views on this particular subject.

[The editorial referred to follows:]

Food And Drug Administration Press Office

Daily Clipping Service

MONDAY, JULY 3, 1978

The Depo Provera Question

SHOULD THE United States permit American drug companies to sell to foreign governments drugs that have not been approved for use in this country? That's the Depo Provera question. It's available for use in this country in treating certain types of cancer. But last month the Food and Drug Administration banned its use here as a contraceptive, after finding in a four-year study that it may cause other types of cancer, irregular uterine bleeding and possible birth defects. Federal regulations bar export of any drug not approved for use at home.

Some underdeveloped nations nonetheless wish to buy the drug direct from its American manufacturer. It's cheap and, because it needs to be injected only once every 90 days, it's attractive to countries where illiteracy and a shortage of medical personnel inhibit the use of other types of contraceptives. Officials of those countries resent the American ban, viewing it as a vote of no confidence in their ability to judge what's best for them. They criticize the United States for not exporting something the government considers too risky for Americans to use.

We do not believe on principle that drugs barred from certain uses in this country should necessarily be barred from export to foreign countries. But there is a big "if": They should not be barred from export if the transactions follow guidelines proposed in the Carter administration's drug-regulation bill now before Congress. These would require foreign governments to certify their request for the drugs; and American producers and sellers to disclose the results of all testing of that drug. In addition, the secretary of health, education and welfare could veto any sale determined not to be in the American public interest.

Those guidelines, in our view, would guard against blatantly fraudulent deals while allowing foreign countries to acquire—at their own risk, well known to them in advance—the drugs they feel they need to deal with what they perceive to be urgent social and medical problems.

THE WASHINGTON POST
Saturday, July 1, 1978

Dr. KENNEDY. A clear parallel is to be found in another area of FDA's jurisdiction.

In South America, there is a need for earlier generation, manually collumated X-ray machines no longer approved for use in the United States.

In this country, X-ray devices that automatically collumate or shrink the size of an X-ray field are preferred to devices that can only do that same thing manually. We have found that poor operation of the manual machines by U.S. technicians has frequently resulted in unnecessary overexposures.

The manually collumated machines are still used successfully in some European and Asian countries without causing unnecessary exposure to patients. The manual machines are needed in most South American countries, because these countries do not have the equipment or the skilled engineering technicians to maintain the automated collumated equipment.

The Pan American Health Organization recognizes this problem and fully supports the use of the manual equipment in South American countries.

Obviously, for these countries, the benefits of having X-ray equipment available for use outweigh the potential risks of unnecessary exposure from manual operation.

Incidentally, such nations may be able to minimize those risks better by having radiologists or other better trained people doing a larger proportion of the exposures.

You also asked, Mr. Chairman, that I discuss FDA's policy regarding the export of foods, food and color additives, cosmetics, and medical devices that have been banned or that do not meet health or safety standards.

In general, the law states that products within these categories intended for export are not considered adulterated or misbranded if they are: (1) In accord with the specifications of the foreign purchasers; (2) if they are not in conflict with the laws of the country to which they are intended to be exported; (3) if they are labeled on the outside of the shipping package that they are intended for export; and (4) if they are not sold or offered for sale in the United States.

For medical devices, additional criteria have to be met.

Devices that require performance standards or premarket approval must meet all the same requirements specified in the law for domestically marketed products before they can be exported.

The law provides that devices banned in the United States may be exported, but only if the Secretary has determined that the exportation of the device is not contrary to public health and safety and meets the approval of the country to which it is being shipped.

It is the responsibility of the exporting firm to inform the FDA of export shipments and to obtain a determination from the agency that a banned device, or one that does not comply with either standard or premarket approval requirements, is nevertheless suitable for export.

Foods, food and color additives, and cosmetics may be exported if they meet the four criteria that I listed a moment ago.

Although we don't have authority to prevent the exportation of articles that meet these requirements, we do attempt to inform the

appropriate authorities in the destination country if we have any reason to believe that the article may be harmful.

Exporters of these articles are not required by law to obtain our prior permission before making an export shipment, any more than domestic shippers of these articles are required to do so before making shipments in interestate commerce.

Consequently, the export shipment may be outside our jurisdiction before we learn of it.

Other problems may arise from difficulties in obtaining an official ruling from the appropriate officials of the destination country about whether the shipment complies with their laws or of ascertaining whether the shipment accords with the specifications of the foreign purchaser.

Some foreign countries have minimized these difficulties by means of a requirement similar to that of section 801(a)(2) of our act, which reads:

> If such article is forbidden or restricted for sale in the country in which it was produced or from which it was exported, then such article shall be refused admission.

As in the case of drugs and devices, current export policy for foods and food and color additives can be beneficial to foreign countries.

There are obvious advantages, for example, for countries with an insufficient supply of certain foods to import products that despite a failure to meet stringent U.S. standards may nevertheless be safe for consumption and much desired in those countries.

On the other hand, the export provisions covering these product categories provide for fewer safeguards than those for drugs and devices to prevent the export of potentially hazardous substances.

As Esther Peterson reported to you yesterday, Mr. Chairman, the administration is currently conducting a review of the export policies that govern all potentially hazardous products, including those regulated by the FDA.

We are actively participating in this review and are carefully reexamining our policies to determine whether any additional changes should be recommended to Congress at this time.

As you may know, last year the FDA joined with the three other Federal regulatory agencies that regulate hazardous substances—the Environmental Protection Agency, the Occupational Safety and Health Administration, and the Consumer Product Safety Commission—to form the Interagency Regulatory Liaison Group—IRLG.

One of the main purposes of the IRLG is to bring about greater coordination and ccoperation on policy matters.

Within the framework of the administration study, we will work closely with the other IRLG agencies to assure that any changes recommended will result in maximum possible uniformity in the export policies of our laws and regulations.

I might just add that my own general view of the matter, for what it is worth, is that we ought to be aiming at a general principle here that recognizes the differences, and the location specificity, of risk/benefit determinations about drugs and other kinds of risky, but useful, technologies. The principle recognizes that those are decisions for particular nations to make and allows that kind of flexibility in export policy. But it also should build in very careful safeguards, so

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that the person responsible, whether it is the Secretary of the department or the head of an agency, has an override available to him to use in the event of a negative judgment about the impact of that technology on the public health—either on the nation which is importing it or the citizens of the United States.

Thank you, Mr. Chairman. I will be happy to answer any questions you may have.

Mr. ROSENTHAL. The problem, Commissioner, up to now in many respects has been notice—the ability to adequately notify foreign governments.

Yesterday testimony indicated, and the records that the subcommittee has in its presence indicate, that many notifications never get past the embassy. They never reach foreign governments.

There is obviously an extraordinarily sloppy and inefficient and inadequate notification procedure.

Dr. KENNEDY. I think that is an important point, Mr. Chairman.

We are certainly prepared to concede that present notification mechanisms are totally lacking in the case of foods and probably are inadequate in the case of drugs and perhaps other product categories which I know less about.

I would not want to leave you with the impression, however, that we, in particular, rely entirely or even primarily on State Department notification channels.

Mr. ROSENTHAL. Tell us what you did.

Dr. KENNEDY. We notify the World Health Organization which notifies member governments. We also have a list of foreign governments with whom we communicate directly. They have indicated a desire to know about the nature of negative drug approval decisions in the United States.

Mr. ROSENTHAL. On the negative decision, do you have a firm, precise procedure where notification is made to foreign governments that have been purchasing or have been interested in purchasing the negatively approved or the negative decision drug?

Dr. KENNEDY. It might not be as firm as you might wish, Mr. Chairman. We do notify the World Health Organization, and we do notify a list of nations which I think we supplied you for the record earlier—or we will if we did not—of that decision.

We think that that net catches essentially the majority of potentially importing nations, although we cannot guarantee that in any particular instance it catches everyone.

Mr. ROSENTHAL. It says on some of the material that we have put together that the Bureau of Drugs communicates to several foreign countries concerning new drug approval actions.

Then the list of the drugs that we have and the countries that we have are Germany, France, Switzerland, Japan, Canada, Sweden, Australia, the Philippines, Israel, and Egypt. What about the rest of the world?

Dr. KENNEDY. I am not sure whether the list you have been given is an inclusive list of the nations that we would inform in the event of a withdrawal. That is the first response I would make.

We can find that out and supply it for the record.

[The information referred to follows:]

The list of nations that Chairman Rosenthal referred to at page 16, line 2, represents those nations that have expressed a desire to be directly informed of significant drug regulatory actions by FDA. This list does not represent the total number of nations that are notified at any given time concerning any given drug regulatory action. Where a drug that is in wide use internationally is the subject of a significant regulatory action, the FDA also notifies the World Health Organization (WHO). WHO then transmits this information to its member nations. WHO currently comprises 151 member nations. The FDA also routinely notifies the State Department to notify United States embassies around the world concerning significant regulatory actions.

Dr. KENNEDY. Second, we would also inform the World Health Organization, which does have a mechanism for informing other countries.

Mr. ROSENTHAL. How do you know that?

Dr. KENNEDY. They tell us.

Mr. ROSENTHAL. Here is the point I am trying to get at. Let me see if I can develop a hypothetical situation.

Suppose there was an adverse decision made about a drug. Let's assume for the sake of discussion that consumption of this drug was potentially dangerous, unhealthy, and hazardous.

Do you feel you have met your responsibility to society by notifying the World Health Organization? Do you have any additional responsibilities?

Dr. KENNEDY. I think we have a responsibility to make as sure as we can that the information gets to every government that is a significant importer of that drug.

Mr. ROSENTHAL. Let's stop there. How do you do that?

Dr. KENNEDY. I think we would want to do it by inquiring more fully about the distribution that the World Health Organization makes of that.

Mr. ROSENTHAL. Have you ever done that?

Dr. KENNEDY. I have not personally done it in preparation for this hearing, Mr. Chairman, but I will be delighted to do so and supply it for the record.

Dr. John Jennings who is with me is Director of our Office of International Affairs. If you would permit, he might be able to expand.

Mr. ROSENTHAL. What we would like for the record is an example of a decision that was adverse. What happened and what was the scenario, what the chronology was and how far you followed the giving of that information to foreign governments.

[See p. 113.]

Mr. ROSENTHAL. Can anybody do that in any particular case?

Do you have any "Return Receipt Requested" or anything like that?

Dr. JENNINGS. Mr. Chairman, I might just expand a little on what the World Health Organization does.

There are currently 151 member nations in the World Health Organization.

For about 15 years, to my knowledge, we have been providing them with specific information regarding adverse actions on drugs.

Mr. ROSENTHAL. In every single case.

Dr. JENNINGS. Just about.

Mr. ROSENTHAL. What do you mean?

Dr. JENNINGS. Because it is run by human beings, and I am sure that once in awhile something doesn't get reported.

Mr. ROSENTHAL. How is that possible?

How many adverse decisions do you make a year?

Dr. JENNINGS. Not many.

Mr. ROSENTHAL. Ten, twenty, thirty?

Dr. JENNINGS. Probably fewer than that of the kind I think you are interested in.

Mr. ROSENTHAL. And you are not sure that of the 20—you can't send out communications on 20 decisions?

Dr. KENNEDY. Mr. Chairman, I think that all Dr. Jennings is trying to do is to indicate to you that we are not prepared to certify that in all of recorded history no human error has been made in this system.

The system is one that is a routine procedure in the agency, and we are prepared to say that it works.

Mr. ROSENTHAL. Dr. Kennedy, honestly I don't need an interpreter. I understand what he was saying.

Very respectfully, what you have just told me is rhetoric.

I know that human beings run agencies, and I know there is human error. I also know that for about 50 cents you buy a book and you keep track of the decisions and you keep track of the notifications.

Does anybody in the FDA have a book in which there is a compilation of the decisions and the notifications?

Dr. JENNINGS. I don't know the exact statistics, but I would estimate that there were probably about 100 notifications over the past 12 years or so by the World Health Organization.

I would estimate that probably two-thirds of those originated with the U.S. Food and Drug Administration.

Mr. ROSENTHAL. I appreciate that. I merely want to know——

Dr. JENNINGS. We can get that information for you, specifically, as to particular actions that were taken.

I can also tell you that in certain instances—and I can cite an example which is several years old—we felt there was a particular need to go beyond this. We went, say, to the State Department and used the embassies to make sure——

Mr. ROSENTHAL. What happened? Did you follow it up? Did you get any return receipt or any confirmation that the message had been delivered?

Dr. JENNINGS. Yes. We didn't get a return receipt for each capsule that had been distributed, but we had evidence that the practice to which we had taken objection ceased. And that happened to be the exportation of a drug that we felt was hazardous.

Mr. ROSENTHAL. Can you tell us the name of that drug?

Dr. JENNINGS. Yes. It was chloramphenicol.

Mr. ROSENTHAL. Can you submit for the record copies of memorandums where you notified the State Department and where they sent you back a notification saying that they had notified these other countries?

I would like to make sure that the process is working.

Dr. JENNINGS. I think that we can provide documentation that the State Department was notified and took action; that is, they sent out telegrams to the appropriate embassies.

I will undertake to do that.

[The material referred to follows:]

July 7, 1971

CS-40

WHO Drug Information

Dr. John Jennings
Associate Commissioner for Medical Affairs

Pursuant to resolution WHA16.36 of the Sixteenth World Health Assembly on Clinical and Pharmaceutical Evaluation of Drugs, FDA communicated to WHO labeling requirements for chloramphenicol.

On several occasions we discussed the importance of FDA clearly outlining its position to the world through the World Health Organization. This was prepared, cleared, and has now been transmitted to member countries. See Drug Information Sheet No. 95, attached.

K. E. Taylor, D.V.M.
Director
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Enclosure

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In reply please refer to:
Prière de rappeler la référence:

The Director-General of the World Health Organization presents his compliments and, pursuant to resolution WHA16.36 of the Sixteenth World Health Assembly on Clinical and Pharmacological Evaluation of Drugs, has the honour to transmit information on drugs which he has received under provision (2) of that resolution.

Enclosed is drug information sheet No. 95. (The original communication from which this information is drawn is retained in the archives of WHO for consultation).

Geneva, 25 June 1971

ENCLS: As mentioned

DIS/71.95

WORLD HEALTH ORGANIZATION

ORGANISATION MONDIALE DE LA SANTÉ

CLINICAL AND PHARMACOLOGICAL EVALUATION OF DRUGS

DRUG INFORMATION No. 95
25 June 1971

Resolution WHA16.36

ORIGINAL : ENGLISH

The Food and Drug Administration of the United States of America has communicated to the World Health Organization that labeling for oral and parenteral forms of chloramphenicol[1] should contain - inter alia - the following:

INDICATIONS

Chloramphenicol must be used only in those serious infections for which less potentially dangerous drugs are ineffective or contraindicated. Chloramphenicol, however, may be chosen to i n i t i a t e antibiotic therapy on the clinical impression that one of the conditions below is believed to be present; in vitro sensitivity tests should be performed concurrently so that the drug may be discontinued as soon as possible if less potentially dangerous agents are indicated by such tests. The decision to c o n t i n u e use of chloramphenicol rather than another antibiotic when both are suggested by in vitro studies to be effective against a specific pathogen should be based upon severity of the infection, susceptibility of the pathogen to the various antimicrobial drugs, efficacy of the various drugs in the infection and the important additional concepts summarised under "warning".

1. Acute infections caused by Salmonella Typhi: Chloramphenicol is a drug of choice. It is not recommended for the routine treatment of the typhoid "carrier state".

2. Serious infections caused by susceptible strains in accordance with the concepts expressed above:

a. Salmonella species

b. H. influenzae, specifically meningeal infections

c. Rickettsia

d. Lymphogranuloma-psittacosis group

e. Various gram-negative bacteria causing bacteremia, meningitis, or other serious gram-negative infections

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[1] chloramphenicol is the International Nonproprietary Name (INN) proposed by WHO for D-threo-2,2-dichloro-N-[β-hydroxy-α-(hydroxymethyl)]-p-nitrophenethylacetamide

f. Other susceptible organisms which have been demonstrated to be resistant to all other appropriate antimicrobial agents

3. Cystic Fibrosis Regimens.

CONTRAINDICATIONS

Chloramphenicol is contraindicated in individuals with a history of previous hypersensitivity and/or toxic reaction to it. It must not be used in the treatment of trivial infections or where it is not indicated, as in colds, influenza, and infections of the throat, or as a prophylactic agent to prevent bacterial infections.

WARNING

Serious and fatal blood dyscrasias (aplastic anemia, hypoplastic anemia, thrombocytopenia, and granulocytopenia) are known to occur after the administration of chloramphenicol. In addition, there have been reports of aplastic anemia attributed to chloramphenicol which later terminated in leukemia. Blood dyscrasias have occured after both short term and prolonged therapy with this drug.

Precautions: 1. It is essential that adequate blood studies be made during treatment with the drug. The drug should be discontinued upon appearance of reticulocytopenia, leukopenia, thrombocytopenia, anemia, or any other blood study findings attributable to chloramphenicol; however, it should be noted that such studies do not exclude the possible later appearance of the irreversible type of bone marrow depression.

2. Repeated courses of the drug should be avoided if at all possible. Treatment should not be continued longer than required to produce a cure with little or no risk of relapse of the disease.

3. Concurrent therapy with other drugs that may cause bone marrow depression should be avoided.

4. Excessive blood levels may result from administration of the recommended dose to patients with impaired liver or kidney function, including that due to immature metabolic processes in the infant. The dosage should be adjusted accordingly or, preferably, the blood concentration should be determined at appropriate intervals.

5. There are no studies to establish the safety of this drug in pregnancy.

6. Since chloramphenicol readily crosses the placental barrier, caution in use of the drug is particularly important during pregnancy, at term or during labor because of potential toxic effects on the fetus (gray syndrome).

7. Precaution should be used in therapy of premature and full term infants to avoid "gray syndrome" toxicity (See "Adverse Reactions"). Serum drug levels should be carefully followed during therapy of the new-born infant.

8. Precaution should be used in therapy during lactation because of the possibility of toxic effects on the nursing infant.

9. The use of this antibiotic, as with other antibiotics, may result in an overgrowth of nonsusceptible organisms including fungi. If infections caused by nonsusceptible organisms appear during therapy, appropriate measures should be taken.

ADVERSE REACTIONS

1. Blood dyscrasias: The most serious adverse effect of chloramphenicol is bone marrow depression. Serious and fatal blood dyscrasias (aplastic anemia, hypoplastic anemia, thrombocytopenia, and granulocytopenia) are known to occur after the administration of chloramphenicol.

An irreversible type of marrow depression leading to aplastic anemia with a high rate of mortality is characterized by the appearance weeks or months after therapy of bone marrow aplasia or hypoplasia. Peripherally, pancytopenia is most often observed, but in a small number of cases only one or two of the three major cell types (erythrocytes, leukocytes, platelets) may be depressed. A reversible type of bone marrow depression, which is dose related, may occur. This type of marrow depression is characterized by vacuolization of the erythroid cells, reduction of reticulocytes, and leukopenia and responds promptly to the withdrawal of chloramphenicol.

An exact determination of the risk of serious and fatal blood dyscrasias is not possible because of lack of accurate information regarding (a) the size of the population at risk, (b) the total number of drug-associated dyscrasias, and (c) the total number of nondrug associated dyscrasias.

In a report to the California State Assembly by the California Medical Association and the State Department of Public Health in January 1967, the risk of fatal aplastic anemia was estimated at 1:24,200 to 1:40,500 based on two-dosage levels.

There are reports of aplastic anemia attributed to chloramphenicol which later terminated in leukemia.

Paroxysmal nocturnal hemoglobinuria has also been reported.

2. Gastrointestinal reactions: Nausea, vomiting, glossitis and stomatitis, and diarrhea and enterocolitis may occur in low incidence.

3. Neurotoxic reactions: Headache, mild depression, mental confusion, and delirium have been described in patients receiving chloramphenicol. Optic and peripheral neuritis have been reported; usually following long term therapy. If this occurs, the drug should be promptly withdrawn.

4. Hypersensitivity reactions: Fever, macular and vesicular rashes, angioedema, urticaria, and anaphylaxis may occur. Herxheimer reactions have occurred during therapy for typhoid fever.

5. "Gray syndrome": Toxic reactions including fatalities have occurred in the premature and newborn; the signs and symptoms associated with these reactions have been referred to as the "gray syndrome". One case of "gray syndrome" has been reported in an infant born to a mother having received chloramphenicol during labor. One case has been reported in a 3-month infant. The following summarizes the clinical and laboratory studies that have been made on these patients:

a. In most cases therapy with chloramphenicol had been instituted within the first 48 hours of life.

b. Symptoms first appeared after 3 to 4 days of continued treatment with high doses of chloramphenicol.

c. The symptoms appeared in the following order: Abdominal distension with or without emesis; progressive pallid cyanosis; vasomotor collapse, frequently accompanied by irregular respiration; and death within a few hours of onset of these symptoms.

d. The progression of symptoms from onset to exitus was accelerated with higher dose schedules.

e. Preliminary blood serum level studies revealed unusually high concentrations of chloramphenicol (over 90 mcg./ml. after repeated doses).

f. Termination of therapy upon early evidence of the associated symptomatology frequently reversed the process with complete recovery.

CHLORAMPHENICOL FOR INTRAVENOUS ADMINISTRATION

As soon as is feasible an oral dosage form of chloramphenicol should be substituted for the intravenous form because adequate blood levels are achieved with chloramphenicol by mouth.

SCI-8

DEPARTMENT OF STATE

AIRGRAM

INCO-DRUGS 17
cc: BD-1
cc BD-14
cc: BD-Jennings

FILE DESIGNATION

Original to be Filed in ____________ Decentralized Files.

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CA-3184

HANDLING INDICATOR

NO.

TO : ALL ARA Diplomatic Posts

JUN 10 3 18 PM '70

FROM : DEPARTMENT OF STATE

DATE:

SUBJECT : Labeling for Chloramphenicol

REF :

FROM DEPARTMENT OF HEALTH, EDUCATION AND WELFARE

We have been informed by the Food and Drug Administration (FDA) of sales of the antibiotic chloramphenicol (Parke, Davis' trade name Chloromycetin) to Latin American countries with labeling which is believed to constitute a hazard to health. This antibiotic is manufactured in Puerto Rico, but it is not certified by the FDA and therefore does not have to conform with the labeling (including the "physician's brochure") required for such products in interstate commerce. The FDA believes that the omission in the Spanish-language version of mention of serious and fatal blood dyscrasias (aplastic anemia, hypoplastic anemia, thrombocytopenia, and granulocytopenia) known to occur after the administration of chloramphenicol should be brought to the attention of the medical profession in the countries where this antibiotic may be prescribed, through the responsible health authorities. Although an exact determination of the risk of fatal blood dyscrasias is not possible, it has been estimated at 1:24,200 by the California Medical Association and the State Department of Public Health.

The Spanish-language version of the Chloromycetin labeling also contains indications for use in conditions where the FDA knows of no data to substantiate its effectiveness: measles, mumps, ulcerative colitis, herpes zoster, chicken pox, and infectious hepatitis. Many of the other indications listed are as well treated with other, safer antibiotics. In addition, Chloromycetin succinate, the injectable form, produces very low blood levels when administered intra-muscularly, and this route of administration

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FORM 10-64 DS-323

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For Department Use Only

Drafted by:	Drafting Date:	Phone No.:	Contents and Classification Approved by:
[illegible] DHEW/FDA:[illegible]	6/8/70	22139	SCI- Nelson F. Sievering, Jr.

Clearances: DHEW/FDA: [illegible], JJCummings and JJDiLorenzo
ARA/LA- John [illegible] Crimmins
Ely [illegible]
L- L/SCI-[illegible]

CA-1

UNCLASSIFIED

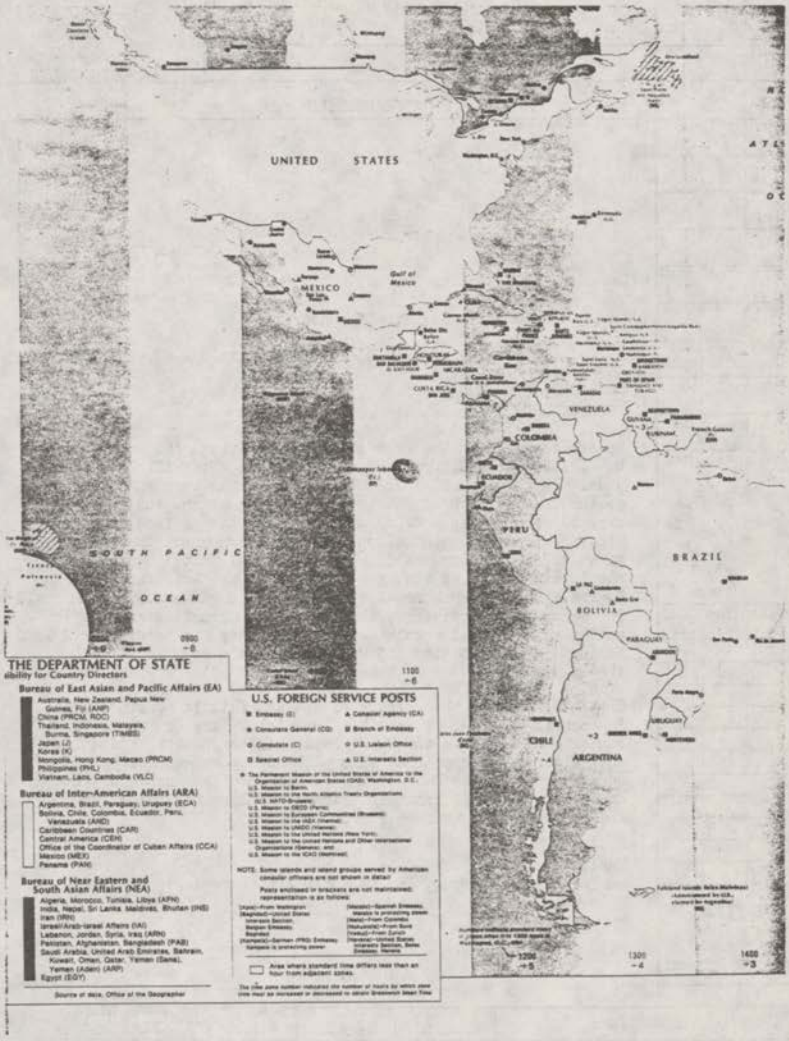
PAGE 2

has been shown to be ineffective in at least two disease conditions (intramuscular and subcutaneous use are not permitted in the FDA-approved labeling.)

A meeting has been held with Parke, Davis and Co. and we anticipate necessary changes in such labeling. FDA also advises while Parke, Davis and Co. is the only American firm that exports chloramphenicol to the Latin American countries, there are other manufacturers of this drug that supply the Latin American market, in which the labeling may also fail to include mention of serious and fatal blood dyscrasias.

Interested persons may obtain a copy of the current labeling for chloramphenicol distributed in the United States by communicating directly with the FDA.

ROGERS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Source of data, Office of the Geographer
U.S. FOREIGN SERVICE POSTS
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U.S. Liaison Office
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Area where standard time differs less than an hour from adjacent zones.
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AIRGRAM TP

Original to be Filed in CUM Decentralized Files. FILE DESIGNATION

UNCLASSIFIED A-36

HANDLING INDICATOR N.O.

TO : Amembassy PANAMA

FROM : Department of State DATE: Jan 27 9 00 AM '70

SUBJECT : Panamanian Registration Requirements

REF : Your A-167 of June 4, 1969 and State's A-29 of May 20, 1969

FROM COMMERCE

In accordance with the Post's request we attach two copies of the U. S. Federal Food, Drug and Cosmetic Act. You will note that under Chapter II - DEFINITIONS, 201(a) 1, the term "State" applies to the Commonwealth of Puerto Rico throughout the Act, with one exception: paragraph 702(a) exempts shipments of food from Puerto Rico from general examination and inspection until they reach the first point of entry within the continental United States. It should also be noted that, for purposes of the Act, trade between Puerto Rico and anywhere else is considered "interstate commerce." It seems clear, therefore, that drugs and cosmetics are subject to the same federal regulations whether they are manufactured in Illinois or Puerto Rico and whether they are sold locally or abroad.

COMMENTS: Should the wording of the Act fail to convince the Panamanian Minister of Health, a special ruling on the matter can be obtained from the U. S. Department of Health, Education and Welfare. We hope that this will not prove necessary, and we request that the Embassy inform Commerce/Washington of any change in or clarification of Panama's policy regarding drug and cosmetic imports from Puerto Rico.

ROGERS

Enclosures:
Federal Food, Drug, and Cosmetic Act (2 copies)

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POST ROUTING

TO:	Action	Info.	Initials
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UNCLASSIFIED

FORM DS-323 10-64

For Department Use Only

Drafted by: R.H.Batcheller, BIC-886 /dea | Drafting Date: 6/24/69 | Phone No.: x-2322 | Contents and Classification Approved by: E/OMA/RMP:HCMallin

Clearances: Bernard J. Cahill, Acting Dir.
L.J.Comella - Commerce
ARA/PAN/A.P.Mulhorn
L/E-Mr. Hallis (in subs)
Clrd. sub. w/ Howard R. Harrison, General Counsel's Office, HEW
BALPA A:COMM/WMHayden
State (phone)

AIR PRIORITY UNCLASSIFIED

FILE DESIGNATION A-167

TO : Department of State

FROM : Amembassy PANAMA DATE: June 4, 1969

SUBJECT : Panamanian Registration Requirements: Distinction Between Continental U.S. and Puerto Rican Origin

REF : Department's A-29, May 20, 1969

FOR COMMERCE

1. Independent of any action taken by the Embassy in response to the referenced airgram, the Ambassador on May 27 received a letter from the Minister of Health of the Panamanian Government requesting the Ambassador to inform him whether the laws and regulations in Puerto Rico relating to the production and authorization of pharmaceutical products are the same as those applicable in the United States. The Minister of Health stated that the information was necessary for the enforcement of Article 1 of Decree No. 93 of 1962. This article requires laboratories outside Panama to submit a document certified by a Panamanian Consul affirming that the laboratory is authorized to produce pharmaceutical products in the country in which it resides. Importation of the products is prohibited without this certification. A copy of the letter from the Minister of Health is enclosed.

2. It should be noted that it is normal practice for the Bureau of Census and Statistics of the Panamanian Government to list Puerto Rico separately from the United States in compiling trade statistics. However, the difficulties encountered by Alberto Culver Products, Inc. appear to stem from the fact that the products fall within the categories covered by Decree No. 93. Presumably, if, as the Embassy assumes, the manufacture of pharmaceutical products in Puerto Rico comes within the jurisdiction of the U.S. food and drug laws, the need to re-register products to reflect Puerto Rican origin will be obviated.

3. ACTION REQUESTED: The Embassy will appreciate being informed specifically of the section of law which states that the food and

ENCLOSURE: As Stated

UNCLASSIFIED

FORM 10-64 DS-323

Drafted by: ECON:RStevenson:jmh — Drafting Date: June 4/69 — Contents and Classification Approved by: DCM:DPDowns

Clearances: ECON:WDMiller

AIR PRIORITY UNCLASSIFIED A-167

drug laws applicable in the United States are also applicable to Puerto Rico. The exact text and references should be provided so that they may be incorporated in a response to the Ministry. If appropriate, copies of any relevant U.S. legislation should also be forwarded for transmittal to the PJG.

ADAIR

Mr. ROSENTHAL. Did the process also include that the Embassy thus distributed the information they received?

Dr. JENNINGS. I am not sure I can document just how far each individual U.S. embassy went in that country to see that the actions of that government were in keeping with our notification. But I think that I can assure you that the government responsible for the health and safety of its citizens was appropriately notified. Beyond that, I doubt that we have any jurisdiction.

Mr. ROSENTHAL. Commissioner Kennedy, this legislation that you speak of which is proposed, what is the status of that? I am not aware of where it is at the moment.

Dr. KENNEDY. It was introduced earlier in this session, Mr. Chairman. Hearings have been held by Chairman Rogers' subcommittee, and it is proceeding to staff markup in the House. On the Senate side, it is about to be marked up in the Senate Health Subcommittee.

Mr. ROSENTHAL. Is it your prognosis that that bill will be reported out essentially as it was submitted by the administration, or do you hesitate to make such a judgment?

Dr. KENNEDY. I am hoping, but I don't know.

Mr. ROSENTHAL. Some of the notification procedures that are explicit in the bill, can they be implemented by Executive order?

Dr. KENNEDY. I would thing so—to a limited degree at least, Mr. Chairman. I really hadn't thought about that, but I think that many of them probably could.

Mr. ROSENTHAL. Would you submit for the record a memorandum detailing which areas of notification in the proposed legislation could be put into practice by Executive order?

Suppose somewhere along the way you ran into a legislative landmine and this bill did not become law in the fashion in which it was submitted. There might be other remedies available that should be exercised.

Dr. KENNEDY. Yes. I think that is a very worthwhile suggestion, Mr. Chairman.

We will certainly try that with that and other portions of the bill.

[The material referred to follows:]

32-427 O - 78 - 9

As noted, the Food and Drug Administration (FDA) uses a number of resources to communicate to foreign governments significant regulatory actions respecting products subject to FDA regulation. Under section 134 of the pending Drug Regulation Reform Act of 1978, the current drug export policy would be amended by permitting the export of drugs that are not approved for domestic marketing. This change in policy is supported by the recognition that there may be drugs that are inappropriate according to domestic standards but that have an important therapeutic potential according to unique foreign settings.

Section 135(a)(18) of the Reform Act requires an exporter of an unapproved or noncomplaint drug to notify the importing government of the legal status of that drug in this country. This form of notification cannot currently be required by exporters by other than legislative amendment because the law does not permit the export of an unapproved or non-complaint new drug.

Section 135 of the Reform Act would authorize the exchange of information with foreign governments and with international organizations concerning drugs. This exchange would include scientific and technical training of foreign personnel. Many of these activities are ongoing now. This form of international cooperation would be explicitly required as a matter of policy at any point by specific Executive Order.

Section 149 of the Reform Act would authorize the dissemination of information regarding the effectiveness, risks, safety and proper use of drugs, and other information that would avoid deception and promote public health. This information is currently disseminated, both domestically and internationally, through a number of FDA publications, as well as educational seminars and Agency consumer and professional information resources. A direct Executive mandate could address this activity.

Currently, certain drugs, such as antibiotics, insulin, and pre-1938 drugs, may be exported without any notice, even if products are misbranded or adulterated. A notification requirement respecting these products cannot be required of exporters by other than a legislative amendment of the Federal Food, Drug, and Cosmetic Act. An Executive Order could require the Secretary to notify foreign governments of known health hazards with these products, but this is being done now where such information becomes available to the Secretary (see attached documents).

WORLD HEALTH ORGANIZATION

ORGANISATION MONDIALE DE LA SANTE

CLINICAL AND PHARMACOLOGICAL EVALUATION OF DRUGS/DRUG EFFICACY/QUALITY, SAFETY AND EFFICACY OF DRUGS

DRUG INFORMATION CIRCULAR NO. 175

22 August 1977

Resolutions WHA16.36/WHA23.48/WHA26.31

ORIGINAL: ENGLISH

The United States Food and Drug Administration has informed the World Health Organization that approval has been suspended for phenformin[1,2] and general marketing of this drug will cease within 90 days (by October 23, 1977). The drug will remain available under a limited distribution system for a small patient population meeting action criteria.

This action results from evidence that phenformin can produce a fatal reaction known as lactic acidosis in some patients; risk of lactic acidosis is felt to outweigh the benefits of phenformin in all but a very limited patient population.

This drug was previously indicated in the USA only for symptomatic diabetics unresponsive to diet, and in whom sulfonylureas were ineffective, or in whom insulin could not be used. The decision of the FDA does not relate to any other oral antidiabetic agent currently available in the USA.

---

[1] phenformin is the International Nonproprietary Name (INN) proposed by WHO for 1-phenethylbiguanide.

[2] See also Drug Information Circular No. 170 dated 18 November 1976.

ORGANIZATION

1211 GENEVA 27 - SWITZERLAND
Telegr.: UNISANTE-Geneva

Tél. 34 60 61 Telex. 27821

DE LA SANTÉ

1211 GENÈVE 27 - SUISSE
Télégr.: UNISANTÉ-Genève

In reply please refer to:
Prière de rappeler la référence:

The Director-General of the World Health Organization presents his compliments and, pursuant to resolutions WHA16.36, WHA23.48 and WHA26.31 of the Sixteenth, Twenty-third and Twenty-sixth World Health Assemblies on Clinical and Pharmacological Evaluation of Drugs/Drug Efficacy/Quality, Safety and Efficacy of Drugs, has the honour to transmit information on drugs which he has received under provision of those resolutions.

Overleaf is drug information sheet No 172. (The original communications from which this information is drawn are retained in the archives of WHO for consultation).

Geneva, 17 December 1976

CLINICAL AND PHARMACOLOGICAL EVALUATION OF DRUGS/DRUG EFFICACY/QUALITY, SAFETY AND EFFICACY OF DRUGS

Resolutions WHA16.36/WHA23.48/WHA26.31

DRUG INFORMATION CIRCULAR No. 1

17 December 1976

ORIGINAL: ENGLISH

The United States Food and Drug Administration has informed the World Health Organization of a notice of withdrawal of approval of a new drug application with regard to the drug azaribine[1]. This action was requested by the FDA following notification by the manufacturer that side-effects, consisting of blood clots in the veins and arteries of patients, had been noticed. This drug received FDA approval in late February 1975, and was marketed in August 1975 for the treatment of severe and recalcitrant cases of psoriasis.

Now the FDA has called on all patients to discontinue using the drug immediately and to consult their physicians, adding that azaribine may cause life-threatening or fatal blood clots.

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[1] azaribine is the International Nonproprietary name (INN) proposed by WHO for 2-β-D-ribofuranosyl-as-triazine-3,5(2H,4H)-dione2',3',5'-triacetate.

WORLD HEALTH ORGANIZATION

ORGANISATION MONDIALE DE LA SANTE

CLINICAL AND PHARMACOLOGICAL EVALUATION OF DRUGS/QUALITY, SAFETY AND EFFICACY OF DRUGS

DRUG INFORMATION NO 159

Resolutions WHA16.36/WHA26.31

3 September 1975

ORIGINAL : ENGLISH

The United States Food and Drug Administration has informed the World Health Organization that it has amended the notice concerning the labelling conditions for diethylstilbestrol[1] and related drug products as published in the Federal Register[2] dated 4 August 1975, inter alia, as follows:

"The products are used in treatment of estrogen deficiency or other disease conditions. Because of a statistically significant association between maternal ingestion during pregnancy of diethylstilbestrol and the occurrence of vaginal carcinoma in the offspring, the labelling of all such products has previously been required to state that their use in pregnancy is contraindicated. An additional warning is now being required concerning the possible development of vaginal adenosis in postpubertal girls whose mothers received diethylstilbestrol during pregnancy.

Reports in the medical literature[3-7] indicate an association between the use of diethylstilbestrol and the occurrence of vaginal adenosis in postpubertal girls and young women whose mothers received diethylstilbestrol during their pregnancy."

---

[1] diethylstilbesterol is the international nonproprietary name (INN) proposed by WHO for trans-α,α-diethyl-4,4'-stilbenediol.

[2] Copies of the relevant paper issued by the Food and Drug Administration can be obtained from WHO on request.

[3] Herbst, A. L. et al. (1972) American Journal of Obstetrics and Gynecology, 40: 287

[4] Herbst, A. L. et al. (1974) American Journal of Obstetrics and Gynecology, 118: 607

[5] Herbst, A. L. et al. (1975) New England Journal of Medicine, 292: 334

[6] Stafl, A. et al. (1974) Obstetrics and Gynecology, 43: 118-128

[7] Sherman, A. I. et al. (1974) Obstetrics and Gynecology, 44: 531

"The Commissioner of Food and Drugs concludes that this association should be brought to the attention of physicians. Accordingly, it is required that the physicians package insert for preparations containing diethylstilbestrol or closely related congeners (including dienestrol,[1] hexestrol,[2] benzestrol,[3] and promethestrol (methestrol)[4]) include the following in the Warnings section:

'Vaginal adenosis has been reported in 30% to 90% of postpubertal girls and young women whose mothers received diethylstilbestrol or a closely related congener during pregnancy. This condition was found most frequently in those cases where diethylstilbestrol had been given in early pregnancy (first twelve weeks). The significance of this finding with respect to potential for development of vaginal adenocarcinoma is unknown. Periodic examination of such patients is recommended.'"

---

[1] dienestrol is the international nonproprietary name (INN) proposed by WHO for 4,4'-(diethylidene-ethylene)diphenol.

[2] hexestrol is the international nonproprietary name (INN) proposed by WHO for 4,4'-(1,2-diethylethylene)diphenol.

[3] benzestrol is the international nonproprietary name (INN) proposed by WHO for 4,4'-(1,2-diethyl-3-methyltrimethylene)diphenol.

[4] methestrol is the international nonproprietary name (INN) proposed by WHO for 4,4'-(1,2-diethylethylene)di-o-cresol.

CLINICAL AND PHARMACOLOGICAL EVALUATION OF DRUGS/QUALITY, SAFETY AND EFFICACY OF DRUGS

DRUG INFORMATION NO 150

6 April 1975

HFM. HFD

Resolutions WHA16.36/WHA26.31

ORIGINAL : ENGLISH

The United States Food and Drug Administration has informed the World Health Organization of a notice of withdrawal of approval of a new drug application with regard to a combination drug containing norethisterone[1] acetate and ethinylestradiol[2] as published in the Federal Register[3] dated 11 February 1975. These two drugs are contained in Gestest tablets used for pregnancy testing.[4] The Commissioner of Food and Drugs concluded, inter alia, as follows:

"Although the drug is effective as a presumptive test for pregnancy, there is a lack of proof of safety for that use in view of the potential danger in the presence of pregnancy and the availability of a number of very accurate chemical tests to detect pregnancy. The holder of the new drug application has waived its opportunity for a hearing, and no other interested person has requested a hearing."

"All identical, related, and similar drug products, as defined in 21 CFR 310.6, not the subject of an approved new drug application, are covered by the application reviewed and are subject to this notice."

"Shipment in interstate commerce of the above-listed product or of any identical, related, or similar product, not the subject of an approved new drug application, will then be unlawful."

---

[1] norethisterone is the International Nonproprietary Name (INN) proposed by WHO for 17α-ethynyl-17β-hydroxyestr-4-en-3-one.

[2] ethinylestradiol is the International Nonproprietary Name (INN) proposed by WHO for 17-ethynyl-estra-1,3,5(10)-triene-3,17β-diol.

[3] Copies of the relevant paper issued by the FDA can be obtained from WHO on request.

[4] Please see Drug Information Circular No: 144 dated 11 February 1975 on a similar subject.

ORGANIZATION DE LA SANTE

CLINICAL AND PHARMACOLOGICAL EVALUATION OF DRUGS/QUALITY, SAFETY AND EFFICACY OF DRUGS

DRUG INFORMATION NO 137

4 October 1974

Resolution WHA16.36/WHA26.31

ORIGINAL : ENGLISH

The Department of Health, Education and Welfare of the United States of America, has informed the World Health Organization of a Food and Drug Administration paper[1] on reserpine[2] announcing the establishment of an Expert Committee to evaluate retrospective studies which report a possible association between long-term treatment with two rauwolfia alkaloids and an increased risk of breast cancer in women over the age of 60. The two antihypertensive drugs are reserpine and rescinnamine[3]. Of the two, reserpine is more commonly prescribed for lowering blood pressure in hypertensive patients.

The findings are being reported in a series of three papers being published in the September 21, 1974, issue of Lancet, a prominent British Medical Journal.

In reviewing cases of newly diagnosed breast cancer, the investigators found that in selected groups of women, up to three times as many had a history of long-term therapy with reserpine than did women in a control group without breast cancer.

The department emphasized that reserpine and rescinnamine are the only antihypertensive drugs associated with the possible increased risk of breast cancer. The studies have not identified an increased cancer risk in hypertensive patients in general, or an increased risk associated with other widely used and effective antihypertensive drugs.

The department stresses the need for independent and complete review of the reports regarding the rauwolfia alkaloids and assures both physicians and the public that the questions raised by the three studies will be examined as thoroughly and as promptly as possible.

The department recommends that until definitive conclusions are possible there should be no general change or disruption of therapy in patients with high blood pressure."

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[1] A full text of the FDA paper on this subject, can be obtained upon request

[2] reserpine is the International Nonproprietary Name (INN) proposed by WHO for 3,4,5-trimethoxybenzoic acid ester of methyl reserpate

[3] rescinnamine is the International Nonproprietary Name (INN) proposed by WHO for 3,4,5-trimethoxycinnamic acid ester of methyl reserpate

CLINICAL AND PHARMACOLOGICAL
EVALUATION OF DRUGS/DRUG EFFICACY

DRUG INFORMATION NO 134

1 July 1974

Resolution WHA16.36/WHA23.48

ORIGINAL : ENGLISH

The United States Food and Drug Administration has informed the World Health Organization of the withdrawal of approval of the following drug products:

1. Combination drugs containing pamabrom and pyrilamine maleate for oral use;

2. Nialamide[1,2] (25 or 100 milligrams per tablet);

3. Procaine[3] isobutyrate (capsules and elixir);

4. Pipradrol[4] hydrocholoride (liquid dosage form, alone or in combination).

The basis for the above actions was the lack of substantial evidence of efficacy.

The relevant detailed documentation concerning these actions is available from WHO upon request.

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1 nialamide is the International Nonproprietary Name (INN) proposed by WHO for isonicotinic acid 2-[(2-benzylcarbamoyl)ethyl]hydrazide

2 please refer to Drug Information Circular No. 4 of 27 November 1963

3 procaine is the International Nonproprietary Name (INN) proposed by WHO for 2-diethylaminoethyl p-aminobenzoate

4 pipradrol is the International Nonproprietary Name (INN) proposed by WHO for α,α-diphenyl-2-piperidinemethanol

ORGANIZATION DE LA SANTE

CLINICAL AND PHARMACOLOGICAL EVALUATION OF DRUGS/QUALITY, SAFETY AND EFFICACY OF DRUGS

Resolutions WHA16.36/WHA26.31

DRUG INFORMATION NO 131

15 February 1974

ORIGINAL : ENGLISH

cc HFD-1 HFM-1 2/25/74

The Food and Drug Administration of the United States of America has informed the World Health Organization of a new programme of conditions for marketing of digoxin[1,2] products. This measure was based on knowledge from extensive observations and studies on dissolution test results (tablets) and clinical biovailability.

In brief, the essential premarketing requirements of the new programme consist of :

1) Compliance with the specifications for digoxin products prescribed by the U.S. Pharmacopeia (U.S.P. XVIII, Sixth Interim Revision Announcement, effective November 15, 1973), to include the dissolution rate test for digoxin tablets.

2) Certification by the Food and Drug Administration of all new batches of digoxin to insure quality uniformity.

3) Demonstration of clinical availability for all digoxin products, according to the Food and Drug Administration approved protocol.

4) Labelling revisions informing on the above for proper directions of use by the physician.

Also, this programme is implemented by monitoring of drug reformulations and utilization and supported by adequate dissemination of this information to all health professionals concerned.

The relevant detailed documentation concerning these actions is available from WHO upon request.

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[1] digoxin is the International Nonproprietary Name (INN) proposed by WHO for "glycoside obtained from the leaves of Digitalis lanata Ehrh."

[2] please refer to Drug Information Circular No 128 of 16 January 1974.

Department of State TELEGRAM

PAGE 01 STOCKH 02279 092104Z 4427

ACTION HEW-06

INFO OCT-01 EUR-12 ISO-00 OES-07 /026 W

010828 102034Z /45

R 091310Z JUN 78
FM AMEMBASSY STOCKHOLM
TO SECSTATE WASHDC 4009

UNCLAS STOCKHOLM 2279

DEPARTMENT PASS TO FDA

E.O. 11652: N/A
TAGS: EIND, ETRD, OGEN, TBIO, SW
SUBJECT: FDA ADVISORY-CATHETER TRAYS CONTAINING DEFECTIVE STERILE GLOVES (RECALL T-097-8)

REF: STATE 137415

TRAVENOL LABORATORIES INFORMED SCIATT TODAY THAT THEY HAD NOT RECEIVED A RECALL LETTER. HOWEVER, TRAVENOL CONDUCTED ITS OWN INVESTIGATION AND FOUND NO COMPLAINTS.
KENNEDY-MINOTT

Department of State TELEGRAM

2772

PAGE 01 MADRID 06269 050919Z
ACTION HEW-06

INFO OCT-01 EUR-12 ISO-00 OES-07 /026 W
----------073841 050928Z /20

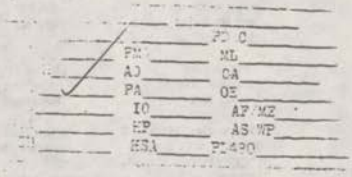
R 050918Z JUN 78
FM AMEMBASSY MADRID
TO SECSTATE WASHDC 4797

UNCLAS MADRID 06269

E.O. 11652: N/A
TAGS: OGEN, ETRD, EIND, TBIO, SP
SUBJECT: FDA ADVISORY - CATHETER TRAYS CONTAINING DEFECTIV STERILE GLOVES (RECALL T-097-8)

REF: STATE 137415

EMBASSY HAS PASSED SUBSTANCE OF STATE 137415 TO TRAVENOL AGENT "LABORATORIOS HESPERIA" IN VALENCIA. SPANISH FIRM HAS NOT HEARD FROM TRAVENOL, BUT HAS IMPORTED VERY FEW OF TRAYS IN QUESTION. FIRM WILL COMMUNICATE WITH TRAVENOL DIRECTLY IN ANY CASE. EATON



UNCLASSIFIED

Department of State

OUTGOING

TELEGRAM

PAGE 01 OF 02 STATE 276847 6845 STATE 276847

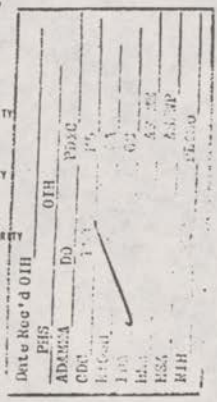
ORIGIN HEW-06

INFO OCT-01 AF-10 ARA-14 EUR-12 EA-12 NEA-10 ISO-00
OES-07 IO-00 CONE-00 /060 R

DRAFTED BY DHEW/A: JRWEINROTH,M.D.:CM
APPROVED BY OES/APT/BMP: WJWALSH, III
DHEW/PHS/OASH/OIH: MKEFAUVER
NEA/EX: JSCONNOLLY (INFO)
EUR/EX: DCLEIDEL (INFO)
EA/EX: JBMORAN (INFO)
ARA/EX: GAPAGANO (INFO)
AF/EX: EGKRYZA (INFO)

------------------040349 181827Z /44

P 181644Z NOV 77
FM SECSTATE WASHDC
TO AMEMBASSY MANAGUA PRIORITY
AMEMBASSY KINGSTON PRIORITY
AMEMBASSY LA PAZ PRIORITY
AMEMBASSY DUBLIN PRIORITY
AMEMBASSY VIENNA PRIORITY
AMEMBASSY ATHENS PRIORITY
AMEMBASSY SAN JOSE PRIORITY
AMEMBASSY BUENOS AIRES PRIORITY
AMEMBASSY BERN PRIORITY
AMEMBASSY MADRID PRIORITY
AMEMBASSY TEHRAN PRIORITY
AMEMBASSY TEGUCIGALPA PRIORITY
AMEMBASSY LONDON PRIORITY
AMEMBASSY HELSINKI PRIORITY
AMEMBASSY GUATEMALA PRIORITY
AMEMBASSY PORT AU PRINCE PRIORITY
AMEMBASSY SANTIAGO PRIORITY
AMEMBASSY BRUSSELS PRIORITY
AMEMBASSY STOCKHOLM PRIORITY
AMEMBASSY SEOUL PRIORITY
AMEMBASSY ACCRA PRIORITY
AMEMBASSY ISLAMABAD PRIORITY
AMEMBASSY NAIROBI PRIORITY
AMEMBASSY NASSAU PRIORITY
AMEMBASSY BANGKOK PRIORITY
AMEMBASSY CANBERRA PRIORITY
AMEMBASSY MAPUTO PRIORITY



UNCLAS STATE 276847

E.O. 11652: N/A

TAGS: OGEN, EINO, ETRD, TBIO, XX

SUBJECT: HEMOLYSIS OF RBC'S (RED BLOOD CELLS) WHEN USED WITH DADE ANTI RHO (ANTI-D) TYPING SERUM, RECALL B-002-8

1. FDA ADVISES OF THE FOLLOWING:

PRODUCT INVOLVED: ANTI-RHO (ANTI-D) TYPING SERUM, 5ML AND 10 ML. SIZE VIALS

PRODUCT IDENTIFICATION: ANTI-RHO (ANTI-D) TYPING SERUM, LABELED: "ANTI-RHO (ANTI-D) SERUM (HUMAN) - 5 ML SLIDE OR MODIFIED TUBE TEST LOT NO. 3-685-T EXP. DATE 1 JUNE 78 CAT. NO. B4665 DADE DIVISION AMERICAN HOSPITAL SUPPLY CORPORATION, MIAMI, FLORIDA 33152 U.S. LICENSE 179 PRESERVATIVE: SODIUM AZIDE, 1:1,000 STORE BETWEEN 2-8C (35-46F)" THE PRODUCT IS PACKED IN 5 ML AND 10 ML SIZES. CODES RECALLED: LOT NO 3-685 (ALL SUFFIXES), CATALOG NOS. B4670-1 AND B4670-11.

MANUFACTURING/RECALLING FIRM:

DADE DIVISION OF AMERICAN HOSPITAL SUPPLY CORP
1851 DELAVARE PKWY.,
MIAMI, FLA. 33152

2. REASON FOR RECALL: MANUFACTURER RECEIVED A TOTAL OF NINE COMPLAINTS REGARDING A HEMOLYSIS PROBLEM. HEMOLYSIS OF THE RED BLOOD CELLS OCCURS WHEN TESTING SOME INDIVIDUALS WITH THIS PRODUCT AND LOT NUMBER. THE CELLS WERE WASHED WITH SALINE WHICH WAS PRESERVED WITH 2-PHENOXYETHANOL. THE PROBLEM HAS NOT BEEN EXHIBITED IN ANY OTHER LOT NUMBERS OR WITH THIS LOT USING SALINE WITHOUT 2-PHENOXYETHANOL.

3. POSTS REQUESTED TO CONTACT FOREIGN CONSIGNEES TO DETERMINE IF THEY HAVE RECEIVED LETTER DATED AUGUST 22, 1977 "WARNING IMPORTANT PRODUCT INFORMATION".

ANY QUESTIONS CONSIGNEES MAY HAVE SHOULD BE REFERRED TO DADE IMMUNO-HEMATOLOGY TECHNICAL SERVICES.

4. FOREIGN CONSIGNEES AS FOLLOWS:

ROBERT TERAN G
APARTADO POSTAL 689
MANAGUA NICARAGUA

BIOCHEMICAL EQUIPMENT AND SERVICES LTD.
128 MAXFIELD AVENUE

LABORATORIOS INDUSTRIALES
GUZMAN LTDA.
CASILLA 6248
LA PAZ BOLIVIA

B M BROWNE
GEORGES PLACE
DUN LAOGHAIRE
DUBLIN IRELAND

LAGERMAX, AG
FLUGHAFEN
5020 SALZBURG AUSTRIA
NOTIFY SANO-DADE

ARKADITIS AND CO. LTD.
P. O. BOX 188
1 PIRAEUS STREET
ATHENS 112 GREECE

CAJA COSTARRICENSE DE
SEGURO SOCIAL
APARTADO 10105
SAN JOSE COSTA RICA

CIENTIFICA ARGENTINA
PICHINCHA 69
BUENOS AIRES
ARGENTINA

PAN TRANSPORT
WALDHEIMSTRASSE 16
3000 BERNE SWITZERLAND
NOTIFY HERZ-DADE

FERRER & CIA
PELAYO 9
BARCELONA SPAIN

SERUM COMPANY
P. O. BOX 2856
TEHERAN IRAN

LAB AND HOSPITAL SUP
P. O. BOX 822
TEGUCIGALPA

JOHNSON'S AIRFREIGHT LTD
OFFICE 18/20G, BLD 521
LONDON HEATHROW AIRPORT
HOUNSLOW ENGLAND

AHS INTERNATIONAL - KOREA
GWANG WHA MOON
POBOX 1058
SEOUL KOREA

JOHN NURMINEN OY FINLAND
NOTIFY DADE FENNICA OY
MARJANIEMENTIE 36 00930
HELSINKI 93 FINLAND

HOLY FAMILY HOSPITAL
P O BOX 36
TECHIMAN, R/A GHANA
W. AFRICA

COMPANIA GENERAL DE
COMERCIO S.A.
VIA LAYETANA 38-4
BARCELONA SPAIN

UNIAO FARMACEUTICA LTDA
P O BOX 334
MAPUTO MOCAMBIQUE

ROBERTO NICOL & CO LTDA
18A AVE 3-96 ZONA 4
APARTADO POSTAL 78-A
GUATEMALA GUATAMALA 42000

LAB AND HOSPITAL SUP.
P. O. BOX 822
TEGUCIGALPA
HONDURAS

Department of State TELEGRAM

PAGE #2 OF #2 STATE 276847

LABORATORIOS SUKIA
APARTADO 2524
SAN JOSE COSTA RICA 44888

DOMINIQUE RAILLY & CO
P O BOX 184
RUE ROUX 34 PORT AU PR
HAITI

PROMEX SA ARTICULOS
MEDICOS Y DE LABORATORIO
P O BOX 9868
SANTIAGO CHILE

SFT GONDRAND FRERES
CARGO BUILDING BRUSSELS
AIRPORT -BELGIUM - NOTIFY
DELFORGE DIV. A.H.S.

LABSTATUS AB-OLSONTVRIGHT
ARLANDA AIRPORT BOX 39
S19854 STOCKHOLM ARLANDA
NOT. LABSTATUS-SWEDEN

GUAM MEMORIAL HOSPITAL
GOVERNMENT OF GUAN
P. O. BOX AX
AGANA, GUAM VANCE

E. T. MONKS & CO. LTD.
KIMATHI STREET
P. O. BOX 30869

MEDICAL LAB SERV LTD.
DOMINION LIFE ASST. BLDG
P O. BOX N-4869 COLLINS AVE.

ANS/AUSTRALIA PTY LTD
MCGAW DIV CTR CT 181-187
EPPING RD EPPING NSW 2121

LABORATORIOS SUKIA
APARTADO 2524
SAN JOSE COSTA RICA

CAJA COSTARRICENSE DE
SEGURO SOCIAL
APARTADO 10105
SAN JOSE COSTA RICA

Department of State

TELEGRAM

PAGE 01 STATE 297273
ORIGIN HEW-06

3082
Recall

INFO OCT-01 NEA-10 ISO-00 OES-07 EB-08 COME-00 /032 R

DRAFTED BY DHEW/FDA: JRWEINROTH, M.D.:CM
APPROVED BY OES/ENP/EN WJWALSH, III
DHEW/PHS/OASH/OIH: REVANS

----------031937 140550Z /14

R 132150Z DEC 77
FM SECSTATE WASHDC
TO AMEMBASSY ISLAMABAD

Date Rec'd DIH
PHS
ADAMHA
CDC
NIOSH
FDA
HRA
HSA
NIH
ASH
AS/IP
PLANCO

UNCLAS STATE 297273

E.O. 11652: N/A

TAGS: OGEN, EIND, ETRD, TBIO, PK

SUBJECT: HEMOLYSIS OF RBC'S (RED BLOOD CELLS) WHEN USED WITH DADE ANTI RHO (ANTI-D) TYPING SERUM RECALL B 002-8

REF: ISLAMABAD 11609
STATE 276847

1. FDA ADVISES THAT CORRECT ADDRESS OF CONSIGNEE IN REFTEL IS:

S. EKACUDDING AND CO.
P. O. BOX 5629
MEDICINE STREET
KARACHI, 2 PAKISTAN

2. ORIGINAL INFORMATION REGARDING CONSIGNEES SUPPLIED TO FDA BY FIRM WAS INADEQUATE AND IN ERROR. FDA APPRECIATES EMBASSY'S EFFORTS IN RESOLUTION OF THIS MATTER. CHRISTOPHER

UNCLASSIFIED
Department of State
INCOMING
TELEGRAM

ACTION

PAGE 01 VIENNA 10129 221522Z 7021
ACTION HEW-06

INFO OCT-01 EUR-12 ISO-00 OES-07 EB-08 COME-00 /034 W
----------082776 221648Z /44

R 221455Z NOV 77
FM AMEMBASSY VIENNA
TO SECSTATE WASHDC 4175

UNCLAS VIENNA 10129

EO 11652: N/A
TAGS: OGEN, EIND, ETRD, TBIO, AU
SUBJ: HEMOLYSIS OF RBC'S (RED BLOOD CELLS) WHEN USED WITH DADE ANTI RHI (ANTI-D) TYPING SERUM, RECALL B-002-8

REF: STATE 276847

1. SANO-DADE, SALZBURG, AUSTRIA NO LONGER REPRESENTS DADE DIVISION. NEW REPRESENTATIVE IS LAEVOSAN GES.M.B.H. & CO. K.G., ESTERMANNSTRASSE 17, A-4020 LINZ, AUSTRIA.
2. HORST KOCH, TECHNICAL MANAGER OF LAEVOSAN, WAS NOT AWARE OF RECALL. LETTER FROM U.S. FIRM WAS PROBABLY SENT TO SALZBURG AND NOT PASSED ON TO LAEVOSAN. EMBASSY MAILED COPY OF RECALL TO LINZ FIRM. KOCH WILL CONTACT U.S. SUPPLIER FOR DETAILS IF NECESSARY. WOLF

UNCLASSIFIED

Department of State

OUTGOING
TELEGRAM

PAGE 01 STATE 027361 4858 STATE 027361
ORIGIN HEW-04

INFO OCT-01 AF-06 ARA-10 EUR-12 EA-09 ISO-00 OES-06 COME-00
HED-03 /055 R

DRAFTED BY DHEW/FDA: JRWEINROTH, M.D.:CCN
APPROVED BY OES/APT/BMP: MJWALSH, III
DHEW/OIH: BROYSTER
EUR/EX: JLTULL (INFO)
EA/EX: JRCUNNINGHAM (INFO)
ARA/EX: CJACOBINI (INFO)
AF/EX: JTIERNEY (INFO)

-----------0686192 090650 /14

R 072223Z FEB 77
FM SECSTATE WASHDC
TO AMEMBASSY MADRID
AMEMBASSY LAGOS
AMEMBASSY ATHENS
AMCONSUL HONG KONG
AMEMBASSY ROME
AMEMBASSY KUALA LUMPUR
AMEMBASSY BUENOS AIRES
AMEMBASSY CANBERRA
AMEMBASSY PARIS
AMEMBASSY MEXICO
AMEMBASSY THE HAGUE
AMEMBASSY PRETORIA
AMEMBASSY WELLINGTON

UNCLAS STATE 027361

E.O. 11652: N/A

TAGS: OGEN, ETRD, TBIO, SP, NI, GR, HK, IT, MY, AR,

SUBJECT: SUBPOTENT IN VITRO DIAGNOSTIC PRODUCT (RECALL T-082-7)

1. FDA ADVISES OF THE FOLLOWING RECALL:

PRODUCT INVOLVED: VERSATOR PEDIATRIC IN VITRO DIAGNOSTIC, 3ML. VIAL, 12 VIALS PER CARTON. THE PRODUCT IS USED AS A BILIRUBIN REFERENCE AND CONTROL FOR IN VITRO TESTING OF CHILDREN'S SERUM.

LOT NUMBERS INVOLVED: 2361125 AND 48855

MANUFACTURER/RECALLING FIRM:

GENERAL DIAGNOSTICS, DIVISION OF WARNER LAMBERT,
201 TABOR ROAD
MORRIS PLAINS, NEW JERSEY 07950

2. REASON FOR RECALL:

CUSTOMER COMPLAINTS REPORTED A FAILURE TO RECOVER LABEL VALUES FOR BILIRUBIN. THE FIRM'S QUALITY CONTROL TESTING FAILED TO CONFIRM CUSTOMER PROBLEMS, HOWEVER, THEY DID RECOVER VALUES SLIGHTLY BELOW THE LABEL STATEMENT.

3. POSTS ARE REQUESTED TO CONTACT FOREIGN CONSIGNEES TO DETERMINE IF THEY HAVE RECEIVED RECALL LETTERS DATED 13 OCTOBER 1976 FOR LOT 2361125 AND 19 NOVEMBER 1976 FOR LOT 48855. ANY QUESTIONS CONSIGNEES MAY HAVE REGARDING THIS RECALL SHOULD BE DIRECTED TO FIRM. CONTACT AT FIRM IS R. A. WEBB, MANAGER QUALITY ASSURANCE AND REGULATORY COMPLIANCE, TELEPHONE 800-631-3860.

4. FOREIGN CONSIGNEES AS FOLLOWS:

LABORATORIO SUBSTANCIA, S.A.
POLIGONO INDUSTRIAL MANSO
MATEU S/N
PRAT DE LLOBREGAT
BARCELONA, SPAIN
(SOLD TO)

LABORATORIOS SUBSTANCIA, S.A.
C/O COMMERCIAL COMPAÑIA-SAGRERA S.A.
BARCELONA AIRPORT
(CONSIGNED TO)

PARKE DAVIS AND CO
P O BOX 2764
LAGOS, NIGERIA
(SOLD TO)

P. BACACOS
OMONIA SQUARE
ATHENS, GREECE
(SOLD TO)

P. BACACOS
C/O GENERAL BANK OF GREECE
SOCRATOUS BRANCH
ATHENS, GREECE
(CONSIGNED TO)

M-L HONG KONG LTD
NEW INDUSTRIAL BUILDING "D"
7TH FLOOR, TONG CHONG STREET
(TAIKOO SUGAR REFINERY)
QUARRY BAY, HONG KONG
(SOLD TO)

A. ANGELINI AND CO SPA
CASELLA POSTALE 4077
MILAN, ITALY
(SOLD TO)

WARNER-LAMBERT (MFG) SDN
BERHAD
JALAN 13/4A
PETALING JAYA, SELANGOR
MALAYSIA
(SOLD TO)

W. R. WARNER Y CIA. S.A.
SARMIENTO 3421
BUENOS AIRES, ARGENTINA
(SOLD TO)

WARNER-LAMBERT PHT. LTD
32-42 CAMARA ROAD NORTH
CARINGBAH, N.S.W. 2229
AUSTRALIA
(SOLD TO)

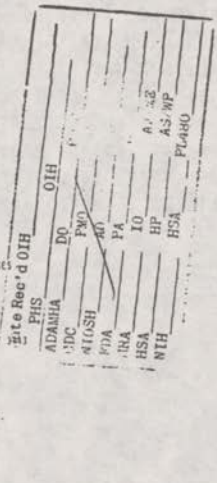
PRECHEIO S.A.
58 RUE DU CESSOUS DES BERGES
PARIS 13E FRANCE
(SOLD TO)

CIA MEDICINAL "LA CAMPANA"
S.A. DE C.V.
AVENIDA DIVISION DEL NORTE 3[illegible]
ZONA POSTAL 21
MEXICO, D.F., MEXICO

TRAFICO ABOCO INTER.
AEROPUERTO INTER
DE LA CIUDAD DE MEXICO D.F.
(CONSIGNED TO)
VANCE

N.V. SUBSTANTIA
INDUST. 9-19
WIJDRECHT, NETHERLANDS
(SOLD TO)

WARNER-LAMBERT
37 BARNS ROAD
MT. WELLINGTON
AUCKLAND, NEW ZEALAND
(SOLD TO)



Department of State **TELEGRAM**

UNCLASSIFIED 1409

PAGE 01 KUALA 00912 092913Z
ACTION HEW-06

INFO OCT-01 EA-09 ISO-00 OES-06 COME-00 HED-03 /025 W
------------------------092920Z 107012 /20

R 090712Z FEB 77
FM AMEMBASSY KUALA LUMPUR
TO SECSTATE WASHDC 6208

UNCLAS KUALA LUMPUR 0912

E.O. 11652: N/A
TAGS: OGEN, ETRD, TBIO, MY
SUBJECT: SUBPOTENT IN VITRO DIAGNOSTIC PRODUCT (RECALL T-0??-?)

REF: STATE 27341

EMBASSY CONTACTED MR. P.K.W. LEE, DIRECTOR-MANAGER, WARNER-LAMBERT (MFG) SDN. BERHAD, JALAN 13/4A, PETALING JAYA, SELANGOR ON FEB. 9. FIRM HAS NOT RECEIVED RECALL LETTERS DATED OCTOBER 13 AND NOVEMBER 19, 1976 FROM GENERAL DIAGNOSTICS, DIVISION OF WARNER-LAMBERT, 201 TABOR ROAD, MORRIS PLAINS, N.J. EMBASSY HAS PROVIDED FIRM COPY REFTEL.
UNDERHILL

Date Rec'd OIH
PHS
ADAMHA — OIH
CDC — PD&C
NIOSH — PMO — ML
FDA — AO — CA
HRA — PA — OE
HSA — IO — AF ME
NIH — HP — AS/WP
HSA — PL480

Department of State **TELEGRAM**

UNCLASSIFIED 7666

PAGE 01 WELLIN 00251 210318Z
ACTION HEW-06

INFO OCT-01 EA-09 ISO-00 OES-06 EB-07 CUME-00 /029 W
------------------210509Z 122564 /11

R 210230Z JAN 77
FM AMEMBASSY WELLINGTON
TO SECSTATE WASHDC 2611

UNCLAS WELLINGTON 0251

Recall

E.O. 11652: N/A
TAGS: OGEN, ETRD, TBIO, XX, NZ
SUBJECT: EXCESSIVE MOISTURE INVITRO DIAGNOSTIC PRODUCT (RECAL NO. [redacted]

REF: STATE 005220

ETHNOR PTY LTD OF NEWMARKET, AUCKLAND CONFIRMS RECEIPT OF RECAL NOTICE FROM ORTHO DIAGNOSTICS INC, RARITAN, NEW JERSEY.
SELDEN

Date Rec'd [illegible]		
THS	OIH	
ADAMHA	[illegible]	[illegible]
CDC	[illegible]	[illegible]
NIOSH	[illegible]	[illegible]
FDA ✓	PA	OF
HRA	IO	AP/[illegible]
HSA	LP	AS WP
NIH	HSA	PL480

UNCLASSIFIED

Department of State

OUTGOING
TELEGRAM

Recall
A-259-7

PAGE #1 OF #2 STATE #05211 1461
ORIGIN HEW-25

INFO OCT-01 AF-06 ARA-10 EUR-12 NEA-10 ISO-00 OES-05 /053 R

DRAFTED BY DHEW/FDA: JRHEINROTH, M.D.:CCA
APPROVED BY OES/APT/BMP: MWALSH, III
DHEW/OIH: BROYSTER
ARA/EA:CJACCOVINI (INFO)
AF/EX:JTIERNEY (INFO)
NEA/EA:EGABRINGTON (INFO)
EUR/EA:JLTULL (INFO)

P 102248Z JAN 77
FM SECSTATE WASHDC
TO AMCONSUL SAO PAULO PRIORITY
AMEMBASSY KINSHASA PRIORITY
AMEMBASSY SAN SALVADOR PRIORITY
AMEMBASSY LONDON PRIORITY
AMEMBASSY BONN PRIORITY
AMEMBASSY TEHRAN PRIORITY
AMEMBASSY ROME PRIORITY
AMEMBASSY MADRID PRIORITY
AMEMBASSY BERN PRIORITY
AMEMBASSY LA PAZ PRIORITY
AMEMBASSY CARACAS PRIORITY

UNCLAS STATE #05211

E.O. 11652: N/A

TAGS: OGEN, ETRD, TBIO, BR, CG, ES, UK, GM, IR, IT, SP,

SZ, BL, VE
SUBJECT: SUB-POTENT IN-VITRO ANTIBIOTIC SENSITIVITY
DISC RECALL [redacted]

1. FDA ADVISES OF THE FOLLOWING PRODUCT RECALL:

PRODUCT INVOLVED: OXACILLIN SENSITIVITY DISC, INCO.
STRENGTH, LABELED AS FOLLOWS: DIFCO DISPENS-O-DISC,
DIFCO LABS, DETROIT, MICHIGAN. THE PRODUCT IS PACKAGED
5# DISCS PER MAGAZINE, SOLD AS EITHER SINGLE MAGAZINES OR
6 MAGAZINES PER CARTON. THE PRODUCT IS USED AS AN IN-VITRO
ANTIBIOTIC SENSITIVITY DISC FOR CLINICAL LABORATORY USE.
PRODUCT IS LABELED AS ABOVE WITH INFORMATION INDICATING
EXPIRATION DATE XXX STORE AT 2-8 DEGREES C. XXX LOT NO. XXX
DIFCO LABORATORIES, DETROIT, MICHIGAN USA. LABEL ON THE
CARTON OF 6 MAGAZINES IS SEEN AS THE FOREGOING EXCEPT IT
ALSO LISTS "6 MAGAZINES, 5# DISCS EACH. A INSERT IS
INCLUDED WITH THE PRODUCT AND IS A STANDARD INSERT FOR
ALL ANTIBIOTIC SENSITIVITY DISCS WHICH READS IN PART
"BACTO-SENSITIVITY DISCS, ANTIBIOTIC SUSCEPTIBILITY DISCS
FOR USE IN THE STANDARDIZED ANTIBIOTIC DISC SUSCEPTIBILITY
TEST XXX DIFCO LABS, DETROIT, MICHIGAN. JANUARY 1976".

#

UNCLASSIFIED

LOT #OS:

PRODUCT CODE	PACKED	CONTROL NO.
6351-50-3	1 MAGAZINE	620965
6351-51-2	6 MAGAZINE	618241
6351-51 (EXPORTED ONLY)	6 MAGAZINE	625841

ALL OF THE THREE ABOVE CONTROL NUMBERS ARE BEING RECALLED
BECAUSE THEY WERE PACKAGED FROM THE SAME BULK BATCH.

MANUFACTURER/RECALLING FIRM:

DIFCO LABORATORIES, 920 HENRY STREET, DETROIT, MICHIGAN.

2. REASON FOR RECALL:

STATE #05211

ON 6 OCTOBER 1976 THE FIRM RECEIVED A USP LABORATORY
PRODUCT PROBLEM REPORT NUMBER D-2214 WHICH REPORTED
THAT OXACILLIN DISCS OF THE ABOVE MENTIONED LOT GAVE
ERRATIC RESULTS UPON USE. ASSAYS WERE PERFORMED BY
THE FIRM AND THE FDA. THE ASSAY RESULTS INDICATED
MARGINAL TO LOW POTENCY. RECALL WAS INITIATED BY LETTER
DATED 10 NOVEMBER 1976. FOREIGN CONSIGNEES WERE INST-
RUCTED TO NOTIFY THEIR CUSTOMERS TO RETURN THE STOCK ON
HAND TO DIRECT ACCOUNT AND THE DIRECT ACCOUNT WAS
INSTRUCTED TO DESTROY ANY STOCK ON HAND OR RETURNS FROM
CUSTOMERS AND ADVISE DIFCO OF THE NUMBER OF UNITS DES-
TROYED.

3. POSTS ARE REQUESTED TO CONTACT FOREIGN CONSIGNEES
TO DETERMINE IF THEY HAVE BEEN INFORMED OF THE RECALL.
ANY QUESTIONS CONSIGNEES MAY HAVE SHOULD BE DIRECTED TO
THE FIRM. CONTACT AT THE FIRM IS MR. HERMAN NELSON,
VICE PRESIDENT, TELEPHONE 313-961-8800.

4. FOREIGN CONSIGNEES AS FOLLOWS:

INTERLAB
RUA LUIZ GOES 664
VILA MARIANA
CAIXA POSTAL 15152
SAO PAULO, BRAZIL

UNCLASSIFIED
DROGUERIA Y
DISTRIBUIDORA MARIN
SAN SALVADOR, EL SALVADOR

OTTO NORDWALD AG
HEINRICHSTRASSE 5
HAMBURG 5#, GERMAN

M/S MIDAL CO., LTD.
55 AVE SHAHREZA
KAKH CROSS
TEHRAN, IRAN

MARTIN HISPANICA
CASTELLO 149
MADRID, SPAIN

FOMECO
HOSPITAL NM YEMO
BP 189
KINSHASA, REPUBLIC DU ZAIRE

DIFCO LABORATORIES
P O BOX 14 B/CENTRAL AVE.
EAST MOLESEY
SURREY KT 8, OSE
ENGLAND

BIOTEST SERUM INSTITUTE
POSTFACH 7302#2
6 FRANKFORT /MAIN 73
WEST GERMANY

DIFCO SAS
PLAZZA C AMATI 6
20147 MILAN
ITALY

CHEMIE BRUNSCHWIG AG
P O BOX 252
CH-4#05 BASEL
SWITZERLAND

LABORATORIO INDUSTRIALES

UNCLASSIFIED

Department of State

OUTGOING
TELEGRAM

GUZMAN LTDA
CASILLA 4240
LA PAZ, BOLIVIA

UNCLASSIFIED
CENCO ZOTTI CIENTIFICA SA
APARTADO 80252
CARACAS 108
VENEZUELA
KISSINGER

Department of State **TELEGRAM**

UNCLASSIFIED 3727

PAGE 01 KINSHA 00797 3107442
ACTION HEW-06

INFO OCT-01 AF-06 ISO-00 OES-06 /021 W
----------3107477Z 119853 / 3

P 3107127 JAN 77
FM AMEMBASSY KINSHASA
TO SECSTATE WASHDC 1492

UNCLAS KINSHASA 0797

E.O. 11652: N/A
TAGS: OGEN, ETRD, TBIV, BR, CG
SUBJECT: SUB-POTENT IN-VITRO ANTIBIOTIC SENSITIVITY DISC (RECALL O-059-77)

REF: STATE 005211/1

FOMECO REPRESENTATIVE DR. BLONDLAUX ADVISES HE HAD NOT BEEN INFORMED OF RECALL PRIOR TO VISIT BY EMBASSY REPRESENTATIVE. AT THAT POINT ALL OF THE PRODUCT HAD BEEN USED.
CUTLER

Department of State **TELEGRAM**

UNCLASSIFIED 0009

PAGE 01 CARACA 00879 272117Z
ACTION HEW-06

INFO OCT-01 ARA-10 ISO-00 OES-06 /023 W
----------2807202 074216 /15

R 2720077 JAN 77
FM AMEMBASSY CARACAS
TO SECSTATE WASHDC 6389

UNCLAS CARACAS 00879

E.O. 11652: N/A
TAGS: OGEN, ETRD, TBIO, VE
SUBJ: SUB-POTENT IN-VITRO ANTIBIOTIC SENSITIVITY DISC
(RECALL D-050-7)

REF: STATE 005211

1. EMBASSY CONTACTED CENCO-ZOTTI CIENTIFICA S.A. AS REQUESTED IN REFTEL.

2. DR. BELKYS RUJANA, ASSISTANT MANAGER FOR LABORATORY PRODUCTS STATED THAT IN FACT TWO RECALL LETTERS HAD BEEN RECEIVED FROM DIFCO LABORATORIES. THE FIRST ONE DATED 5 NOVEMBER 1976 REFERRED TO LOT CONTROL NUMBERS 620965 AND 618241, WHICH ON CHECKING WERE FOUND NOT TO BE IN STOCK. SECOND LETTER DATED 10 NOVEMBER 1976 REFERRED TO LOT CONTROL NO. 625841 WHICH CENCO-ZOTTI DID HAVE IN STOCK AND WHICH WAS THEN DESTROYED ACCORDINGLY.
VAKY

UNCLASSIFIED *Department of State* OUTGOING TELEGRAM

PAGE 01 STATE 071218 9883 STATE 071218
ORIGIN HEW-06

INFO OCT-01 AF-10 ISO-00 ARA-14 EUR-12 EA-12 OES-07
SIG-03 EB-08 COME-00 /073 R

DRAFTED BY: DHEW/FDA: JRWEINROTH
APPROVED BY: OES/ENP: EN: WJWALSH III
DHEW/PNS/OASH:OIH: REVANS
EA/AMP: WGALLAGHER (INFO)
EUR/WE: BMCINLEY (INFO)
AF/S: JTAYLOR (INFO)
EA/AMP: TWAJDA (INFO)
EUR/WE: JDOBBINS (INFO)
EUR/NE: WNEWLIN (INFO)
----------068712 211203Z /11/42

R 282026Z MAR 76
FM SECSTATE WASHDC
TO AMEMBASSY WELLINGTON
AMEMBASSY CANBERRA
AMEMBASSY MEXICO
AMEMBASSY PARIS
AMEMBASSY BRUSSELS
AMEMBASSY ROME
AMEMBASSY PRETORIA

UNCLAS STATE 071218

C O R R E C T E D C O P Y - FOR ADDRESSEE

E.O. 11652: N/A

TAGS:OGEN, ETRD, EIND, TBIO, NZ, AS, MX, FR, BE, SF, IT

SUBJECT:FDA ADVISORY - POTENTIAL FIRE HAZARD IN NEBULIZER FOR RESPIRATORY THERAPY. (RECALL T-052-3)

1. FDA ADVISES OF THE FOLLOWING RECALL:
PRODUCT INVOLVED - THE PRODUCTS INVOLVED IN THIS RECALL ARE "MAXICOOL" AND "HYDRO-SHPERE" NEBULIZERS USED FOR RESPIRATORY THERAPY IN HOSPITALS.
PRODUCT IDENTIFICATION - THE NEBULIZERS INVOLVED IN THIS RECALL ARE PRODUCED BY MCGAW RESPIRATORY THERAPY, IRVINE, CA. UNDER THE NAMES "MAXI-COOL" AND "HYDRO-SPHERE". THE SPECIFIC UNITS INVOLVED ARE THOSE WITH METAL COMPONENTS IN THE INTERIOR PORTION OF THE MANIFOLDS WHICH ARE INSERTED, SCREWED INTO, THE OUTER CONTAINER.
MANUFACTURER/RECALLING FIRM - MCGAW RESPIRATORY THERAPY, 16812 MILLIKEN AVE., IRVIE, CALIFORNIA.

2. REASON FOR RECALL RECOMMENDATION - THE PRODUCT HAS BEEN IMPLICATED IN TWO HOSPITAL FIRES IN THE "RESPIRATORY THERAPY" ROOMS. THE FIRM INVESTIGATED THE FIRES AND WHILE NOT DEFINITELY DETERMINING THE CAUSE THEY DID DETERMINE THAT THE POTENTIAL FOR IGNITION DID EXIST WITHIN THE DEVICE GIVEN ANY CONTAMINATION OF THE HOSPITAL'S OXYGEN SUPPLY.

IN ANY NEBULIZER A POTENTIAL FOR STATIC ELECTRICITY EXISTS WITH THE MIST ASSUMING A POSITIVE CHARGE AND THE WATER ASSUMING A NEGATIVE CHARGE. IN THE NEBULIZERS UNDER "RECALL" (ACTUALLY A FIELD CORRECTION" THERE ARE SOME STAINLESS STEEL PARTS USED IN THE MANIFOLD LOCATED IN THE INTERIOR OF THE MACHINE WHICH CREATE THE POTENTIAL FOR "SPARKING" OF THE ELECTRICAL CHARGE BUILT-UP. (THE NEBULIZERS NOT UNDER RECALL AND THOSE RETROFITTED HAVE ALL PLASTIC INTERIOR PORTIONS OF THE MANIFOLD WICH ESSENTIALLY ELIMINATES THIS POTENTIAL FOR SPARKS).

3. ACTION - POSTS ARE REQUESTED TO CONTACT FOREIGN CONSIGNEES TO DETERMINE IF THEY HAVE RECEIVED ADVISORY FROM FIRM REQUESTING "NOT TO USE SUBJECT UNITS UNTIL THEY ARE RETROFITTED WITH THE NEW MANIFOLD WITH QUALIFICATION THAT IN EVENT OF EMERGENCY THE PRODUCT COULD BE USED WITH COMPRESSED AIR BUT NOT OXYGEN." DEALERS PRESUMED TO HAVE BEEN SENT REPLACEMENT MANIFOLDS AND TECHNICAL BULLETINS WITH INSTRUCTIONS TO CONTACT MCGAW WITH REGARD TO QUESTIONS OR FOR ASSISTANCE, IF NECESSARY.

4. FOREIGN CONSIGNEES AS FOLLOWS:
MCGAW ETHICALS LTD., P.O. BOX 18-069, AUCKLAND 6, NEW ZEALAND

AHS/AUSTRALIA PTY LTD., P.O. BOX 371, EPPING NSW 2121, AUSTRALIA HOSP.

DEL SAGRADO CORAZON, TIJUANA, MEXICO

AMERICAN HOSP. CUPPLY, MISSISSAUGA, ONTARIO, CANADA

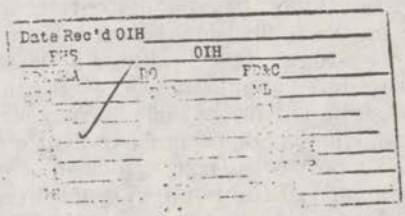
AHS FRANCE, BOITE, POSTALE 716, 95804 CERGY, FRANCE

VANDER HYDEN, RUE DU MARIAS, 1000 BRUXELLES, BELGIUM

AHS SOUTH AFRICA, P.O. BOX 2726, JOHANNESBURG, S. AFRICA

POCHTECA INTERNACIONAL, MEXICO CITY, MEXICO

FLETES AEREAS DE MEXICO, AEROPUERTO INTERNACIONAL, MEXICO CITY LABORATORI DON BAXTER SPA, 122/124 VIA FLAVIA, TRIESTE ITALY. VANCE



Mr. ROSENTHAL. You said that the FDA is participating in the so-called Peterson committee—the working group. How many meetings have you had?

Dr. KENNEDY. I think that that group has actually physically met together once.

Mr. ROSENTHAL. Is there progress being made? Do you have any comment on how things are going?

Dr. KENNEDY. I did not, myself, attend that meeting. Mr. Cooper, the Chief Counsel for the Food and Drug Administration, attended for us.

I have reviewed all the documents that have emerged, the draft documents, so far.

I would say that the progress which has been made is pretty encouraging, considering how long the effort has been going on.

There is a lot of just plain comparative information to be gathered from the several agencies; and that has proceeded, I think, reasonably well. I think there remain some hard decisions and maybe some arguing to be done.

Mr. ROSENTHAL. Which hard decisions in the areas of your jurisdiction have yet to be made?

Dr. KENNEDY. I am just predicting, Mr. Chairman, but I think because some of the decisions that I expect to be easy turn out to be hard. Who knows, maybe someday one of the ones I expect to be hard might turn out to be easy.

Mr. ROSENTHAL. Which ones?

Dr. KENNEDY. But in this particular case, the ones I would expect to be hard are decisions about whether in a particular class of technology—drugs or pesticides or a class of substances of that sort—the United States should take the position that because there is enough risk distributed in the class, a very strong position ought to be taken that we should not permit exportation within that class to take place at all, or only with restrictions so strong that it essentially takes out of the hands of the importing nation entirely the decision of whether or not to import.

I think that is where some people tend to disagree.

In the export provisions in our drug bill, which I have outlined to you, that is where we have found people having the most difficulty.

Mr. ROSENTHAL. The notification and export provisions in your bill, how would you describe that in terms of policy ? Is it a change in policy, a major change in policy, a dramatic change in policy, or what?

Dr. KENNEDY. That is a surprisingly difficult question to answer, because our own law is so internally inconsistent that it is very hard to know what the policy is.

Remember that under present law, you cannot export a new drug that is not approved at all; whereas, with appropriate notification and other restrictions, you can do so with an unapproved medical device.

So even within the same subsection of our law, there are differences.

Our proposals for drugs would bring the situation, with respect to drugs, rather close to the situation with respect to medical devices.

It would be a much more stringent export provision than we have in some areas of our law—for example, foods—but less stringent in some ways than the present blanket on unapproved new drugs.

Mr. ROSENTHAL. Congressman Brown?

Mr. GARRY BROWN. Thank you, Mr. Chairman.

I presume, Commissioner Kennedy, that you are aware of Esther Peterson's testimony before us yesterday.

In that testimony, she said and I quote:

> Different economic, social, and cultural conditions in a foreign country may suggest that product whose recent ban or severely restricted test may be justifiable for use in that other country.

Jacob Scherr of the Natural Resources Defense Council said and I quote:

> We want to stress at the outset that we do not advocate a prohibition of the export of all products that are banned for domestic use.

Is it correct that any drug that is banned for domestic use is banned for export?

Dr. KENNEDY. Unless it is an antibiotic, insulin or a drug that is a "grandfather" drug under the provisions of our law, then it is not subject——

Mr. GARRY BROWN. The so-called old drugs.

Dr. KENNEDY. All of these—in fact, you can export antibodies even if they are not certified. There are some respects where that part of the law, of course, is much too loose.

But for post-1962 drugs if they are banned here you can't export them.

Mr. GARRY BROWN. Since Esther Peterson raised Depo Provera as an example and you have mentioned it in your testimony, I noticed you say that when you announced you were not approving it for domestic use, you said:

> In announcing our decision, I made it clear that the drug which is approved for use as a contraceptive in nearly 70 countries may well have favorable benefit/risk ratios in those other countries.

Yet, that is almost a meaningless announcement, isn't it, because U.S. companies can't export it?

Dr. KENNEDY. That is correct, Mr. Brown. I am glad you asked the question.

The reason I made the announcement was because several people, including your colleague, Congressman Scheuer, and some other members of the House Select Committee on Population, believed that our decision would hurt in some extralegal, but nevertheless important, way the use of Depo Provera overseas.

U.S. drug approval decisions are influential decisions, with respect to exportation.

Mr. GARRY BROWN. Very definitely.

Dr. KENNEDY. The purpose of my letter was to try to say that our decision has to be based on the risks and benefits as applied to American women, but it is not a decision that we would expect could be transposed with confidence to other nations of the world because the availability of alternatives is different, the——

Mr. GARRY BROWN. That is the key, isn't it, the availability of alternatives.

In the Depo Provera case, it seems to me that, to the extent that there was a scientific decision made, the availability of alternatives in the United States was the cornerstone of your decision to reject the application.

But the availability of alternatives is not the same in Bangladesh, for instance, as it is in the United States.

If you were serving in a similar capacity in one of the lesser developed countries—say in Bangladesh—what would have been your decision with respect to Depo Provera?

Dr. KENNEDY. I don't want to weasel, Mr. Brown, but I have to preface my answer by saying that any developing nation that had me in charge of its drug approval process would be in deep trouble. [Laughter.]

Nevertheless, if I were in that situation and had to make the decision on present knowledge all by myself, I think it is likely that for most nations with the population structure, disposable personal income, and health care systems of Bangladesh I would approve it.

Mr. GARRY BROWN. I think you are saying that in looking at the efficacy hazard equation, you have to look at the hazard of nonuse.

Dr. KENNEDY. That is correct.

Mr. GARRY BROWN. I believe that there is 13 to 20 times the mortality rate in childbearing in other countries as there is in this country.

Dr. KENNEDY. Yes; that is very important.

To return to an earlier decision. I would emphasize that the availability of alternatives—although it is a factor in a risk/benefit decision—is only one of a number of factors.

I think that the demographic profile of a nation might be important if people lived to an average age in nation A that is 10 years older than in nation B. And if a side effect involves a condition that only appears near the very end of life, the risk/benefit decision might be very different on that ground alone.

Mr. GARRY BROWN. Would it be better if in many of these cases instead of banning, you take some lesser action.

Once you ban in this country, I think the psychological impact from a political standpoint in any other country is severe.

In other words, I think that if it is banned for use here, any leader of another country serving in a capacity such as yours who would approve it would be, in effect, saying: We will permit our population to be exposed to more hazardous products than America will.

It seems to me that that creates a real problem from a political and social standpoint in these other countries.

Isn't there some way that under labeling of some kind that you then say that this is approved but on a very limited basis.

That, it seems to me, would give greater justification for its utilization, as you recommend, in these other nations.

Dr. KENNEDY. I think that does create a better psychological——

Mr. GARRY BROWN. I'm thinking not only of Depo Provera, but of many similar cases.

Dr. KENNEDY. I think that is correct.

In that connection, I would want to emphasize that the term "banned" is not an appropriate one for our action with respect to Depo Provera.

Mr. GARRY BROWN. But nevertheless that is the effect of the action.

Dr. KENNEDY. No; not exactly, Mr. Brown.

Depo Provera is approved for use in the United States in the treatment of endometrial cancer.

The manufacturers had asked for its approval for a new indication; namely, as an injectable contraceptive. That approval was ultimately not granted, but Depo Provera is still available here for its more limited indication.

Even if it were not, our decision was not to remove it from the market but rather not to permit it to enter for this particular indication; and that is different from banning it.

Mr. GARRY BROWN. What has been your recommendation in this regard with respect to this issue before the Rogers subcommittee?

Dr. KENNEDY. The recommendation consists essentially of the proposals made in the Drug Regulation Reform Act of 1978; namely, that unapproved drugs of all kinds can be exported but that the Secretary may, if need be—and he is instructed under the proposed law to make the judgment in terms of the public health of the citizens of the country and the citizens of the United States—choose not to permit that exportation.

Furthermore, the government of the importing nation must indicate to the United States that it does not object to that importation. And there is provision in the law for providing technical assistance to that government from the United States in order to assist it in making that determination if such assistance is needed and requested.

Mr. GARRY BROWN. In connection with these hearings, would you like this subcommittee to indicate to Paul Rogers' subcommittee that we feel that your position is correct and justified?

Dr. KENNEDY. It would be very helpful, Mr. Brown.

Mr. GARRY BROWN. Thank you, Mr. Kennedy. I have no further questions.

Mr. ROSENTHAL. Congressman Drinan?

Mr. DRINAN. Thank you, Mr. Chairman.

Commissioner Kennedy, I take it that you feel that the medical device amendments are sort of a model and that if you could have a law along those same lines then the problems to some extent would be resolved.

Dr. KENNEDY. Our proposals in the Drug Regulation Reform Act are similar to the medical device amendments, though they do go a little further in some respects.

Mr. DRINAN. The medical device amendments have not yet been applied, have they? There has been no case yet where the medical device has been banned.

Dr. KENNEDY. That is because the implementing regulations for those amendments are not finished yet as you know.

Mr. DRINAN. Are there any loopholes there that could possibly also reside in H.R. 11611?

Dr. KENNEDY. We don't believe so.

Could I ask Mr. Cooper to give me some help on that?

Mr. DRINAN. Yes.

Mr. COOPER. We examined the background of the device amendments in drafting our recommendations in the drug legislation.

We believe we have provided for an adequate system.

Mr. DRINAN. All right.

The bottom line is this. If that bill is passed, will you have control over the export of cyclamates?

As you know now, Abbott Laboratories and others are exporting them widely—all through Europe and Canada—despite the ban of the Food and Drug Administration.

Dr. KENNEDY. We won't have control over cyclamates.

Mr. DRINAN. Do you want control over cyclamates? Do you want to ban them because they are in the 109 ingredients that the FDA has banned?

Dr. KENNEDY. I would not think that—let me back up a minute.

I think that it is probable that in many cases it would be useful to have some of the notification provisions and the restrictions available to us in the proposals for drugs and also for food additives, although there would be some administration problems for us in that section of the law.

But I don't think that I would want to be able to put a blanket ban on the export of unapproved food additives here, any more than I would want to for unapproved or banned pesticides.

I think you can think of cases—and I have a couple in mind—in which——

Mr. DRINAN. No one is banning that completely. The Administrator has the power to give a license in certain cases.

But the new bill that is being touted as the model still will not do anything about cyclamates.

Here is one instance where the companies are exporting them widely. There may or may not be notification; there is no notification on the cyclamates that go to Canada or to Europe that this item has, in fact, not been registered or has ever been banned by the FDA.

So this is one area where this new law that is proposed—and it may become law—does zero.

Dr. KENNEDY. Yes. It does not apply to food additives.

Mr. DRINAN. Why not?

Dr. KENNEDY. Because another part of our law defines food additives in such a way that it clearly differentiates them from drugs.

Mr. DRINAN. But if they are dangerous and if they can be cancer causing, why shouldn't we include them?

Dr. KENNEDY. I guess my belief is that if we did so, it would produce more difficulties for us than it would solve.

Mr. DRINAN. That is not very satisfactory.

If they should be banned for the American people, why should we allow their export when we are seeking to ban the export of other substances which have also been banned?

Dr. KENNEDY. I have no argument with the merit of your suggestion.

Mr. DRINAN. Why didn't the FDA put that in the bill that is before the Rogers subcommittee?

Dr. KENNEDY. Because we had to limit this bill to drugs. We are going to do food legislation next year, and then I hope that we will be able to settle the import question for foods.

Mr. DRINAN. I don't see the difference though. It will be before the same subcommittee, it is the same substance. It may be the same question. Maybe it is a different statute.

Dr. KENNEDY. We just did not consider that to raise the entire set of issues connected with food, which are under a different title of the Food, Drug and Cosmetic Act, was something that we could do

when we were addressing primarily a whole set of problems having to do with drugs.

I guess it was a decision about how much we could accomplish at one time.

Mr. DRINAN. All right. It is a rule of convenience then.

Let me go back to the adulterated foods.

The FDA, as I understand it, has no systematic surveillance or inspection of adulterated foods.

We have examples in the material the staff has prepared that some 6,700 boxes of insect-contaminated rice were sent to Chile. And quite by happenstance, the FDA apparently intercepted that.

Under the new bill, is there any new power given to the FDA where they could inspect or have some control over the exportation of adulterated food?

I suppose your answer is that food comes next year; right?

Dr. KENNEDY. I am afraid so; yes, sir.

Mr. DRINAN. I hope it is early next year, because somehow food has not surfaced as much as the things that are before us.

I thank you for your testimony.

Dr. KENNEDY. Thank you, sir.

Mr. ROSENTHAL. Congressman Levitas?

Mr. LEVITAS. Thank you, Mr. Chairman.

I regret I was not able to be at the hearing yesterday because of another oversight hearing.

I would like at this point, before I ask Mr. Kennedy some specific questions, to make some general observations with respect to the thrust of these interesting and important hearings you are conducting.

What concerns me is that in some ways the thrust of what these hearings are pointed at manifests a colonial mentality of some sort, or a missionary complex, is that what is good for the United States is necessarily good for everybody in the world, and that we ought to be making decisions for other economies, other environments, and other health profiles.

Mr. DRINAN. Would the gentleman yield?

Mr. LEVITAS. In just a moment. [Laughter.]

I realize my good friend, Father Drinan, wants to take specific exception to the use of the words "missionary complex."

Mr. DRINAN. You read my mind. [Laughter.]

Mr. LEVITAS. But while I think it is certainly incumbent upon the United States and its governmental agencies not to engage in a pattern of practice of poisoning or polluting the world, I think that the issues are not black and white.

The types of efficacy/hazard ratios, the cost/benefits, the economic needs are all matters of balance.

I do not think it is the responsibility of the Colonial masters or the holders of Christian doctrine to be the missionaries for the world.

While we need to make the information available and provide such technical assistance and advice as is appropriate, what may be good for the United States may not be good for some other nation in the world, and vice versa.

With those few comments, let me turn to the problem of the Delaney amendment and saccharine, for example, or cyclamates.

Under our present statutory framework, leaving aside the 18-month postponement, if a food additive is found to produce cancer in laboratory animals, it is automatically prohibited.

That is not the test elsewhere in the world—in all places of the world; is that correct?

Dr. KENNEDY. It is not the test in all places in the world.

Mr. LEVITAS. Do you understand that if the food area, which will be taken up next year, is treated in the same way as devices, and leaving aside any change in the Delaney amendment, that you as the head of the Food and Drug Administration almost would have to ban the export of foods prohibited in this country under the Delaney amendment?

Dr. KENNEDY. If the provisions in the hypothetical food regulation reform act of 1979 followed our design for the Drug Regulation Reform Act of 1978, we would be able to do so judgmentally if we thought that exportation provided a public health hazard.

We would be able to permit it if, in our judgment, it did not.

You give me the opportunity to cite a useful example. I am treading on dangerous ground here, because there is a pending hearing and I am separated from it.

But I think it would be fair to say that two large national groups of capable scientists could conceivably draw different conclusions from the results of a chronic toxicology test. Indeed, it appears that that situation might one day exist between Canada and the United States with regard to two chemically, slightly different types of red coloring matter.

I don't see anything wrong with the world in which each nation would be free to trade with other nations, according to its own scientific convictions—if I make my point.

Mr. LEVITAS. I think that responds to the main question I had. Do you feel that the type of proposals which are presently in place or under consideration give you, as an Administrator, sufficient flexibility to exercise that type of judgment or do you think there is a need for more flexibility?

Dr. KENNEDY. If by proposals now under consideration you mean something approximately modeled on the same plan as our proposals in the new drug law, then the answer is yes; I think they do provide adequate flexibility.

Mr. LEVITAS. Thank you.

Now I will be happy to yield to my colleague who has much more experience and history in the perpetuation and propagation of the true faith.

Mr. DRINAN. I just want to commend him for reading my mind and correcting his misstatement. [Laughter.]

Mr. ROSENTHAL. Mr. Brown?

Mr. GARRY BROWN. Thank you, Mr. Chairman.

I would just like to go back to an earlier discussion.

Your authority for banning the export of new drugs, I assume, stems from section 505 which says: "No person shall introduce or deliver for introduction in interstate commerce any new drug unless an approval of an application filed pursuant to subsection (b) is effective with respect to such drug."

That is in interstate commerce.

Let us assume that firm X decides to manufacture a drug. It doesn't engage in interstate commerce—not to offer it for sale and not to submit it for approval by you but only for export.

I know the answer to the question, Mr. Kennedy. It is in your definition of interstate commerce.

I don't think I have ever seen it defined the way it is in your statement.

I think our Founding Fathers would turn over in their graves, since they also discussed foreign commerce in the Constitution.

But in interstate commerce, which is defined in your basic law as "The term 'interstate commerce' means commerce between any State or territory and any place outside thereof."

Mr. COOPER. Perhaps that should be read as a shorthand reference to interstate and foreign commerce—both of which are within the power of Congress.

Mr. GARRY BROWN. Sure. I just wondered about the source of your authority. And then I read the definition of interstate commerce.

Mr. COOPER. Constitutionally, they are both within the power of Congress.

Mr. GARRY BROWN. Of course.

But do you think that our Founding Fathers would have contemplated that interstate commerce and the interstate commerce clause would read as it has been defined in this act?

It is not your fault; it is Congress, obviously.

But isn't that a rather strange definition?

Mr. COOPER. It is strange, but I think it can be read as interstate and foreign.

Mr. GARRY BROWN. Thank you.

Mr. ROSENTHAL. Thank you very, very much. We appreciate your testimony, and we appreciate your understanding of the nature of the problem.

We also appreciate the information that we requested and your giving attention to whatever remedies can be dealt with by Executive order quickly—just in case there are any landmines in the legislative route.

Thank you for being with us.

Dr. KENNEDY. Thank you, Mr. Chairman.

Mr. ROSENTHAL. Our next witness is Barbara Blum, Deputy Administrator of the Environmental Protection Agency.

Congressman Levitas?

Mr. LEVITAS. Thank you, Mr. Chairman.

I would like to take this opportunity to welcome a constituent of mine to this committee, Ms. Blum, who is the Deputy Administrator of the Environmental Protection Agency. She has for many years been very active as a business person and as a public participant in advocacy before State and Federal legislative bodies.

I am very proud of the service she is rendering to this administration.

I believe that there have been some major improvements in the Environmental Protection Agency under the leadership of Mr. Costle and Ms. Blum.

It is a pleasure to have her with us today, and I would like to introduce her in that fashion to this subcommittee.

32-427 O - 78 - 11

Mr. ROSENTHAL. Thank you very much, Congressman.

Ms. Blum, we are delighted to have you here.

We know you have a prepared statement, and we are very anxious to hear it.

STATEMENT OF BARBARA BLUM, DEPUTY ADMINISTRATOR, ENVIRONMENTAL PROTECTION AGENCY; ACCOMPANIED BY ALICE B. POPKIN, ASSOCIATE ADMINISTRATOR, OFFICE OF INTERNATIONAL ACTIVITIES; AND ROBERT H. WAYLAND III, OFFICE OF LEGISLATION

Ms. BLUM. Thank you, Mr. Chairman.

I would like to give you the prepared statement for the record.

Mr. ROSENTHAL. Without objection, it shall be included in the record.

Ms. BLUM. I have here with me today Alice Popkin, who is the Associate Administrator for International Activities for the agency, and Robert Wayland of our Office of Legislation.

With your permission, what I really want to do is submit the prepared statement and then comment on some of the questions that I think you may have from the testimony yesterday—the NRDC testimony and the General Accounting Office testimony.

Let me say first that I agree that notification procedures should be improved and that there have been deficiencies in the past. This is something that I have been aware of and personally interested in looking into, even prior to the GAO report.

I think that there are some things that we can do within the framework of the pesticide notification policy that Congress has mandated in FIFRA.

We are also supporting the new amendments to FIFRA that will strengthen the export notification provisions.

We have, however, gone beyond the requirement of the law to advise other countries of some of the specific regulatory actions. One example would be the Leptophos tolerance revocation through the 17(b) mechanism.

That, of course, is our mechanism for notifying the State Department of final actions on pesticide registrations.

We have conducted embassy briefings about possible regulatory actions and procedural aspects of our rebuttable presumption risk reviews. I participated in one of those.

And we are an active participant in the world organizations which are sharing pesticide regulatory information on a continuing basis.

One example of that is the OECD, in which we participate in two active chemical groups. If there are any notifications of any of the member nations of OECD, some 24 nations, we notify both through OECD and through the member nations, as they do us.

U.S. law mandates use-by-use pesticide regulation. The degree of hazard and the extent of each use vary widely. They vary both in the United States and abroad, and we don't regard all cancellations as having equal significance, requiring 17(b) notification.

We would not wish our notices or these hearings to create the impression that each EPA regulatory action has been prompted by a grave threat to human health or the environment.

Let me cite some examples to clarify that a little.

Although we did cancel one use of quaternary ammonium compounds in 1973, our decision not to make a 17(b) notification was based in part on the widespread and continuing lawful use of the chemicals and disinfectants still approved by EPA, which were unaffected by the 1973 action to discontinue only one area of use, poultry drinking water and disinfectant uses.

Regulatory action was not completed on the widely used insecticides, heptachlor and chlordane, until this past March due to protracted administrative appeals by producers and users of these pesticides.

17(b) notice was transmitted to the State Department early in April, a month after regulatory action was concluded. The terms of the cancellation provide for up to 5 years of additional domestic use, however, for some purposes.

EPA's agreement to phase out use of these chemicals, when cancellation proceedings were initiated because of cancer-causing properties exhibited by them in laboratory experiments, demonstrates our agency's appreciation for the considerable benefits a dangerous pesticide may afford. By law, we weigh the benefits against the risks in making our regulatory judgments.

If this doesn't clearly suggest that pesticide regulatory issues are exceedingly complex, let me illustrate a further consideration for U.S. policy on exports of these compounds—very few of which are completely innocuous from a health or environmental viewpoint. I need to stress that.

Much of the Third World is looking to pesticides as one part of the answer to life-shortening epidemic illnesses and starvation, and I think this is a point that Congressman Levitas made very early.

These are not benefits which we typically weigh here in the United States. One rather simple example would be whether or not a country should use a pesticide to control malaria when that pesticide is possibly carcinogenic. But that country is weighing the immediate prospect of young people contracting a pest-borne illness and dying against the long-term effects of something that is possibly carcinogenic.

I think that decision, as Congressman Levitas pointed out, is very difficult for us to make for another country. It is a moral decision that I think is theirs.

Mr. ROSENTHAL. I assume the underlying assumption of that proposition is that the foreign country should receive all adequate information.

Ms. BLUM. Absolutely.

Mr. ROSENTHAL. And presumably they are in a position to understand and digest that information.

Ms. BLUM. I should hope so.

Yes; I certainly think that they should have that.

Mr. ROSENTHAL. I think we all probably generally agree with that, that we have to let each sovereign nation make its own judgments.

The question is: Are our notification procedures adequate and do we follow them up adequately?

In the case of EPA, it would appear to me prima facie that we have not done that.

You kind of admit that EPA has not done an adequate job of notification; is that correct?

Ms. BLUM. Yes. I don't think we have done an adequate job of notification in the past.

Mr. ROSENTHAL. How would you describe the job you have done of notification if you had to rate it?

Ms. BLUM. You mean if I am rating it A, B, C, or D?

Mr. ROSENTHAL. Somewhere between satisfactory to pitiful.

Ms. BLUM. Between satisfactory and pitiful, I think we have done just a very ordinary job, where we should be doing a very extraordinary job.

Mr. ROSENTHAL. The question is: What are you going to do about it?

Ms. BLUM. We are doing several things about it right now.

We are examining our own internal processes. We are trying to work with the State Department to find a better way to implement 17(b). There seems to have been too many places where it fell through the boards—both at our agency in getting it to the State Department in a timely fashion and on the part of the State Department whose responsibility it is under FIFRA to notify various embassies and the embassies then notifying the people in various nations.

In the case of the lesser developed countries, there may also be institutional problems in making effective use of information on pesticides which is conveyed by the United States. For example, I came back just recently from Nigeria. I was discussing the pesticide problem with the Minister of Environment of Nigeria.

The whole EPA in Nigeria is one person. The Minister has one professional and one secretary.

He said that the person you notify in this country is me. There are just three of us, and I can't really cope with it.

I think that we are going to have to take some responsibilities, particularly with some of the lesser developed countries, to make sure that we are not only notifying the right person but that the right person can handle the material that we give them.

One of the things that we have put together that may make it simpler is a pamphlet on "Suspended and Canceled Pesticides" that we hope to translate into foreign languages. It is in English right now.

We hope this will make it a little bit simpler to understand.

Mr. ROSENTHAL. What countries do you distribute those to?

Ms. BLUM. We are going to distribute them to every country with which we have diplomatic relations. But this will not be in lieu of notification.

Mr. ROSENTHAL. You state on page 3 of your testimony that of the 15 pesticides canceled or suspended, 5 are exported.

The information we have is that at least 10 are exported.

Ms. BLUM. To my knowledge, the only five that are exported are chlordane, heptachlor, DDT, leptophos, and mercury.

Mr. ROSENTHAL. I have some figures for 1976:

Aldrin, 342,000 pounds were produced and 342,000 pounds were exported.

Benzene hexachloride, 1,432,000 pounds were produced and 456,000 pounds were exported.

Chlordane in three forms, 159,000 pounds were produced and 159,000 pounds were exported.

Chlordane in one form, 82,710 gallons were produced and 82,460 gallons were exported.

DBCP—Dibromochloropropane—25,000 pounds were produced and 25,000 pounds were exported.

DDT in 13 forms, 25 million gallons were produced and 25 million gallons were exported.

DDT in five forms, 286,000 pounds were produced and 286,000 pounds were exported.

Heptachlor in nine forms, 1,511,000 pounds were produced and 1,347,000 pounds were exported.

Heptachlor in one form, 23,000 gallons were produced and 20,000 gallons were exported.

And it goes on.

There is apparently a discrepancy in what you tell us and what the information reveals.

Ms. BLUM. That is because you are reading from 1976 imports and my information is coming from the 1977 report.

In 1977, of the 15 canceled or suspended, there are now only 5 that are exported.

Mr. WAYLAND. We provided a complete list by manufacturer and production volumes to the committee this morning.

DBCP, for example, is no longer produced in the United States.

Aldrin/dieldrin production moved out of the United States in 1975, and I think what you see in the 1976 export data are exports of existing stocks on hand at the time the cancellation was effective.

Mr. ROSENTHAL. Do you want to disclaim responsibility—and I suppose you should—for anything this agency did prior to January of 1977?

Ms. BLUM. No. I think I would just rather say that we are going to do better after January of 1977.

No; we won't disclaim responsibility. But I was simply pointing out that the information we provided you this morning was the more up-to-date information which probably has not reached you yet.

Mr. ROSENTHAL. Yesterday the GAO testified that EPA had determined that nine regulatory actions taken by EPA were not appropriate for notification to foreign governments. Are you aware of that testimony?

Ms. BLUM. Yes.

Mr. ROSENTHAL. Can you explain it to us?

Mr. WAYLAND. I think Barbara Blum's example of quarternary ammonia illustrates that whenever you are faced with a subjective judgment, such as whether a particular regulatory action has "national or international significance," you have the potential for reasonable people to arrive at different conclusions. Apparently, the GAO and EPA came to different conclusions when applying this standard to at least some of the cancellation actions cited by GAO.

Quaternary ammonia is very widely used in the United States in a variety of disinfectants.

The cancellation of the poultry drinking water disinfection use came about primarily because the manufacturers of quaternary ammonia didn't wish to do testing that would be necessary to establish a tolerance for that particular use.

Rather than go to that expense they said it is not worth it. Since it was not possible to make the judgments necessary to establish a tolerance without the submission of additional data, that use was canceled.

But we, frankly, don't think that that ranks with aldrin and dieldrin or heptachlor or chlordane in significance.

The record is certainly spotty, and there are instances where notification should have been made and there wasn't and——

Mr. ROSENTHAL. Which instances were there of notification that should have been made and were not; can you tell us some of the circumstances surrounding those instances?

Mr. WAYLAND. One that comes easily to mind is that I think we probably should have notified on the heptachlor/chlordane suspension action.

In fact, when our cancellation action was concluded, we did make notification. We made notification some 5 years prior to the effective date of that cancellation.

But suspension is an intermediate action for emergency purposes taken before final cancellation. The law provides that we can provide notice upon suspension, and we didn't do so.

Mr. ROSENTHAL. What about kepone? You didn't notify anybody on kepone.

Mr. WAYLAND. Oh, yes, we did. Absolutely.

Mr. ROSENTHAL. The GAO said you didn't.

Mr. WAYLAND. The GAO is incorrect.

Mr. ROSENTHAL. Did they submit their report to you before they submitted it to the Congress?

Mr. WAYLAND. Yes; they did.

Mr. ROSENTHAL. And you had a chance to correct it or discuss it with them.

Mr. WAYLAND. And we told them that the kepone notice was sent out in April.

The report was prepared in March, and released in May, and there was no modification of the report between those two times.

We commented on the draft report, and the kepone notice went out in April. This is a month prior to the effective date of the cancellation for certain of the kepone products.

It does follow, by about 6 months, the conclusion of our regulatory activity. That is an example, I think, of where we should have acted sooner.

But in point of fact, kepone production stopped sometime well before our regulatory action was concluded.

Mr. ROSENTHAL. When did you take the regulatory action on kepone?

Mr. WAYLAND. The final action was in December of 1977.

Mr. ROSENTHAL. But the determination was made 6 months prior to that?

Mr. WAYLAND. No.

Our determination was made in December of 1977. The action was effective in May of 1978. We provided our notice in April of 1978.

Mr. ROSENTHAL. Why didn't you provide the notice in 1977?

Mr. WAYLAND. I think that we should have provided it.

Mr. ROSENTHAL. Kepone was a deadly chemical.

Mr. WAYLAND. I don't know that I would share that opinion, Congressman.

Pesticides can harm you in a lot of ways. Some pesticides can kill you if you have a small amount on your skin.

Mr. ROSENTHAL. What damage does kepone do to people?

Mr. WAYLAND. It causes nerve damage after presumably long periods of exposure at relatively high levels, or lower levels of exposure over a lifetime.

Mr. ROSENTHAL. And you didn't think people should be notified about that when you took the regulatory action or when you made the decision of its——

Mr. WAYLAND. We do think that people should be notified.

Mr. ROSENTHAL. Six months elapsed in 1977 after the new administration had taken hold of this agency. Six months elapsed between the time you knew of this threat and the time that you sent out the notice.

Ms. BLUM. I think you are absolutely right. I think there should not have been a 6-month lag if there was—and you say that there was, Mr. Wayland.

Mr. WAYLAND. That is correct. However, the notice went out before the effective date of the cancellation.

Mr. ROSENTHAL. I understand that. You could have made the effective date 25 years from now, but once you have the information, it would be nice to let people know about it.

Ms. BLUM. You are absolutely right.

You asked for examples, and Mr. Wayland mentioned chlordane-heptachlor. That was suspended in 1975; it was canceled in 1978; and our notification didn't go out until the cancellation in 1978.

The countries should have been notified at the time of the suspension in 1975. So I don't think we are in disagreement.

Mr. ROSENTHAL. One of the things we are concerned with is not only with the damage pesticides can do overseas to the citizens of foreign countries but is there a threat of agricultural products being treated with banned pesticides and then being reimported into the United States?

Ms. BLUM. Yes and no. The reimportation problem——

I don't know if you are aware of it, but under the Federal Food, Drug and Cosmetic Act, EPA is responsible for establishing tolerances. These are tolerances on the legal limits of pesticide residues which can safely remain on agricultural products being sold in interstate commerce or imported into the United States.

So at the border, fruits, vegetables, and so forth which are grown in another country, or at the dock or wherever they are coming in, are all tested by the Food and Drug Administration for the tolerance levels that we have established.

Insomuch as that process works, we are protected from unsafe residues of pesticides on agriculture commodities, regardless of country of origin.

Mr. ROSENTHAL. Does it work?

Ms. BLUM. I am told that it does.

I feel that with any kind of a testing procedure, there is always going to be room for some kind of error occasionally. But, in general, yes, I am sure that tolerances work.

Mr. ROSENTHAL. Do you have any statistics on actions taken by FDA on products that were rejected because of a high tolerance on pesticides?

Ms. BLUM. I don't have that with me, but I can provide it for the record or ask FDA to provide it for the record.

There have been some, yes.

[The material referred to may be found on p. 200.]

Mr. WAYLAND. I couldn't give you specific numbers of lots that are examined and instances where the produce was refused at the border, but one thing many exporting countries are acutely aware of is the tolerance system and U.S. EPA tolerance requirements.

Very frequently, they will adjust their pesticide usage in a country to assure that they do not exceed the U.S. domestic tolerance on commodities exported to the United States.

We were in a dialog quite recently with Mexico over the question of whether or not Mexican produce is contaminated with pesticide residues exceeding the limits established by EPA. By and large, it is not.

Ms. BLUM. We also work closely with Canada on this, which is another big——

Mr. ROSENTHAL. But there is a difference between high levels of residue on pesticides that are approved and pesticides that are disapproved.

Mr. WAYLAND. The food commodity cannot be imported unless there is a tolerance established for that pesticide on that food.

Consequently, residues which have not been approved for food imported into the United States because pesticides have not been approved for use are not permitted.

Mr. ROSENTHAL. What foregin countries are using today pesticides that we have disapproved and are not permitted for use in the United States?

Mr. WAYLAND. Quite a few, though not always for agricultural purposes.

Ms. BLUM. A lot of them.

Mr. ROSENTHAL. Could you tell us the names of some of them?

Ms. BLUM. The lesser developed countries—India, many of the African nations.

Mr. ROSENTHAL. Which African nations?

I am trying to follow through which products we import.

Ms. BLUM. I can tell you just generally, and I can provide that for the record.

[The material referred to may be found on p. 191.]

Ms. BLUM. There are many countries now, for example, manufacturing their own DDT. So although we do export DDT, most of the purchases are now made abroad—a fact over which we have very little control.

Mr. ROSENTHAL. Can you think of specific countries and specific pesticides that we disapprove that are being used in those countries?

Mr. WAYLAND. I think there is one area we ought to clear up before we get into examples.

That is that there are still on the books in the United States tolerances for pesticides that have been cancelled for use in the United States. This is because there is a background level of DDT, for example, in the environment.

Crops grown in the soil in your state and all over this country have DDT residues on them when they come to market.

Mr. ROSENTHAL. From years ago?

Mr. WAYLAND. Absolutely.

Mr. ROSENTHAL. How long does that residue level continue?

Mr. WAYLAND. I think the DDT soil half-life is something like 12 years.

There is also a considerable amount of aldrin/dieldrin in the soil.

We have lowered the DDT tolerance level to account for gradual decline in the background levels of DDT in the soil and water of the United States. Our cancellation was probably too recent to permit us to crank down the tolerances on aldrin and dieldrin, however, without posing problems for U.S. farmers who have stopped using these chemicals but whose crops nevertheless bear residues.

These are the major pesticides which were used in agriculture and which have been canceled. Many of the others you discussed were not used in substantial quantity on food.

Mr. ROSENTHAL. I understand.

But now having that information, what I am interested in knowing is what countries today are using pesticides that we prohibit the use of in the United States?

Ms. BLUM. As I said, I can only answer that in general and provide the specifics for the record. But many of the lesser-developing countries are——

Mr. ROSENTHAL. I would like to try to have an example of a country and a product that we import.

Mr. WAYLAND. I have quite a few FAO figures—U.N. Food and Agricultural Organization—on pesticide use overseas. But the figures are really pretty poor.

We don't have good figures on what pesticides U.S. farmers use, because they are not required to report that.

We know what moves in commerce in the United States, but we don't know what is being used on a given crop at a given time.

Benzene hexachloride, for example, those registrations were converted to lindane registrations in the United States some years ago. BHC is evidently used in cocoa-producing countries to control a pest of cocoa. There are, presumably, BHC and lindane tolerances which apply to both the residues on raw cocoa beans imported into the United States and finished chocolate products.

Mr. ROSENTHAL. Do we import any food products from Nigeria, for example.

Ms. BLUM. Not that I know of.

Mr. WAYLAND. I am not an expert on Nigeria.

Ms. BLUM. I couldn't guarantee that we don't, but I don't believe that we do.

I can provide you that for the record.

In my informal discussions with the Nigerian Government, I asked them that question. I don't believe that they——

Mr. ROSENTHAL. How about Uganda?

Mr. WAYLAND. Certainly Uganda is a major coffee producer.

Mr. ROSENTHAL. Do we import a lot of their coffee?

Ms. BLUM. And Kenya is a major——

Mr. ROSENTHAL. I just want to stick with Uganda for a minute.

Mr. WAYLAND. Although we established tolerances, they are enforced by FDA. FDA has people on the docks looking at the——

Mr. ROSENTHAL. We don't have a diplomatic mission in Kempala do we?

Mr. WAYLAND. That doesn't mean that the produce can enter the United States in violation of tolerances.

Mr. ROSENTHAL. How do you know that?

Mr. WAYLAND. Imports are examined by FDA for tolerance compliance. It is done on a spot-check basis.

We don't take their word for it that they don't use these things. We examine on a random basis food lots which are imported.

If a violative sample is found, the shipment is refused.

Mr. ROSENTHAL. And you think the examination is adequate for the protection of American society?

Mr. WAYLAND. I think FDA could better comment on that. It is their very large responsibility to detect "adulteration" of food and prevent sale of food bearing unhealthy pesticides residues.

I know they are able to inspect a relatively small number of samples of the total——

Mr. ROSENTHAL. As Ms. Blum brought up, for example, in Nigeria they have only three people in their environmental agency. I doubt they would be in a position to make the kind of examinations and have the kind of intellectual inquiry that the situation warrants.

I am trying to find an example of a country where we do import a lot of foodstuffs, such as Uganda, a presumably developing country. I would like to know if we are selling them any pesticides that are prohibited for sale and use in the United States.

Mr. WAYLAND. I may be able to tell you whether we shipped any DDT to Uganda recently, but that is probably the only figure we have available.

Ms. BLUM. While he is looking for that figure let me say that even if he finds it, it does not mean that Uganda did not get DDT from another source.

Mr. ROSENTHAL. I understand that completely.

Mr. WAYLAND. Uganda imported 4,400 pounds of DDT from the United States in 1969.

Bureau of Census data does not show any further Ugandan DDT imports for this country subsequently.

Mr. ROSENTHAL. Are there any other prohibited chemicals that they purchased?

Mr. WAYLAND. I have FAO figures on imports——

Mr. ROSENTHAL. Do you have any way you could tell how long the DDT they purchased in 1969 would last?

Mr. WAYLAND. That is not very much DDT—India and Pakistan——

Mr. ROSENTHAL. But DDT lasts 12 years you say.

Mr. WAYLAND. It will be in the soil; that is correct.

Mr. ROSENTHAL. So we have until 1981.

Mr. WAYLAND. I think we have a good bit beyond that.

Mr. ROSENTHAL. I know that. But Uganda is a developing country that we have problems with in diplomatic relations.

But we are importing a lot of their coffee, and you say it has no DDT because the Food and Drug Administration has taken a good look at it.

Mr. WAYLAND. I think there probably is some DDT there—just as there is in U.S.-grown products.

Mr. ROSENTHAL. Do you think there is more DDT in Uganda coffee than in Colombian coffee?

Mr. WAYLAND. If there is and it is over the tolerance, it is refused at the border if it is detected.

There cannot be more than the allowed tolerance level and the import be lawful.

Mr. ROSENTHAL. Is every bag examined or is this by spot check?

Mr. WAYLAND. Spot checks of less than 1 percent.

Mr. ROSENTHAL. You have a lot of confidence in that?

Does the FDA work at a more efficient level than the rest of this Government of ours?

Mr. WAYLAND. I think they do a good job with pesticide residue detection and enforcement within the limits of the resources devoted to this activity and the technical challenge presented by analyzing food for numerous residues.

Mr. ROSENTHAL. How do they do in terms of notification—as officially the EPA has done in the last 2 years?

Mr. WAYLAND. I don't have any knowledge of that.

Mr. ROSENTHAL. Congressman Brown?

Mr. GARRY BROWN. Thank you, Mr. Chairman.

When you make a determination to act on a pesticide as of a certain effective date, does your effective date have to be prospective rather than immediate?

Mr. WAYLAND. No; it does not.

Mr. GARRY BROWN. You just decide that the effective date of your determination in that one case would be 6 months on kepone; is that correct?

Mr. WAYLAND. That's right.

Most of our cancellation decisions have permitted the registrants to dispose of existing stocks. Otherwise there is a problem of trying to collect them and destroy them in some fashion.

Sometimes it makes more sense to allow them to be used and get whatever pest control benefit that can be derived from the chemical than to try to collect and destroy it.

Mr. GARRY BROWN. So you attempt to look at what the stocks are in arriving at what your effective date will be.

Mr. WAYLAND. That's correct.

Mr. GARRY BROWN. We have discussed pesticides and insecticides. What about food additives for livestock such as DES?

That is agriculture, isn't it, or do you have that now? I forget who has it.

Ms. BLUM. That is the Food and Drug Administration.

Mr. GARRY BROWN. Do you know what the situation is there with respect to the importation of livestock products?

Ms. BLUM. I believe it is exactly the same as it is for the importation of food crops except that USDA has responsibility to sample and analyze meat and poultry products.

Mr. GARRY BROWN. And that is that they are inspected and only the same tolerances permitted for domestically marketed products can be in the import products?

Ms. BLUM. That is correct.

Mr. GARRY BROWN. In section 8 of your act, you have provision for manufacturers to maintain records and provide you with information.

What happens to that information? Do you compile it for a congressional committee, or do you utilize it in examining what is going on?

Ms. BLUM. The latter. We utilize it in examining what is going on. Some of the information that we provided you is confidential information.

Mr. GARRY BROWN. In that information you supplied, some of the data came from your section 8 reporting requirements.

Ms. BLUM. Yes, sir.

You see they warned me before I came up here that if I disclosed any confidential information, I would be fined $45,000. I am being very cautious. Plus loss of employment.

Mr. GARRY BROWN. That is per word. [Laughter.]

I have no further questions at this time, Mr. Chairman.

I would just like to say that on your appropriations bill recently, there was great concern expressed about a legislative effort of mine.

I want you to know EPA was not being singled out. That type of amendment—like Mr. Levitas' which stirred up everybody—is being done with every appropriations bill based upon the increase of appropriations over previous years.

I think you would have to agree that your duties may have expanded, but a 60-percent increase over a 2-year period is rather extensive.

Mr. ROSENTHAL. Congressman Drinan?

Mr. DRINAN. Thank you, Mr. Chairman.

Ms. Blum, I am more and more convinced that this notification is very nugatory, and that we are somehow copping out by saying that we are informing all these other nations.

You, yourself, said very eloquently that Nigeria is not in a position to use it.

I wonder if the EPA goes to the American corporations that manufacture pesticides and sells them abroad and makes a good profit. I would assume there are probably three, four, or five multinationals. I suppose companies like Upjohn would be involved.

Do you work with the companies and urge them to follow some type of ethical or medical standards?

Ms. BLUM. Yes—informally.

Mr. DRINAN. Tell us about that.

Do they have any professional standards? I assume that they are just as self-righteous as the members of this subcommittee, and they don't want to hurt people abroad.

What do you mean by informally?

Ms. BLUM. We have had conversation with almost all of the manufacturers about our feeling about exportation of chemicals.

Mr. DRINAN. Have any of them been "born again"?

Ms. BLUM. They all claim to be; yes.

Mr. DRINAN. But the pesticides go up in volume.

Ms. BLUM. I can't pass any judgment on this.

Mr. DRINAN. I see a lot of representatives of pesticide corporations out there wearing $400 suits, and they are very concerned that we don't make them bad guys.

What do you say to these informal gatherings?

Ms. BLUM. I think, in general, no pesticide manufacturer or chemical manufacturer wants to be responsible for any kind of a mass poisoning or mass cancer——

Mr. DRINAN. That is consoling to hear.

So what do they say after you tell them about the dire consequences?

Ms. BLUM. They are generally agreeable. There have been some voluntary withdrawals of chemicals from the market and also from export on the part of the manufacturers.

Mr. DRINAN. On page 9, you say something that I have trouble with: "We do not feel that we should attempt to impose our pesticide decisions on foreign governments."

I am certain that the pesticide companies will take that and say: That is our philosophy as long as we warn them or notify them.

But why can't you have more informal gatherings with these people and urge them to follow a higher standard—the standard that is followed by American law?

Ms. BLUM. We have enough fights with them over following our law.

There are enough problems there that we certainly do pursue this, but it is not in any kind of a formalized way.

Mr. DRINAN. Would you need any further statutory power to bring about consulting and that type of thing?

Ms. BLUM. Yes; we need statutory power to bring about any kind of mandatory consulting.

If we do mandatory consulting, I might say at this point that we would also need a few more people to help us out.

Mr. DRINAN. Why don't you publish a list of the companies that export pesticides? What are the companies? What are three or four of the major companies?

Ms. BLUM. There are about 20 major companies.

Mr. DRINAN. Why don't you name them? We ought to know who they are.

And if they have been recalcitrant and they have not submitted and taken up the recommendation of the highest U.S. official agency, and they continue to export things which on the record are known to be deleterious to human beings, why shouldn't we have their names?

Ms. BLUM. We would be happy to provide the names for you.

[The material referred to may be found on p. 191.]

Mr. DRINAN. I think it would be very helpful. I would like to talk to some of these gentlemen.

If the new FIFRA bill passes, will that satisfy most of the difficulties that we have come across in these hearings?

Ms. BLUM. Yes; I think so.

Mr. DRINAN. Are there any recommendations that you will be making to Mrs. Peterson's task force that are not included in the new FIFRA bill?

Ms. BLUM. Let me let Alice Popkin address that, because she has been working very closely with the committee. Although they have had only one meeting, there has been a tremendous amount of staff work that has gone on, on the part of our staff in providing information to hers.

Ms. POPKIN. Our basic position with Mrs. Peterson's committee is that contained in the FIFRA amendments.

Mr. DRINAN. Therefore, your answer is no. That you are satisfied with what is in the FIFRA amendments.

Ms. POPKIN. Yes.

Mr. DRINAN. So you have no higher standards than those proposed by this Congress that may or may not be watered down?

Ms. POPKIN. With the one exception that the change in the Toxic Substances Control Act that applies a clear standard for——

Mr. DRINAN. Why even have the task force? Is the administration playing games with us?

She came here yesterday—a very fine lady—and said: We are all thinking together. But they have nothing to offer that has not already been offered in the FIFRA bill.

Ms. POPKIN. The task force has a much broader perspective on what needs to be accomplished and is seeing if we can harmonize all laws relating to exports of hazardous substances.

Mr. DRINAN. But the EPA has nothing to offer to that task force, except what they have already offered in the FIFRA bill.

Ms. POPKIN. In terms of legislation.

Mr. DRINAN. Thank you. My time has expired.

Mr. ROSENTHAL. Congressman Levitas?

Mr. LEVITAS. Thank you, Mr. Chairman.

Ms. Blum, it has been acknowledged that there were undue and improper delays in official notification to foreign governments in the Kepone matter, and there was one other that you referred to.

But it was not clear in your answer as to why there were such delays.

Ms. BLUM. I think that we cannot finger any one agency or any one division.

I think there were delays on the part of the Environmental Protection Agency in getting the information to the State Department in a timely manner.

Once having gotten it to the State Department, the procedure over there is a little vague. We give it to the Office of Environment via a mailgram or a cable. They then disperse that cable to their various missions around the world.

That is the procedure; but although that part of it is clear, the timing is not very clear.

We are presently negotiating and having rather constant meetings with the State Department to clarify this so that we can make sure that these notification provisions get to them in a timely way, and that having once arrived at the State Department are sent out in a timely way.

The third problem we have had is the one that I mentioned earlier when I used Nigeria as an example.

Once our embassies locate the responsible official, the problem is whether that official is somebody who has the time and the knowledge to be able to comprehend what we are giving them.

Mr. LEVITAS. Is the responsibility for notification to the foreign government the responsibility of the State Department?

Ms. BLUM. Yes, sir, under section 17(b).

Mr. LEVITAS. What I don't understand is that in December of 1977, EPA made a regulatory decision. Why would it take until May to get that information over to the State Department, and why would it take them another period of time to get that information out?

The State Department may be 2 miles away from EPA. Even given the difficulties of the U.S. Postal Service, it should not take that long.

Ms. BLUM. I would have to say, in all honesty, that it goes back to our overall resource problems.

We have ben trying to regulate pesticides and get the Toxic Substances Control Act off the ground with very inadequate and very limited resources.

Although we are adding to our staff now, those resources are still going to be in very short supply.

Mr. LEVITAS. It just seems to me that the problem of setting up a toxic substances program is very complex. But to send a letter or pick up the telephone and call the State Department and say, we have just done this and now you need to notify your people, is very simple. I think that could be remedied without a great deal of regulatory or bureaucratic overburden.

Ms. BLUM. The information that we provide the State Department is rather complex and complicated. It takes a good deal of time to put together.

Mr. LEVITAS. Who is the responsible official at the State Department? Or who was in December of 1977?

Ms. BLUM. That would have been Patsy Mink, who at that time was Assistant Secretary of that division.

Mr. LEVITAS. Your regulatory determination on Kepone, for example, is that made in the form of a notice published in the Federal Register?

Ms. BLUM. Yes.

Mr. LEVITAS. Is it your belief that the State Department has available to it copies of the Federal Register?

Ms. BLUM. Yes.

Mr. LEVITAS. Again, that leads me to the conclusion that if they are reading the Federal Register—and I hope they do—and you are making a decision in December, why is there such a problem in getting that information into their minds and out to whoever it should go?

Ms. BLUM. You are absolutely right. It is a problem that both the State Department and we share, which I acknowledge. This is why we must work more closely with the State Department to see why these procedures are not working. Some of them should be automatic.

Mr. LEVITAS. I would also assume that most of the embassies in Washington also subscribe to the Federal Register and have environmental attachés who work with the State Department on occasion.

Ms. BLUM. Yes, sir; they do.

Mr. LEVITAS. Let me just ask one specific question, along the lines of my distinguished and learned chairman, about foreign countries which use certain substances which are prohibited in this country.

I have read in the press about the use by the Mexican Government of a substance called paraquat. What is paraquat?

Ms. BLUM. Paraquate is a herbicide that is a defoliant that has been used to spray on the marijuana crop.

Mr. LEVITAS. Is that permitted to be used in this country?

Ms. BLUM. No.

Excuse me, Mr. Wayland says that it is.

Mr. WAYLAND. There are a number of registered uses of paraquat in the United States, including as a dessicant on sugarcane for Puerto Rico and Hawaii.

Mr. LEVITAS. Was there any cooperation between our Government and the Mexican Government in the use of this herbicide?

Mr. WAYLAND. There absolutely was. I don't know that EPA was involved—it not being our mission to keep people from smoking marijuana—but certainly other elements of the Government cooperated very closely with Mexican officials in their program for controlling the fields.

Mr. LEVITAS. I recognize the fact that marijuana is not a legal substance in all places in the United States, but I think it would be fair to say that a substantial amount of that material is used and brought into the United States illegally.

Our participation in the project, which would bring a great deal of this dangerous material, seems one that would also call upon the Environmental Protection Agency to express its views.

Ms. BLUM. We have been working with Peter Bourne at the White House on this very closely. I have had several conversations myself with Peter and much correspondence has gone on, looking for a substitute for paraquat.

Mr. LEVITAS. Thank you, Mr. Chairman.

Mr. ROSENTHAL. Thank you very, very much.

The matters that we requested from you, you will presumably submit forthwith?

Ms. BLUM. Yes.

Mr. ROSENTHAL. Thank you.

[Ms. Blum's prepared statement follows:]

PREPARED STATEMENT OF BARBARA BLUM, DEPUTY ADMINISTRATOR, ENVIRONMENTAL PROTECTION AGENCY

I appreciate the opportunity to be here this morning, Mr. Chairman, to discuss the role of the Environmental Protection Agency regarding the export of chemical substances banned by EPA for use in the United States. As you know, several months ago EPA responded to a number of questions concerning our policy regarding export of banned chemical substances, and I request that this correspondence be included as part of the hearing record.

The primary statute under which pesticides are regulated is the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), which requires that pesticides be registered with EPA before they are marketed and used in this country. Registration is dependent upon the Agency's finding that a product can perform its intended function without "unreasonable adverse effects on the environment," defined as "...any unreasonable risk to man or the environment taking into account the economic, social, and environmental costs and benefits of the use of any pesticide." This statutory

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standard, which requires a balancing of risks and benefits, is our primary guide in regulating pesticides. Likewise, the Administrator of EPA is authorized under FIFRA to initiate administrative proceedings to cancel or, in cases of more immediate hazard, suspend product registrations if he finds that the product poses the risk of "unreasonable adverse effects" to man or the environment.

To date EPA has cancelled or suspended for reasons of human health or environmental safety 15 pesticide active ingredients or groups of active ingredients. Five of these products are exported to varying extents.

Under FIFRA, pesticides produced in the United States solely for export are exempt from the requirement for registration. Export producers are, however, subject to provisions of FIFRA relating to maintenance of books and records, and registration and inspection of production establishments. EPA does not require export producers to provide information concerning export products, but we have discussed arrangements for obtaining this information with the subcommittee staff.

While FIFRA does not provide for regulating the export of pesticides, Section 17(b) requires notification of foreign governments and appropriate international organizations through the State Department when final action to cancel or suspend a pesticide has been taken. EPA has developed certain criteria for determining which suspension or cancellation actions will be transmitted to the governments of other countries and international agencies. Under these criteria, notification will be made of any cancellation or suspension action which has become effective and which is determined to have "national or international significance." Such significance may be due, among other things, to the fact that all, or a vast majority, of uses of a pesticide have been cancelled, that the action involves issuance of a policy applicable to the entire pesticide industry, or that the decision may have widespread health, environmental, economic, or political implications. Determinations are made on a case-by-case basis; notification of every cancellation action would not serve the purpose of the Act, since cancellations may be initiated for reasons other than to protect against a general endangerment to health or the environment. For example, an individual product may be cancelled due to the manufacturer's voluntary withdrawal from the market, which would not affect other registrations of products containing the same active ingredient.

Recently the General Accounting Office suggested that EPA does not always notify the State Department of cancellation actions which fit the criteria of "national and international significance" and therefore merit notification. The GAO also found that the information provided to the State Department had not reached "cognizant foreign officials."

It is our view that foreign governments have been advised of the major pesticide decisions made on the basis of concern for human health. In fact, we have gone beyond the "letter of the law" and informed other nations, through the State Department, of actions other than cancellations and suspensions which were felt to be of interest to other countries and which were, in our opinion, within the spirit of Section 17(b). For example, notices were transmitted to the State Department when tolerances for leptophos were revoked, and other countries have been notified of the registrations of certain new pesticide active ingredients. We do, however, agree with GAO that the system of notification of foreign governments and appropriate international agencies of final pesticide cancellations and suspensions can be improved.

EPA is re-evaluating its notification procedures in light of the GAO report and in anticipation of enactment of amendments to FIFRA which would modify the notification

procedures in current law and augment them with provisions for export product labeling. I will discuss these amendments in some detail later in my testimony. We are also participating in the Ad Hoc Working Group on Hazardous Substances Export Policy, which is concerned with the evaluation of export policy from a Federal government-wide standpoint, and the exploration of opportunities for improvement, about which your Subcommittee heard testimony yesterday from Esther Peterson.

The reassessment of our current notification process will include consideration of procedures necessary to assure that the notification process is initiated by EPA when appropriate, and that notices are transmitted from EPA to the State Department in a timely fashion. Further, we will be discussing with the State Department methods of ensuring that notices are received by the foreign officials to whom they are directed. Initial discussions with the State Department indicate that one major reason that notifications may not reach "cognizant foreign officials" is that many nations do not have ministeries comparable to EPA charged with responsibility for overseeing the environmental and health consequences of pesticide use. Hence, regardless of procedures developed for notification of foreign governments, there may not always be an "appropriate official" to receive the notification. And even when other governments are

notified of cancellation or suspension of a pesticide in the U.S., purchasers of the export product may not be aware of U.S. regulatory action taken, and the basis for that action.

Among those countries that do actively regulate pesticides there are varying degrees of interest in U.S. regulatory action to ban pesticide products. A 1978 National Academy of Sciences survey of 23 foreign nations elicited a spectrum of respondents' interest from "none" to "very interested". For example, Canadian and Mexican authorities indicated that any action by the United States to restrict or ban a pesticide receives immediate attention and scrutiny. On the other hand, countries such as India reported that EPA decisions have little or no impact on their regulatory policies.

The United States participates in a number of international organizations whose goal is the promotion of uniform chemical regulation and discussion of common regulatory issues. The Organization for Economic Cooperation and Development (OECD) has two chemical working groups, and a member country taking regulatory actions on chemicals is expected to notify other member nations as well as the OECD. The United Nations Food and Agricultural Organization and World Health Organization have several activities relating to the regulation of pesticides and pesticide residues on

agricultural commodities. Through multilateral and bilateral agreements, EPA maintains close contact with a number of countries concerned about pesticide regulation and eager to exchange information.

Both houses of Congress have passed bills which contain provisions for tighter control of pesticides intended for export. Since both bills contain similar controls, we can anticipate that the final legislation will adopt these new proposals.

Both the Senate and House bills, S. 1678 and H.R. 8681 respectively, would impose on export products current EPA statutory labeling and misbranding requirements in addition to the requirements for registration of pesticide producing establishments and maintenance of books and records. Both bills would further require all pesticides that are not registered, including those whose approval had been denied or revoked by EPA, to be prominently marked "Not Registered for Use in the United States of America." H.R. 8681 further requires the purchaser of an unregistered pesticide to sign a statement acknowledging that he is aware that the pesticide is not registered in the U.S., and a copy of the statement must be submitted to an "appropriate official" of the importing country. In addition, EPA is directed to provide,

upon request of a foreign government, all information related to a cancellation or suspension action, and information on alternatives to the banned product.

EPA generally supports these revisions of the pesticide law. The amendments to FIFRA are currently in Conference Committee, and we hope that a conference bill will result in the near future.

We do not doubt that the health of Americans and the quality of our environment can be affected by the toxic chemical and pesticide regulatory decisions reached by foreign governments. We have a means to protect the American people from the reimportation of cancelled pesticides in the form of residues on imported agricultural commodities:

Under the Federal Food, Drug, and Cosmetic Act (FFDCA), EPA is responsible for establishing tolerances, or the legal limits of pesticide residues which may safely remain in or on raw agricultural commodities, processed food, or feed. All produce marketed in the United States, whether of domestic or foreign origin, must meet tolerance requirements under the FFDCA. Tolerances are generally established at the level of pesticide residues expected to occur from a particular use pattern, i.e., rate and frequency of application, so long as that level does not exceed the limits of reasonable risk to health determined by animal

feeding studies. The necessity of meeting tolerance requirements, thus, in many cases indirectly imposes limitations on what pesticides can be used and how pesticides can be used on commodities to be marketed in the United States.

Our policy of communicating our pesticide regulatory decisions to other countries is a more direct way to influence the decisions of other nations to reduce exposure of American citizens to banned chemical pesticides. To the extent we can also provide information about the inherent risk characteristics of pesticide chemicals, we may aid foreign governments to make better informed decisions.

However, we do not feel we should attempt to impose our pesticide decisions on foreign governments. We base our decisions on the risks and benefits of domestic use of a pesticide which may not fit the risk/benefit balancing in another country. Actual use practices, crops, pests, and disease vectors, are quite different in many parts of the world from the U.S. and risk and benefits of pesticide use can therefore vary widely from nation to nation. Other countries must have the opportunity to reach their own risk/benefit conclusions with regard to specific substances, whether or not they are banned in the U.S.

Thus, EPA's position is that foreign governments should be notified about the hazards of products they import. They should have an opportunity to refuse imports which they deem on the basis of their own risk/benefit assessments to be unduly hazardous. EPA supports export product labeling which would directly advise importers and import control officials of the U.S. regulatory status and hazards associated with the product being imported. The best way to promote unanimity on toxic chemical regulation is to provide our best information to other nations, in order that they can make fully informed regulatory decisions.

That concludes my prepared statement, Mr. Chairman. I will be pleased to answer any questions you may have.

[Ms. Blum's submissions for the record follow:]

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

NOV 8 1977

THE ADMINISTRATOR

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Honorable Benjamin S. Rosenthal
Chairman, Subcommittee on Commerce,
Consumer, & Monetary Affairs
Committee on Government Operations
U. S. House of Representatives
Washington, D. C. 20515

Dear Mr. Chairman:

Thank you for your letter of September 29, 1977, requesting information about the Agency's policy toward export of chemical substances which may be banned pursuant to the Toxic Substances Control Act (TSCA). An interim response to the questions you raised was provided to Ms. Jean Perwin by telephone on October 7, since delay in receiving your letter prevented a full written response by October 11, as you requested.

In response to your first question, before TSCA was enacted in 1976, the only statute which authorized EPA to remove or suspend products from the U.S. market was the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA). With regard to exports, section 17(a) of FIFRA states that "...no pesticide or device shall be deemed in violation of this Act when intended solely for export to any foreign country and prepared or packed according to the specification or directions of the foreign purchaser...." EPA is required under section 17(b) to notify foreign governments and international organizations (through State Department channels) of final cancellation or suspension of the registration of a pesticide. The export policy mandated by FIFRA reflects the fact that the U.S. cannot impose its domestic pesticides policy upon other countries which, in any case, will make their own policy decisions regarding the use of hazardous pesticides in the light of their own cost/benefit analyses. We are, of course, aware of the international environmental impact of the spread of certain pesticides through the world's ecosystem. EPA does inform foreign governments and concerned international organizations whenever a registration, cancellation, or suspension of a pesticide occurs. As you may know, several amendments to FIFRA have been proposed which would require that additional measures be taken--such as labelling--with regard to exports of pesticides banned on the U.S. market.

Pesticides which have been cancelled to date include DDT, aldrin and dieldrin, some mercury pesticides, and certain predator poisons. Chlordane and heptachlor have been suspended. Foreign governments have been informed of these actions. Of these pesticides, only DDT is now being exported in significant quantities.

In response to your second question, no final action has yet been taken under TSCA involving the export of chemical substances since none have yet been banned in the U.S. However, we expect to take such measures in the future with regard to two categories of chemicals--PCBs and chlorofluorocarbons--under TSCA. This Agency has proposed regulations which would phase out over an 18-month period the manufacture, processing and distribution in commerce of nonessential aerosol propellant uses of chlorofluorocarbons covered under TSCA. These regulations are intended to reduce the emissions of these substances to the atmosphere, thereby reducing the health and environmental risks caused by depletion of the ozone layer. These regulations contain a finding under section 12(a)(2) that they present "...an unreasonable risk of injury to health within the United States or to the environment of the United States;" thus exports of such chlorofluorocarbons would be subject to the same regulations which apply to those produced for domestic use.

We expect to propose regulations soon which will also phase out the manufacture, processing and distribution in commerce of PCBs and articles containing PCBs. The regulations would subject export of those substances to the section 6(e) ban on PCB production and use. I have enclosed a copy of the chlorofluorocarbons regulations and will see that you receive a copy of the PCB regulations as soon as they are proposed.

Regarding your third question, TSCA does not require regulations to implement section 12. However, we may publish guidance or interpretive rules to clarify the relationship between section 12 and rules affecting specific chemicals which may be issued pursuant to other sections of the Act (e.g., sections 4, 5, and 6).

In answer to your final question, EPA's policy with regard to the export of toxic substances will apply only to chemical substances, as defined in TSCA. We have no legislative authority to apply regulations promulgated under TSCA to exports of products regulated under other statutes enforced by this Agency.

I hope you find the information I have provided useful. Please do not hesitate to let me know if I can be of further assistance.

Sincerely yours,

Douglas M. Costle

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

8 MAR 1978

Honorable Benjamin S. Rosenthal
Chairman, Commerce, Consumer, and
Monetary Affairs Subcommittee
Committee on Government Operations
House of Representatives
Washington, D.C. 20515

Dear Mr. Chairman:

Thank you for your letter of February 21, 1978, concerning EPA's policy regarding exports of banned chemical substances, including pesticides. You requested certain information, which it is my pleasure to provide you and your subcommittee. For your convenience the information is presented according to the format of your request.

1. Under Section 17(b) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), EPA is required to notify foreign governments of final cancellation or suspension of the registration of a pesticide.

EPA has developed certain criteria for determining which suspension and cancellation actions will be transmitted to the governments of other countries and appropriate international agencies in accordance with the intent of Section 17(b). Under these criteria, foreign governments and international organizations expressing interest will be notified of any cancellation or suspension action which has become effective and which is determined to have national or international significance. Determinations are made on a case-by-case basis. Criteria used to determine "national or international significance" are listed on page 2, enclosure 2, and full discussion of provisions for notification of foreign governments appears in the Section 17(b) regulations (enclosure 1).

a. Please describe the precise State Department channels used for notification.

When a cancellation or suspension action meeting the criteria for transmittal to foreign governments occurs, a notice is prepared by EPA including information on why the pesticide was cancelled or suspended, which uses are affected, and other terms of the regulatory action. The notice is drafted in the form of an airgram, according to State Department format, and sent to the Bureau of Oceans and International Environmental and Scientific Affairs of State for transmittal to all diplomatic posts and U.S. AID missions. Each diplomatic post is responsible for ensuring that information on the banned chemical is communicated to the appropriate organization in the host country.

b. Please list all cases in which EPA has asked the State Department to notify foreign governments.

EPA has notified foreign governments of cancellation or suspension actions on the following pesticide chemicals:

- DDT
- Aldrin and Dieldrin
- Vinyl Chloride
- Mirex
- Mercurial Compounds
- Predator Poisons (Sodium Fluoroacetate (1080), Strychnine, and Sodium Cyanide)
- 2,4,5-Trichlorophenoxyacetic acid
- Benzene Hexachloride

In addition, notification was made of the revocation of the leptophos tolerances. While revocation of a tolerance does not come within the wording of 17(b), it was felt that this action was within the spirit of the section, and that there was sufficient worldwide interest in leptophos to warrant notice. Further, notification has been made on certain registration actions on new active ingredients or changed use patterns. Copies of all notifications are enclosed for the subcommittee's persual.
(Enclosures 2-5)

c. Please provide copies of all correspondence with the State Department regarding the export of banned substances.

For the most part this correspondence consists of the airgrams and attachments provided in response to item 1(b). Copies of responses and requests from foreign governments transmitted through diplomatic posts to the State Department are received by EPA, and copies of these documents are enclosed for the subcommittee's convenience.

2. Please provide copies of the proposed amendments to FIFRA which would require additional measures to be taken with regard to exports of pesticides.

Copies of both the Senate (S.1678) and House (H.R.8681) amendments, enacted on July 29, 1977 and October 31, 1977, respectively, affecting export of pesticides are included in enclosure 6. A Conference Committee is expected to convene in the next several weeks.

3. Please provide the subcommittee with a complete list of all substances (pesticides, chemicals, etc.) which have been banned or which may be banned by EPA.

Enclosed is a copy of the EPA publication, "Cancelled and Suspended Pesticides," which details specific regulatory actions taken under FIFRA through May 1977. In addition, I am enclosing a fact sheet describing the rebuttable presumption against registration (RPAR) process, which may lead to cancellation proceedings, and a status report dated February 15, 1978, detailing chemicals under RPAR review, chemicals which are candidates for RPAR review, voluntary cancellations, and notices of intent to cancel and their dates of publication (enclosure 7).

Thus far, EPA has issued no final rules prohibiting or limiting the manufacture or use of chemicals under the Toxic Substances Control Act (TSCA). Within the next several days, however, I expect to sign final rules phasing out the manufacture, processing, and distribution of chlorofluorocarbons (CFCs) for non-essential aerosol uses. These rules will include a ban on processing of CFCs for export; thus, after December 15, 1978, it will be unlawful to place CFCs into non-essential aerosol products being made either for domestic use or export. I should note that this rule will not impose a total ban on CFC exports. CFCs are used, both here and abroad, for many non-aerosol purposes, primarily as a refrigerant, foam-blowing agent, and solvent. Approximately 90 percent of U.S. exports of CFCs are used for these purposes. CFCs manufactured and packaged for these purposes are indistinguishable from CFCs intended for aerosol use. EPA is examining the question of whether regulatory action should be taken with respect to these non-aerosol uses. Based on these factors, EPA has determined that it is neither practical nor equitable to impose a total ban on CFC exports at this time. If and when regulatory action is taken with respect to non-aerosol uses, the question of how to deal with exports for such uses will be addressed. In the meantime, by making it unlawful to place CFCs into non-essential aerosol products for export, the Agency has ensured that the U.S. will not be a source of products which could cause harm to public health and welfare on a global scale.

As soon as the Agency's rules on non-essential aerosol uses are issued, EPA will inform foreign governments by contacting Embassies in Washington, and by requesting the State Department to transmit the regulations to all diplomatic posts and AID missions, who will make them available to their host governments. EPA will also provide copies of the regulations to countries which are members of the Chemicals Group of the Organization for Economic Cooperation and Development (OECD) and to the Secretariat of that group. (Procedures for information exchange between member countries of the OECD are detailed in enclosure 8. I am the designated U.S. contact of the OECD. This mechanism has been used in the past for notification of regulatory action taken on pesticide chemicals.)

Further, regulations which would phase-out the manufacture, processing and distribution in commerce of polychlorinated biphenyls (PCB's) will be proposed in the near future. As I noted in my last letter these regulations would subject export of those substances to the Section 6(e) ban on PCB production and use. (For your information, I enclose a copy of the final regulations published in the Federal Register on February 17, 1978, regarding the disposal and marking of PCB's.) Notification of foreign governments of this action would be accomplished in a manner similar to that of the chlorofluorocarbon action.

On-going reviews of high-volume, high toxicity chemicals will probably produce other candidates for regulation over the next 6 to 9 months. It is impossible at this time, however, to be more specific as to which chemicals might be banned as a result of those investigations.

a. For each item banned, please indicate:

(1) a short statement of the reason for the ban;

See enclosure 9.

(2) a list of the largest manufacturers of the substance; and

(3) whether or not EPA has any information regarding the extent to which the substance is being exported and, if so, please include what information is available.

Names of current U.S. manufacturers producing pesticides cancelled in the U.S. solely for export and export production figures are maintained in computer files. We would be glad to supply your subcommittee with this information; however, the information must be retrieved, and will be submitted as soon as possible. This information, submitted to EPA pursuant to FIFRA Section 7(c),

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is held to be confidential business information under the trade secret provision (Section 10) of the Act. The Agency's regulations on public disclosure specifically authorize release of such confidential information to a subcommittee of Congress upon written request with a letter from the Agency stating that the data are entitled to confidential treatment. Should the subcommittee wish to make any of this information part of the public record, we would be happy to work with your staff to appropriately consolidate or disguise the information so as not to reveal the identity of individual producers and their production figures.

I hope that the information we have supplied will be of use in the subcommittee's inquiry. If I may be of any further service, please let me know.

Sincerely,

Steven D. Jellinek
Assistant Administrator
for Toxic Substances

Enclosures

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

AUG 11 1978

OFFICE OF THE
ADMINISTRATOR

Honorable Benjamin S. Rosenthal
Chairman
Commerce, Consumer, and Monetary
Affairs Subcommittee
Committee on Government Operations
House of Representatives
Washington, D.C. 20515

Dear Mr. Chairman:

When Deputy Administrator Barbara Blum testified before the Commerce, Consumer, and Monetary Affairs Subcommittee on July 12, 1978, concerning the export of chemical substances banned by EPA for use in the United States, she promised to supply certain information for the record. I would like to provide a portion of this information at this time, and to outline steps we have taken to develop the remainder of the information.

During the course of the hearing, you asked what foreign countries currently use pesticides which are not permitted to be used in the United States. The Agency does not collect data on pesticide use in other countries, but we rely on figures compiled by international organizations. The figures available to us do not include all countries nor has data on all pesticides been collected. However, the Yearbook of Production published by the Food and Agricultural Organization of the United Nations does give usage figures for a number of countries for several major pesticides which have been cancelled in the U.S. Usage figures for DDT, Benzene Hexachloride (BHC), and aldrin/dieldrin and related compounds for the countries reported generally indicate a decrease from 1974 to 1975 in the number of countries using such materials, and in those still using such compounds in 1975, a decrease in usage volume. I have enclosed copies of charts from the 1976 Yearbook of Production for your information.

In general terms, it is likely that many countries use pesticides which have been cancelled or are not registered for use in the U.S., although not all those nations use such products for agricultural purposes. American consumers are protected from the "reintroduction" of such pesticides in the form of residues on imported agricultural

commodities through the tolerance requirements under the Federal Food, Drug, and Cosmetic Act as we explained in our testimony. Such tolerance requirements are enforced at ports-of-entry by the Food and Drug Administration (FDA). In this regard, the Subcommittee requested statistics on actions taken by FDA on imported agricultural commodities which were found to have pesticide residues in excess of established U.S. tolerances. We have requested that FDA provide such information, and in particular, to indicate if there are specific import commodities which are sampled more frequently, or on a regular basis due to past problems with excessive residues of cancelled or unregistered pesticides. We will be glad to provide this information to the Subcommitee when we receive it.

A question was also raised concerning firms that produce pesticides for export and why EPA does not publish a list of these companies. Until the Subcommittee suggested such a list, no one had sought such information, nor have we needed such a list in carrying out our pesticide regulatory responsibilities. A comprehensive list of all exporters would be very difficult to develop since EPA does not under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), register exported pesticides, and thus has imposed no record keeping requirements on registrants which could yield overall export information at the "push of a button."

Many, if not most, pesticides which are exported from the United States are also marketed in domestic commerce. Products which are marketed domestically must be registered with EPA, and producers must report production volumes to the Agency. However, no distinction is made when reporting production volumes between products destined for the domestic market and those that will be exported. In order to discriminate between domestic and export products, EPA would have to survey every pesticide producing establishment. The large number of establishments (over 7,000) would make this a task of enormous magnitude. Once compiled, such a list would have to be constantly updated as producers entered and left the export market.

In the case of cancelled and suspended products, only a handful of the producers at the time of regulatory action have remained in production for the international market. We have provided the Subcommittee a list of producers of cancelled or suspended products for export. This list was compiled by our Regional offices by survey of the producers in their area. The fact of cancellation or suspension makes the task considerably easier because so few firms have remained in production, and are more easily identified. As we have explained previously, production figures and information produced by these companies is considered to be trade secret information under section 10 of FIFRA and entitled to confidential treatment by EPA.

I believe, Mr. Chairman, that the amendments concerning pesticides produced for export which were recently agreed to in Conference Committee will go a long way to identify for other countries those products which have not been approved for use in the United States. The requirements that unregistered or cancelled pesticides be labeled "Not For Use in the United States", and that foreign importers sign a statement acknowledging that a product is not approved for use in the U.S. will provide foreign users the necessary information concerning the status of products imported from the U.S. The provision that EPA provide information to countries concerning the bases for cancellation and suspension actions, and advise foreign officials of appropriate alternatives that we have identified will further improve the ability of other countries to make their own informed decisions on the use of products which are not approved for use in the U.S.

Allow me to express Ms. Blum's appreciation for the opportunity to present EPA's policy and views on the export of substances regulated by the Agency. You may expect further information from FDA in the near future. If I may be of any further service, please let me know.

Sincerely yours,

Charles S. Warren

Charles S. Warren
Director
Office of Legislation

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TABLE
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	D D T DDT DDT CONSUMPTION				B H C HEXACHLORURE DE BENZENE H C B CONSOMMATION				LINDANE LINDANE LINDANO CONSUMO			
	100 KG				100 KG				100 KG			
	1961-65	1973	1974	1975	1961-65	1973	1974	1975	1961-65	1973	1974	1975
WORLD												
AFRICA												
BOTSWANA	6	30F	30F	30F								
BURUNDI		246	226									
CHAD	13	8				29						
CONGO										30		
EGYPT	22212	1090	1090							3280	6890	
IVORY COAST		700F	516			800F	399					
MADAGASCAR	200	648				2947						
NIGER			20			4756	600	1000		10		3
RWANDA	440	940	1034	880								
SUDAN		6039	6501									
SWAZILAND		23	21									
N C AMERICA												
CANADA	5808	200F	200F	200F	92	25F	25F	25F				
EL SALVADOR	7253	9000F	10000F	11326								
MEXICO		87540	40980	41290		30660	18780	13170				
PUERTO RICO		100F	100F	100F								
USA	248532	4774										
SOUTH AMERIC												
ARGENTINA	2306	3220				340				2103		
BOLIVIA		690										
CHILE		5442	2897	256								31
COLOMBIA	3500	10000F	10000F	10000F								
URUGUAY	164	100				450						
ASIA												
BURMA	430	181	498				42			504	713	
CYPRUS	1239			134	189			60				
INDIA	17701	27000	40000	43600		210000	229000	242980		650	488	40
IRAN		4923				734				305		
ISRAEL	1360	100	100		130	10	250					
JAPAN	7230				28411							
JORDAN	140	10	70	58								
KAMPUCHEA DR	108	1500F	1500F	1500F		16F	16F	16F				
KOREA REP						15681	30477					
KUWAIT						2	2	2		1	1	2
LAO	34	10F	10F	10F	4	120F	120F	120F				
PAKISTAN			1284			201	929					
SAUDI ARABIA												
EUROPE												
AUSTRIA	428	187	175	67		245	302	435		1410	988	1078
CZECHOSLOVAK	3600	1980	900	100							74	48
FINLAND										1118		
GERMANY FED	2479	93				99				55446	27723	18638
HUNGARY	31000	36	18							3	2	1
ICELAND										18037	23918	
ITALY	13134	24621	20192			68530	75515					
POLAND	23045	720	500			3048	4050	1780				
PORTUGAL		285								78	34	
SWEDEN										230	150	100
SWITZERLAND			100	100								
OCEANIA												
COOK ISLANDS										21	15	11

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TABLE
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CUADRO

ALDRIN AND SIM INSECTIC
ALDRINE ET INSECT SIMIL
ALDRINA E INSECT SEMEJ

CONSUMPTION 100 KG

TOXAPHENE
TOXAPHENE
TOXAFENO

CONSOMMATION 100 KG

OTHER CHLOR HYDROCARBONS
AUTRES HYDROCARB CHLORUR
OTROS HIDROCARB CLORADOS

CONSUMO 100 KG

	1961-65	1973	1974	1975	1961-63	1973	1974	1975	1961-65	1973	1974	1975
WORLD												
AFRICA												
BURUNDI		45	14							27	62	
CHAD		273								1450		
CONGO		30										
EGYPT		2740	10020		7844	40	10			17663	13730	
IVORY COAST		80F	100									
LESOTHO										2	2	2
MADAGASCAR		24										
NIGER		79	125	10							13	
NIGERIA		87										
SOUTH AFRICA										56210	90540	
SUDAN										914	1482	
SWAZILAND		158	4							36	30	
N C AMERICA												
CANADA		1803		1381						1900*		
CUBA										15000		
EL SALVADOR					8720	16000F	18000F	20387				
MEXICO		1700	920			27470	30520	22563				
PUERTO RICO		1000F	1000F	1000F						400F	400F	400F
USA		403337										
VIRGIN IS UT		2	1									
SOUTH AMERIC												
ARGENTINA		2432								15036		
BOLIVIA		19										
CHILE				1659						19095	20647	
COLOMBIA						13000F	13000F	13000F				
URUGUAY		262										
ASIA												
BURMA		30	9									
CYPRUS				7								4
INDIA		12000	12700	8520*	75	4250	2000	8210		6000	9333	9333F
IRAN		1231				824				4217		
ISRAEL		8			520	500	160			595	805	
JAPAN		12	4									
KAMPUCHEA DM		130F	130F	130F		950F	950F	950F				
KOREA REP		12467	15336			184	10					
KUWAIT		8	11									
LAO												
PAKISTAN			1305							150F	150*	150F
											2444	
EUROPE												
AUSTRIA		54	23	18						53	18	54
CZECHOSLOVAK				70		400	380	300		950	350	350
FINLAND										58	51	
GERMANY FED		172				151				448		
GREECE										640	990	580
HUNGARY						4368	4163	4630		1394	1403	1237
ITALY		155412	45400*							4272		
NORWAY										64	62	
POLAND					695	1410	1400	1060		350	5080	550
PORTUGAL		142	153							188	167	
SWEDEN										590	640	873
OCEANIA												
NEW ZEALAND										2803		

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TABLE
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CUADRO

PARATHION
PARATHION
PARATHION

CONSUMPTION 100 KG

MALATHION
MALATHION
MALATHION

CONSOMMATION 100 KG

OTH ORG PHOSPH INSECTIC
AUTRES INSECT ORG PHOSPH
OTROS INSECT ORG FOSFOR

CONSUMO 100 KG

	1961-65	1973	1974	1975	1961-65	1973	1974	1975	1961-65	1973	1974	1975
WORLD												
AFRICA												
BURUNDI										5	3	
CHAD		158								67		
EGYPT	574	660	320		1664	3250	3120		24732	58070	67400	
IVORY COAST									32	1400F	1762	
MADAGASCAR		1				14				18		
NIGER		1					5					
SOUTH AFRICA										20220	28530	
SUEZN										3665	6767	
SWAZILAND						2				32	17	
N C AMERICA												
CANADA	218	246	238		1012	905	1381	3048		9100*	6900*	16288*
CUBA										20000		
EL SALVADOR	14002	25000F	28000F	30209								
MEXICO		6140	38230	56110			230			3600	3950	
PUERTO RICO										3000F	3039F	3000F
USA	142043	237908	242108						211767	524024	615336	
VIRGIN IS US										1	1	1
SOUTH AMERIC												
ARGENTINA	2982	6900				3000			2000	3700		
BOLIVIA		683				140				60		
CHILE				92								146
COLOMBIA		20000F	20000F	20000F		3700F	3700F	3700F				
URUGUAY		285				190			263	198		
ASIA												
BAHRAIN		5	5									
BANGLADESH		7				5F	4	1		12	8F	4
BURMA					418		288					
CYPRUS	216			196	91			64	7			104
INDIA	3384	9500	8140	11630	529	13500	14530	14920	398	14050	12100	16193
INDONESIA										4000F	4030F	4003F
IRAN						3267				14338		
ISRAEL	935	1500	800		960	400	600		974	4200	3250	
JAPAN	7106				4043	2303	2677		9550	17368	20348	
JORDAN	265	79	164	157								
KAMPUCHEA DR					2	50F	50F	50F		45204	140203	
KOREA REP						2195	4252					
KUWAIT		5	6	4		8	6				21762	
PAKISTAN							2255					
SAUDI ARABIA						564				187	98	
EUROPE												
AUSTRIA	126	120	151	96	8	2	10		164	844	802	823
CZECHOSLOVAK		20	30	10		250	300	110		3330	3250	3472
FINLAND	124	61	73		12	81	72		134	378	326	
GERMANY FED									2510	6416		
GREECE	1206	1060	2800	3160	126	1090	2440	1510	309	2810	5890	8090
HUNGARY		34264	36757	25403		2021	2715	2843		48570	75052	69191
ICELAND									2	2	3	3
ITALY	10345	19541	25760		1421	6778	8478		16387	54714	75275	
NORWAY										167	191	
POLAND					138	320	500	490	1165	5930	6500	6883
PORTUGAL		227	271			154	125			773	959	
SWEDEN		2750	2320	2940								
SWITZERLAND			900	700								
OCEANIA												
COOK ISLANDS						898	754	726				

TABLE
TABLEAU 104
CUADRO

PYRETHRUM
PYRETHRE
PELITRE

CONSUMPTION 100 KG

OTHER BOTANICAL INSECTIC
AUTRES INSECTICID BOTAN
OTROS INSECTICIDAS BOTAN

CONSOMMATION 100 KG

ARSENICALS
PREPARATIONS ARSENICALES
ARSENICALES

CONSUMO 100 KG

	1961-65	1973	1974	1975	1961-65	1973	1974	1975	1961-65	1973	1974	1975
WORLD												
AFRICA												
BURUNDI												
EGYPT		5				20	20			1510	730	
N C AMERICA												
CANADA						2				550*	270*	
USA	762	848	762	894	964	747	1068	663	54773	19522		
VIRGIN IS US										1	1	1
SOUTH AMERIC												
ARGENTINA		100F	100F	100F		20				10000F	10000F	10000F
COLOMBIA												
URUGUAY									130	83		
ASIA												
INDIA				200				20				
ISRAEL									1699	1680	1430	
JAPAN					1328	663	1071		10140	816	774	
EUROPE												
AUSTRIA		111	54	3		3	2	1				
FINLAND	4	18	19		2	6	6					
GERMANY FED					144	107						
GREECE		230	240	830						190	60	63
HUNGARY						17	4	17				
ITALY	126	137	175		1368	1007	1043		7453	1036	1468	
NORWAY						8	4					
POLAND		18	20									
SWITZERLAND						10*	10	10				

TABLE
TABLEAU 105
CUADRO

CARBAMATES INSECTICIDE
CARBAMATES INSECTICIDE
CARBAMATOS INSECTICIDA

CONSUMPTION 100 KG

DINITRO COMPOUNDS
COMPOSES DINITRES
COMPUESTOS DE DINITRO

CONSOMMATION 100 KG

MINERAL OILS
HUILES MINERALES
ACEITES MINERALES

CONSUMO 100 KL

	1961-65	1973	1974	1975	1961-65	1973	1974	1975	1961-65	1973	1974	1975
WORLD												
AFRICA												
EGYPT									8222	53020	42740	
IVORY CCAST										10000F	10475	
LESOTHO				85								
MADAGASCAR		136										
SOUTH AFRICA										13400	14180	
SUDAN		837	1590									
N C AMERICA												
CANADA		5550*	8350*	8344					15103	11253	20420	22691
CUBA		4000										
MEXICO		4040	10070	9450								
USA									708864	461053	548494	
SOUTH AMERIC												
ARGENTINA		1705							24949	29150		
CHILE				208								4883
COLOMBIA										15000F	15000F	15000F
URUGUAY		71				170			1054	1280		
ASIA												
BANGLADESH		1252	500F	229								
CYPRUS				9					2891			286
INDIA		45000	50000	25000								
IRAN		305								160		
ISRAEL									1660	5002	6030	4800
JAPAN		9217	11473		59	7			47635	119949	136814	
JORDAN									151	4	70	15
KOREA REP										5125	6870	
KUWAIT		4	4	1						2	5	3
PAKISTAN			127									
SAUDI ARABIA		111	85							115	75	
EUROPE												
AUSTRIA		451	330	131		86	88	34	660	1223	1076	1812
CZECHOSLOVAK				1570		630	800	1270		3400	3455	2787
FINLAND		9	7						230	170	251	
GERMANY FED		1217				400			8792	3768		
GREECE		4930	8520	6950		210	10	10	8664	1760	1600	1414
HUNGARY		4630	4195	5863		10350	10138	8150		2947	3607	3723
ITALY		22911	27053						62825	103317	99043	
NORWAY										45	68	
POLAND		18350	19500	11330		350		2625				
PORTUGAL		466	190							2332	1918	
SWITZERLAND			200	100						390*	405	359

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TABLE
TABLEAU 106
CUADRO

	OTHER INSECTICIDES AUTRES INSECTICIDES OTROS INSECTICIDAS CONSUMPTION 100 KG				SULPHUR SOUFRE AZUFRE CONSOMMATION 100 KG				LIME SULPHUR BOUILLIE SULFOCALCIQUE CAL-AZUFRE CONSUMO 100 KG			
	1961-65	1973	1974	1975	1961-65	1973	1974	1975	1961-65	1973	1974	1975
WORLD												
AFRICA												
BURUNDI						4						
EGYPT		47430	36650		40324	57270	11600					
IVORY COAST		2500F	3217									
MAURITIUS		1510	1690	1930								
MOROCCO		7000F	7000F	7000F								
REUNION		5210	5210									
SOUTH AFRICA		26700	23020									
SWAZILAND		15	300									
N C AMERICA												
CANADA		1800	1200	2350	2284	1880	1883					
GUATEMALA		129532										
MARTINIQUE		13000F	13000F	13000F								
MEXICO						18000	50000					
PUERTO RICO		2800F	2600F	2800F								
TRINIDAD ETC		5000F	5000F	5000F								
USA	449711	982979	1303001									
SOUTH AMERIC												
ARGENTINA	1015	261			17528	53500			4044	20000		
BOLIVIA						9						
CHILE						66540	48066	35974				367
COLOMBIA						430F	430F	430F				
URUGUAY		19				4919						
ASIA												
BAHRAIN		7	7									
CYPRUS				31	12685			11458				54
INDIA				2000	10537	31000	44000	48000				
IRAN		167				1682						
ISRAEL		420	458		5096	8000	10000		281	1560	780	
JAPAN		268	443		9950	16597	22178		152768	184459	338070	
JORDAN						1500	90	900		307		
KOREA REP		114254	136882							5938	8922	
KUWAIT					2	8	10					
PAKISTAN			272									
SAUDI ARABIA						300	150					
EUROPE												
AUSTRIA					2760	3510	5278	4498		57	59	63
CZECHOSLOVAK				148		3520	4000	5810				375
FINLAND		3	2		-	484715	510072		4		7	
FRANCE					11419	14582						
GERMANY FED		366			141716	202992	220800	240000		1750	2340	1098
GREECE		215	400	340		36170	47812	55728		10136	13062	14635
HUNGARY		13273	26688	46991				15				
ICELAND												
ITALY		15787	20550		645923	659390	732568		136188	45316	49146	
NORWAY		6	5									
POLAND		380	4990	830		1920	5000	5683				
PORTUGAL		1925	2047		104068	128965	116092					
SWEDEN	5150	1030	1650	1770	1	1020	280	430				
SWITZERLAND			100	100		2900	3000	2400	1080	250	250	
YUGOSLAVIA	82146	99730	104480									
OCEANIA												
COOK ISLANDS						76	167	227				

TABLE
TABLEAU 107
CUADRO

COPPER COMPOUNDS
COMPOSES CUPRIQUES
COMPUESTOS DE COBRE

CONSUMPTION 100 KG

	1961-65	1973	1974	1975
WORLD				
AFRICA				
EGYPT	784	4930	4410	
MADAGASCAR		84		
NIGERIA		13		
N C AMERICA				
CANADA		8004	8804	
MEXICO		12450	11800	
USA		45599	43640	36714
SOUTH AMERIC				
ARGENTINA		15370		
BOLIVIA		15		
CHILE				
COLOMBIA		950F	950F	950F
URUGUAY		15		
ASIA				
BANGLADESH				125
BURMA		1	2	44
CYPRUS	446			
INDIA		6500	45000	3660
IRAN		64		
ISRAEL		6800	6620	
JAPAN	64101	78630	62689	
JORDAN		13	11	15
KAMPUCHEA DM		5F	5F	5F
KOREA REP		1041	1937	
KUWAIT				1
PAKISTAN			71	
SAUDI ARABIA		10		
SRI LANKA		600F	600F	600F
EUROPE				
AUSSRIA		7823	9593	3432
CZECHOSLOVAK		5540	5200	7080
FINLAND	41	17	9	
GERMANY FED	13732	6055		
GREECE	25477	28250	50400	32450
HUNGARY		61858	55166	67968
ITALY	567329	256183	271947	
NORWAY		250	281	
POLAND	2071	1160	3210	920
PORTUGAL		14500F	14625	
SWEDEN	568	410	120	220
SWITZERLAND		3400M	2900	2300

DITHIOCARBAMATES
DITHIOCARBAMATES
DITIOCARBAMATOS

CONSOMMATION 100 KG

	1961-65	1973	1974	1975
WORLD				
AFRICA				
EGYPT			30	
MADAGASCAR		16		
NIGERIA				
N C AMERICA				
CANADA	4398	13000M	13000F	12830M
MEXICO		16140	15000	
USA	46682	188616	191490	
SOUTH AMERIC				
ARGENTINA	4775	17170		
BOLIVIA		19		
CHILE			72	
COLOMBIA		16000F	16000F	16000F
URUGUAY		5472		
ASIA				
BANGLADESH				
BURMA				
CYPRUS	244			
INDIA		22700	18000	13580
IRAN		2869		
ISRAEL	1768	2275	2925	
JAPAN	11496	27635	31919	
JORDAN				
KAMPUCHEA DM		20F	20F	20F
KOREA REP		5400	2560	
KUWAIT	1	3	8	1
PAKISTAN				
SAUDI ARABIA		39		
SRI LANKA		25F	25F	25F
EUROPE				
AUSSRIA	384	1993	2989	2640
CZECHOSLOVAK		7970	7520	6360
FINLAND	12	306	567	
GERMANY FED	5101	11932		
GREECE	8337	9710	9350	19900
HUNGARY		43227	38528	39018
ITALY	147744	178878	192874	
NORWAY		547	577	
POLAND	4608	3070	3800	6380
PORTUGAL		6143	6533	
SWEDEN		4870	3890	4460
SWITZERLAND				

AROMATIC COMPOUNDS
COMPOSES AROMATIQUES
COMPUESTOS AROMATICOS

CONSUMO 100 KG

	1961-65	1973	1974	1975
WORLD				
AFRICA				
EGYPT				
MADAGASCAR				
NIGERIA				
N C AMERICA				
CANADA				
MEXICO				
USA				
SOUTH AMERIC				
ARGENTINA		443		
BOLIVIA				
CHILE				
COLOMBIA				
URUGUAY		180		
ASIA				
BANGLADESH				
BURMA				
CYPRUS				8
INDIA				
IRAN		12		
ISRAEL		375	480	
JAPAN				
JORDAN				
KAMPUCHEA DM				
KOREA REP			1034	
KUWAIT				
PAKISTAN				
SAUDI ARABIA				
SRI LANKA				
EUROPE				
AUSSRIA		200	1700	330
CZECHOSLOVAK		10	14	
FINLAND		4449		
GERMANY FED				
GREECE		260	2250	1540
HUNGARY		8644	5505	4285
ITALY		7854	7017	
NORWAY		106	115	
POLAND		6740	7050	3700
PORTUGAL		72	84	
SWEDEN				
SWITZERLAND				

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION
ROCKVILLE, MARYLAND 20857

AUG 31 1978

Honorable Benjamin Rosenthal
Chairman, Subcommittee on Commerce,
Consumer and Monetary Affairs
Committee on Government Operations
House of Representatives
Washington, D.C. 20515

Dear Mr. Rosenthal:

The Environmental Protection Agency (EPA) has advised us by letter dated August 18, 1978 that during EPA's testimony before your Subcommittee on July 12, 1978, the Subcommittee had several questions regarding the possible reimportation of banned pesticides in the form of residues on imported agricultural commodities. Because the Food and Drug Administration (FDA) is responsible for determining whether imported foods comply with EPA tolerances for pesticide residues, EPA requested that we respond to the Subcommittee on this matter.

EPA's letter, which was sent to John Wessel, FDA's Office of Regulatory Affairs, identified three main areas in which the Subcommittee is seeking information. Mr. Wessel discussed these items with Ms. Jean Perwin of your staff and she agreed that this is the type of information needed by the Subcommittee. These items, along with our responses, are as follows:

1. Statistics on actions taken by FDA on imported products rejected due to pesticide residues in excess of established tolerances.

Each year FDA samples and tests about 2,000 shipments of imported raw agricultural commodities for pesticide residues. A statistical overview of the results of this sampling activity for fiscal 1977 and fiscal 1978 (up to May 1978) is presented in the enclosed table (Enclosure I). The table lists the number of samples and variety of commodities tested, number of different pesticides detected, percent of violative samples, and number of actions taken by FDA. These statistics are grouped according to whether the food is of Mexican or other foreign country origin. Mexico is listed separately because of the relatively large volume of fresh produce it exports to the United States. As shown in the table, during this 20-month period, FDA denied entry to a total of 211 shipments of imported produce found to contain illegal pesticide residues. Most of these actions were due to the fact that no EPA tolerances were established for the pesticide residues present. It should also be noted that in addition to detention of individual shipments of imported food, FDA has at times closed ports of entry to all shipments of certain food commodities from a particular country when it became evident that a specific residue problem

was continuing. For example, since 1973 FDA has closed the border on seven different occasions to shipments of Mexican strawberries and peppers because of illegal pesticide residues.

2. Information on particular import commodities that are sampled more frequently or on a regular basis due to past problems with excessive residues. Are there any problems with a specific cancelled pesticide or pesticides?

FDA's level of sampling and selection of import commodities take into account various factors, including: data from U.S. Customs and the U.S. Department of Agriculture on volume of import shipments; dietary significance of the imported food; and past residue problems. Therefore, based on these factors, some import commodities are sampled more frequently than others. Particular emphasis is given to raw agricultural commodities, dairy products (mainly cheeses), and fish.

FDA has not encountered any significant residue problems with imported food for those pesticides that have been cancelled by EPA. This is probably due to the fact that many countries have also discontinued food uses of these pesticides. For example, the pesticide leptophos was widely used in Mexico on a variety of food crops and as would be expected, FDA frequently found residues of this pesticide on Mexican produce. However, when EPA cancelled U.S. registrations of leptophos, Mexico immediately followed suit. Since that time, we have not detected leptophos residues in Mexican produce. It is also interesting to note that for the cancelled pesticides DDT and dieldrin that while residues of these pesticides still occur in some imported foods (attributable mainly to the presence of these pesticides in the environment) the levels are comparable to or less than those occurring in the domestically produced foods.

3. One of EPA's witnesses used BHC on cocoa beans as an example of a cancelled pesticide applied to imported agricultural commodities. Is it possible to get sampling statistics for cocoa and another major import (e.g., coffee)?

In 1974 FDA encountered several residue problems with cocoa beans. One problem involved the use of DDT for malaria control in Ecuador, which resulted in the indirect contamination of cocoa. FDA detained a number of shipments of this commodity because of the residue problem. FDA also encountered BHC residues in cocoa beans imported from Ghana. However, this problem took place before EPA cancelled BHC uses in the United States. We are reviewing our files to obtain more current information on BHC residues on cocoa beans. As soon as this review is completed, we will forward the information to the Subcommittee.

In regard to coffee beans, FDA received reports in 1977 that banned pesticides were being used on coffee beans in a number of South American countries. As a result of these reports, we initiated a special survey

to sample and examine this commodity from selected countries to determine the nature and extent of pesticide residue contamination. The results of this special survey are presented in the enclosed report (Enclosure II). The special survey results show the presence of very low levels of banned pesticides such as DDT, BHC, and dieldrin. However, there was no evidence to indicate that any of these pesticides were being used directly in the production of coffee beans. We concluded that these levels of pesticide residues do not pose a hazard to the consumer. We will, however, continue to spot check coffee beans imported into the United States for pesticide residues.

If we can be of further assistance to the Subcommittee in this matter, please do not hesitate to contact us.

Sincerely yours,

Robert C. Wetherell, Jr.

Robert C. Wetherell, Jr., Director
Office of Legislative Services

2 Enclosures

ENCLOSURE I

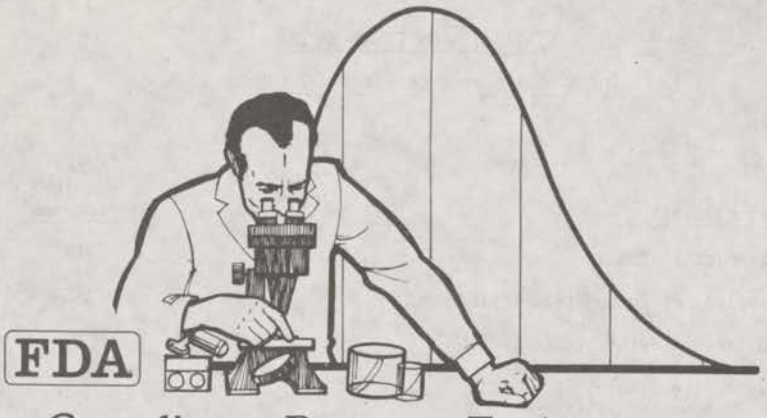
STATISTICS ON FDA SAMPLING

OF IMPORTED PRODUCE FOR FY 77 AND 78

Fiscal 1977	Mexico	Other Foreign Countries
Samples Tested	1,258	708
Variety of Commodities Tested	26	156
Different Pesticides Detected	34	43
Violative Samples (percent)	7.2	7.6
- Above EPA Tolerance	1.7	1.3
- No Tolerance	5.5	6.3
Detentions or Seizures	40	128

Fiscal 1978 (To May 1978)	Mexico	Other Foreign Countries
Samples Tested	531	295
Variety of Commodities Tested	22	115
Different Pesticides Detected	28	33
Violative Samples (percent)	3.2	4.4
- Above EPA Tolerance	0.6	2.0
- No Tolerance	2.6	2.4
Detentions or Seizures	27	16

ENCLOSURE II



Compliance Program Evaluation

FY 77/78 Pesticides in Imported Coffee Beans
(Division Assignment)

Date Accepted January 25, 1978 By J. Paul Hile

U.S. DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION
BUREAU OF FOODS

COMPLIANCE PROGRAM EVALUATION
FY 77/78 Pesticides in Imported Coffee Beans (Division Assignment)

OBJECTIVE

To sample and examine imported coffee beans from selected countries to determine the nature and extent of pesticide contamination.

BACKGROUND

Coffee is imported into the United States as green (unroasted) beans which are sampled and analyzed as such by the Food and Drug Administration (FDA). Approximately 2.75 billion pounds of coffee were imported into the U.S. during 1976. The following ten countries, in order of prominence, accounted for about 75% of the 1976 coffee imports: Brazil, Colombia, Mexico, Ivory Coast, Indonesia, El Salvador, Uganda, Angola, Ecuador, and Guatemala.

During 1977, the FDA received reports that pesticides such as chlordane, aldrin, dieldrin, endrin, and heptachlor may be used on coffee beans in Colombia, Brazil, Ecuador and other South American countries. There are no established tolerances for any of these pesticides in or on coffee beans.

- Tolerance - A regulation established under Section 408 of the Food, Drug, and Cosmetic Act by the Environmental Protection Agency (EPA) which sets forth the maximum level of a particular pesticide that can legally be present in or on a particular food.

During the period July 1974 through May 1977, the FDA examined a total of 19 samples of imported coffee beans from 12 countries. Attachment A shows pesticide residues and levels found during this period. Ten of these samples contained detectable levels of one or more of the following pesticide residues: DDT, DDE, BHC, lindane, malathion, and diazinon. All residues detected were below 0.1 ppm. Of these pesticides, only diazinon has an established tolerance (0.2 ppm).

PROGRAM DATA

Program Design

This Assignment directed each of the seven FDA Field Districts (New York, New Orleans, San Francisco, Houston, Dallas, Orlando and Baltimore), which encompass the principal ports of entry for coffee beans, to do the following:

1. Collect 10 samples of imported coffee beans.

2. Complete sample collections no later than October 31, 1977.

3. Select samples from as many exporting countries as possible.

4. Analyze the samples for pesticide residues using the multiresidue method for organochlorine and organophosphorus residues (Pesticide Analytical Manual, Vol. I, 212.13b, with the additional 50% ethyl ether/petroleum ether elution for complete recovery of malathion).

5. Perform check analysis and confirmation for residues above tolerance levels or for residues above trace levels for which no tolerance exists, and report such findings to FDA Headquarters for review.

Data Summary

This Assignment resulted in the collection and analysis of 55 samples from 19 countries through 8 U.S. ports (Orlando District has 2 ports of entry). Some of the Districts did not have sufficient import entries during this period to achieve the expected total of 70 samples.

Attachment B shows the individual residue findings in the 55 samples collected during this Assignment period of August, September and October, 1977. Twenty-five of the samples (45%) contained one or more residues. A total of 45 residues were detected, with 60% of these at trace levels. Pesticides in decreasing order of detection frequency were; DDT, BHC, DDE, lindane, diazinon, malathion, dieldrin and heptachlor. Highest individual levels were for the organophosphorus pesticides malathion (0.2 ppm) and diazinon (0.13 ppm).

The same pesticide residues found prior to this Assignment (Attachment A) were found during the conduct of the Assignment. In addition, dieldrin and heptachlor were found once each at trace levels in these data but were undetected in the earlier period. In the earlier period 53% of the samples contained one or more residues, and 47% of the residues detected were at trace levels.

Overall, findings in these two periods are similar and no trend appears to be developing. The residues found during this Assignment are of pesticides which have been used on a worldwide basis.

No attempt has been made to determine any statistical differences between countries since the rates of sampling varied widely and the high frequency of traces (barely detectable levels) would render such an attempt meaningless.

Significance of Pesticide Levels

Because of worldwide usage of pesticides, particularly those of the chlorinated hydrocarbon class, such as DDT and BHC, it is not unexpected to detect low levels of these pesticides or their metabolites in almost all food classes grown in the U.S. and elsewhere. Thus, finding trace levels or levels slightly exceeding trace levels of DDT, DDE, BHC, lindane, heptachlor and dieldrin is not unexpected and may be attributed to environmental factors rather than to purposeful applications. Therefore, the FDA considers the presence of these pesticides in green coffee beans as probably being unavoidable at the levels reported in this survey.

Diazinon and malathion belong to a class of pesticides known as organophosphorus, which are characteristically more readily degraded than chlorinated hydrocarbons. The two diazinon findings are well within the 0.2 ppm tolerance. The finding of 0.2 ppm malathion in one sample is not covered by a tolerance and may represent purposeful application. However, the lot was allowed entry because of evidence that there would be no detectable amount in coffee brewed from these beans.

The FDA performed experiments on a few research samples aimed at determining the extent to which pesticide residues in green coffee beans survive the roasting process. A major coffee firm cooperated by roasting the green coffee beans through the commercial roasting process.

All pesticide residues found in the green beans were significantly lower after roasting. Originally detectable BHC, lindane, and malathion residues were either non-detectable or present as incalculably low traces after roasting. The total DDT group appeared to have the highest survival rate; however, even in this case over 90% of the residue was removed by roasting. (The original level of about 0.09 ppm declined to traces estimated at 0.008 ppm.)

It may further be expected that the transfer of residues to brewed coffee would be incomplete. Such experiments were not performed; however, since levels in the brew would have been so low as to be nondetectable even if all the pesticide residues were extracted into the coffee liquid. This assumption is supported by the lack of detectable pesticide residues in the beverage composites in FDA's ongoing Total Diet Study which contain brewed coffee.

An accurate estimate of dietary intake of pesticides from coffee is not possible, but an approximation of the magnitude can be obtained from the following example.

Assume:
1. 4 cups of brewed coffee are consumed daily
2. 50 g. roasted coffee required to make 4 cups of brew
3. All of the residue present in the roasted coffee transfers to the brew
4. 0.09 ppm total DDT residue in the green coffee beans (highest individual survey sample)
5. 10% of the residue in the green beans survives the roasting process

DDT intake from 4 cups coffee per day = $50g \times 0.09 \frac{ug}{g} \times 0.10 = 0.45$ ug

- ppm - parts per million or micro (10^{-6}) gram per gram.

Thus, less than $\frac{1}{2}$ ug of DDT residue is added to the total daily intake from this example even if all the DDT residue were extracted from the brew. The average total DDT intake for the U.S. adult from the entire diet is currently about 6 ug/day (based on FDA's Total Diet Study). The acceptable daily intake for a 70 Kg man is 350 ug established by the World Health Organization/Food and Agricultural Organization.

Based on the above review it is concluded that the current levels of pesticides in imported coffee beans do not pose a hazard to the consumer.

Data Quality

The data used to evaluate this survey were obtained from analytical worksheets submitted by the FDA Field Districts as directed by this Assignment. For the purpose of this evaluation, the submitted data were satisfactory.

FINDINGS

1. The current levels of pesticides in imported coffee beans do not pose a hazard to the consumer.

2. Residues in imported coffee beans include low levels of the following pesticides which have been or are being used on a world-wide basis: DDT compounds, BHC, lindane, diazinon, malathion, dieldrin, and heptachlor.

3. Comparison of these findings with earlier findings from July 1974 - May 1977 does not show a trend in types, levels, and frequency of residues in imported coffee beans.

ACTIONS

1. The FDA continues to monitor the levels of pesticides in the FY 78 Total Diet Study, which includes brewed coffee, as a means of gauging dietary intakes of pesticides from foods as consumed.

2. The FDA is monitoring pesticides in imported coffee beans under the FY 78 Import Foods - General Program.

32-427 O - 78 - 15

Attachment B

COMPLIANCE PROGRAM EVALUATION
FY 77/78 Pesticides in Imported Coffee Beans (Division Assignment)

PESTICIDE RESIDUES IN IMPORTED COFFEE BEANS (August 1977-October 1977)

Country of Origin	Number of Samples Examined	Number With No Residue Found	Number With Residues Detected	Residues Found In Individual Samples (ppm)							
				DDT[1]	DDE	BHC[2]	Lindane	Dieldrin	Heptachlor	Diazinon	Malathion
Brazil	1	0	1			Trace					
Colombia	16	11	5	Trace							
				Trace	Trace						
				0.02						0.13	
								Trace			0.20*
Costa Rica	1	1	0								
Dominican Republic	1	1	0								
Ecuador	8	3	5	Trace	Trace						
				Trace	Trace						
				Trace	Trace				Trace		
				0.03*							
				0.03*		Trace	Trace				
Guatemala	4	3	1	Trace		Trace					
Haiti	1	0	1	0.08*							
Honduras	2	1	1	Trace							
India	2	0	2			Trace					
						0.03*	0.01*				
Indonesia	1	0	1			Trace				0.01	
Ivory Coast	1	1	0								
Kenya	1	1	0								
Mexico	5	1	4	Trace	Trace						
				0.03*	Trace	Trace					
				0.08*	0.01	Trace					
				0.03							
New Guinea	1	1	0								
Nicaragua	1	1	0								
Panama	1	1	0								
Peru	5	3	2	Trace	Trace	Trace					
						Trace	0.02*				
Uganda	1	0	1	0.02*							
Venezuela	2	1	1	Trace		Trace					
TOTALS	55	30	25	18	8	11	3	1	1	2	1

* Values with asterisk were confirmed by check-analysis to be at least as high as values shown.

1 DDT residues were reported primarily as p,p'-DDT. Tabulated values include also the few reportings of o,p'-DDT traces

2 BHC residues were reported primarily as the alpha isomer. Tabulated values include the few low levels of beta and delta isomers. The gamma isomer is reported separately as lindane.

Attachment A

COMPLIANCE PROGRAM EVALUATION
FY 77/78 Pesticides In Imported Coffee Beans (Division Assignment)

PESTICIDE RESIDUES IN IMPORTED COFFEE BEANS (July 1974 - May 1977)

Country of Origin	Number of Samples Examined	Number With No Residue Found	Number With Residues Detected	Residues Found In Individual Samples (ppm)							
				DDT	DDE	BHC	Lindane	Dieldrin	Heptachlor	Diazinon	Malathion
Angola	1	0	1							Trace	
Brazil	1	0	1	Trace		0.05	0.01				0.03
Colombia	5	5	0								
Costa Rica	1	1	0								
Ecuador	2	1	1	0.02							
El Salvador	2	1	1	Trace							
Guatemala	1	0	1	Trace	Trace						
India	2	0	2			0.03	0.01				
Ivory Coast	1	0	1			0.09					
New Guinea	1	0	1	Trace							
Nicaragua	1	1	0								0.04
Rwanda	1	0	1	Trace							
TOTALS	19	9	10	6	1	3	2			1	2

Requests for copies of this Compliance Program Evaluation should be directed to:

The Assistant Commissioner for Professional and Consumer Programs (HFG-1)
Food & Drug Administration, Rm. 15B-41
5600 Fishers Lane
Rockville, Maryland 20857

Mr. ROSENTHAL. Our next witness is Ms. Susan King of the Consumer Product Safety Commission.

We will take a brief recess before we hear from Ms. King.

[Recess taken.]

Mr. ROSENTHAL. I apologize for being late, Ms. King.

You have a prepared statement, and you may proceed as you wish.

STATEMENT OF SUSAN B. KING, CHAIRMAN, CONSUMER PRODUCT SAFETY COMMISSION; ACCOMPANIED BY MICHAEL A. BROWN, EXECUTIVE DIRECTOR; AND ALAN C. SHAKIN, STAFF ATTORNEY

Ms. KING. Thank you very much, Mr. Chairman.

For the record, I was designated Chair of the Consumer Product Safety Commission on July 1, so I have been serving for a little over a week in that capacity.

Mr. ROSENTHAL. Congratulations.

Ms. KING. Thank you.

I am accompanied here today by Michael Brown, to my right, who is Executive Director of CPSC, and to my left by Alan Shakin of the General Counsel's staff.

It is a pleasure for us to appear before this subcommittee today on behalf of my colleagues to discuss the issue of export of hazardous consumer products and our experience with the issue, as well as to advance some thoughts on dealing with future export problems.

I would note at this time that Commissioner Franklin intends to submit her own views to the subcommittee separately.

[See p. 229.]

Ms. KING. The Consumer Product Safety Commission welcomes these hearings.

Recent events concerning the export of Tris-treated children's sleepwear have highlighted an issue that the Commission and similar agencies face regularly: Should products that the U.S. Government deems too hazardous for American citizens be allowed to be shipped abroad where they may still cause harm?

Federal health and safety laws take a variety of approaches in dealing with this question, and there is presently no Governmentwide policy on the export issue.

We hope that these hearings will clarify some of the questions that surround the complex issue of hazardous consumer product export.

This is an issue of vital importance, not only to consumers in foreign countries but to American consumers as well.

With a possible future increase in exports of U.S. consumer goods and a possible acceleration of Government participation in consumer product safety, the export issue deserves greater public attention than it has received to date.

The Consumer Product Safety Commission feels that it has been on the cutting edge of this issue for some time, and has been working to a degree in uncharted waters because there is no Governmentwide agreement as to what export policies should exist.

In that context, we welcome guidance from the Congress as to what the future Governmentwide policy should be.

You have asked that we respond to a number of specific questions. I believe there were seven questions.

We will attempt to do so in the testimony, although not necessarily in the same order in which you posed the questions.

Let me begin briefly by describing the export provisions in the laws administered by CPSC. There are three statutes that deal directly with the export question.

First, section 18 of the Consumer Product Safety Act states that any consumer product that can be shown to be produced or imported for export, and is so labeled, is exempt from the provisions of the act, unless the product is distributed in commerce for use in the United States—15 U.S.C. 2067.

Second, under the Federal Hazardous Substances Act, certain products may be exported as long as they are packaged and labeled to the specifications of the foreign purchaser and in accordance with foreign law.

Under section 5 of the Federal Hazardous Substances Act, people who export such products are exempt from penalties so long as they have not sold or offered the products for sale in domestic commerce—15 U.S.C. 1264 and 15 U.S.C. 1265.

Finally, under the Flammable Fabrics Act, certain products that are intended for export are exempt from the requirements of the act.

The Federal Trade Commission, which formerly administered the Flammable Fabrics Act, debated for years whether the FFA statutory language permitted a product, once intended for domestic sale, to be later eligible for exemption.

The Consumer Product Safety Commission, when it assumed jurisdiction over the Flammable Fabrics Act, denied the exemption to such noncomplying products and generally prohibited their export—16 CFR 1602.2.

Recently, much attention has been focused on the export of Tris products, which we believe are banned under the Federal Hazardous Substances Act.

On April 7, 1977, the Commission interpreted certain Tris-treated products, including children's sleepwear in sizes 0 to 14, to be banned hazardous substances under the Federal Hazardous Substances Act.

Following requests by apparel manufacturers' trade associations, and following litigation with these associations, the Commission expanded its statutory interpretation to include Tris-treated component products.

A fabric mill later obtained an injunction in a separate lawsuit in South Carolina against enforcement of the Commission's interpretations.

Nevertheless, under the terms of an appellate decision, the Commission has filed numerous individual civil actions to enforce the provisions of the Federal Hazardous Substances Act against those who continued to sell Tris products.

On May 5, 1978, the Commission interpreted the Federal Hazardous Substances Act as providing authority to prohibit export of Tris products that have ever been sold or offered for sale in domestic commerce, and that are banned hazardous products.

The Commission's action reversed its earlier interpretation of October 20, 1977.

By its May 5 interpretation which, of course, was based on the FHSA statutory language, the Commission took a decisive step to deal with the problem of hazardous consumer product exports.

The Commission believes that the United States has an obligation to protect the citizens of other countries from the export of certain hazardous products from this country.

Some products—for example, Tris-treated children's sleepwear—are so dangerous that the risks they pose transcend national boundaries.

An action to prohibit the export of hazardous products carries with it the added benefit of helping to protect the U.S. consumer.

If U.S. manufacturers cannot sell to foreign countries products that subsequent to production have been ruled too hazardous for domestic sale, industry has an incentive to produce safe products initially.

Further, prohibiting the export of hazardous products eliminates the possibility of later reentry into this country.

In considering the question of hazardous consumer product export generally, however, we caution that the case of Tris products may not be typical.

Although our May 5 decision provides an important precedent as to how the Commission will interpret its authority to prohibit exports in the future, it does not necessarily indicate how we intend to use our discretionary authority in dealing with the export of other hazardous products under other circumstances.

Within the Commission's statutory framework, three principal factors must be weighed in making a determination regarding the export of products deemed too hazardous for U.S. consumption.

First and foremost is the question of the degree of risk the product presents to U.S. consumers through reimportation, and to foreign consumers.

Second, close attention must be paid to the cultural and geographic context in which the product will be used in the foreign country.

Differing patterns of product use may mean that U.S. product safety requirements make less sense in a foreign context.

In the case of bicycle safety standards, for example, U.S. requirements for headlight beam reflectors very well may not be relevant in a nation that has few cars.

Third, consideration must also be given to the economic consequences of export restrictions. Such restrictions can affect not only the economies of foreign nations but also U.S. domestic manufacturing output and competition, as well as our balance of payments.

Turning again to the Tris export decision and in response to your first question concerning the extent of export of consumer products banned under the Consumer Product Safety Act and Federal Hazardous Substances Act, the Commission's staff has taken several steps to determine the extent of Tris exports and to insure compliance with the May 5 decision.

In anticipation of the May 5 action, the CPSC staff conducted a telephone survey and a number of inspections to determine whether Tris-treated children's garments were being exported and to gather information on how much stock remained in the hands of manufacturers.

The survey indicated that a total of 18 manufacturers exported, or attempted to export, Tris-treated children's sleepwear before the May 5 decision. Four manufacturers may have exported the products.

A total of approximately 2.4 million garments were reported as having been shipped abroad.

To insure compliance with the May 5 decision, on June 14, 1978, the Commission published in the Federal Register a statement of policy explaining that May 5 decision.

Subsequently, the Commission sent the Federal Register notice to 99 manufacturers, all known to have had stocks of Tris products on or after April 8, 1977, to inform them of the export decision.

At the same time, the Commission sent the manufacturers special orders, as provided by section 27(b)(1) of the Consumer Product Safety Act.

Attached is a copy of the special order, the Federal Register notice, and a cover letter, as it was sent to these 99 manufacturers.

The special orders, which are similar to subpenas, require the manufacturers to submit detailed information about their present stocks of Tris products.

They also require manufacturers to provide the Commission with 15-day prior notification of any future disposition of the products.

Responses to the special orders are due July 17, 1978. Manufacturers who fail to respond face possible penalties of up to $2,000 for each violation.

The special orders should give the Commission an accurate accounting of remaining Tris stock and should allow the Commission to use its enforcement resources as efficiently as possible in monitoring the future disposition of the stock.

Based on the information obtained through the special orders, the staff will conduct surveillance spot checks of companies holding Tris products. The staff will also continue to follow up complaints received from industry or other sources regarding possible export activities.

As for other products the Commission has banned under the Federal Hazardous Substances Act, the Commission know of no exports of noncomplying FHSA products since the May 5 decision.

Prior to that decision, the CPSC staff followed the Commission's earlier interpretation of the FHSA permitting export of noncomplying products. Thus the staff took no legal steps to preclude export of noncomplying products and did not collect data on the export of banned Federal Hazardous Substances Act products.

As for products banned under the Consumer Product Safety Act, prior to the May 5 decision, the staff regarded the Consumer Product Safety Act's export provisions as having the same practical effect as the Federal Hazardous Substances Act export provisions and thus was not involved in efforts to prevent export.

Additionally, bans under the Consumer Product Safety Act have not resulted in the same kinds of problems as we encountered with Tris.

The subcommittee has asked whether we are considering ban-and-repurchase actions under the Federal Hazardous Substances Act that would result in the export of significant quantities of banned products. We are not now considering any such action.

You have asked what is the current Commission view with regard to an export policy for the Consumer Product Safety Commission.

Although we have not yet developed a comprehensive export policy, the Commission's May 5 decision on Tris indicates how we are likely to approach the export issue in the future.

Further, the staff is currently reviewing another case that will require the Commission to consider procedures regarding the export of products subject to the Federal Hazardous Substances Act or the Consumer Product Safety Act.

The case involves children's toy banks subject to FHSA lead-in paint regulations.

The importer is presently holding banks that were recalled or never distributed, and he has requested permission to export the products.

The staff is currently preparing a briefing package for the Commissioners on this case.

You asked whether the Flammable Fabrics Act export policy has proven effective.

The Commission cannot fully assess the policy's effectiveness at this time.

The Commission learns of noncomplying exports through our field offices' surveillance efforts and through reports of defective products in accordance with section 15(b) of the Consumer Product Safety Act.

Firms are not required to report their intentions to export noncomplying products, and the Commission's limited resources do not allow us to fully monitor the export activities of the large and diverse fabrics industry.

Despite what we acknowledge to be the limited amount of information available, there are two instances that provide at least some indication of the policy's effectiveness.

The first case involved the importation of noncomplying general wearing apparel in which the importer reported the matter to the Commission under section 15(b).

The staff informally advised the importer that the Flammable Fabrics Act export policy prohibits export of noncomplying goods. The importer has not disposed of the goods, and the case is still pending.

Second, the Commission's FFA export policy is presently the subject of litigation in the U.S. District Court for the Northern District of Georgia.

The Commission is seeking civil penalties against a carpet manufacturer for violating a cease-and-desist order. The case is based in part on an allegation of exportation of noncomplying carpet.

The company has raised as a defense the illegality and inapplicability of the Commission's export policy. This issue may be resolved in the course of that litigation.

You have asked us whether the State Department has been helpful in notifying foreign governments of relevant CPSC actions.

The State Department has been helpful whenever contacted by the Commission for assistance.

For example, in August of 1977, at the Commission's request, the State Department forwarded information on the hazards associated with Tris to the Director of the International Agency for Research on Cancer, a subsidiary body of the World Health Organization.

On two other occasions—one concerning defective pacifiers from Spain and the other regarding saddle blanket yarn contaminated with anthrax spores from India, Pakistan, and Afghanistan—the Commission provided information to the State Department about a hazardous

product imported into the United States. Please note that we were dealing with an import problem rather than an export problem.

This subcommittee has asked that we comment as to what defects we believe exist in our statutory authority on exports.

Under the Federal Hazardous Substances Act, as well as the Consumer Product Safety Act and the Flammable Fabrics Act, it is clearly permissible to export products that have not been introduced into domestic commerce, regardless of the degree of hazard they may present.

This different treatment of goods, depending upon whether they have been introduced into domestic commerce, causes problems in administering the statute.

Further, the statutory export language is subject to varying interpretations as to whether it provides clear legal authority for the Commission to prohibit exports.

For these reasons, the Commission urges congressional action to state in clear statutory terms our authority to prohibit exports of hazardous products. Such legislation could also provide an opportunity to coordinate export policies among various Federal agencies.

Mr. ROSENTHAL. The Peterson committee, I presume, is considering this matter; right?

Ms. KING. Yes. We would very strongly favor a national export policy and some method for coordinating——

Mr. ROSENTHAL. The committee that Ms. Peterson told us about yesterday presumably is working on this very issue.

Ms. KING. Yes. We are very actively participating in that effort. Because we are working with them on the report that they plan to have available by September, at this time we do not want to make any comments as to what we think a national export policy should be. We will first let them issue the final report on that.

In response to your request for legislative recommendations, in the absence of a national policy we will speak directly to our statutory authority only.

You have asked us for legislative recommendations on the export issue. The Commission recommends, if there is no national export policy, that Congress give the Consumer Product Safety Commission clear statutory authority to ban on a discretionary basis the export of products that the Consumer Product Safety Commission has ruled to a hazardous for domestic sale.

Under this discretionary authority, CPSC could determine that selected consumer products are unsuitable for export. The Commission would make this determination in a rulemaking or adjudicatory proceeding and base it on specific criteria.

For example, the degree and nature of the hazard presented; the legality and acceptability of the product in the countries of possible destination; and the possible economic impact.

The Consumer Product Safety Commission should have the authority to block export pending completion of such a proceeding.

Similar discretionary authority to ban exports already exists in several Federal statutes.

As you have discussed with prior witnesses before the subcommittee, the medical device amendments to the Food, Drug and Cosmetic Act, 21 U.S.C. 381(d) 1976, empower the Secretary of HEW to prohibit

on a discretionary basis the export of medical devices that do not comply with specified performance standards, have not received premarket clearance, or have been banned.

While such legislation would be our strong preference, other legislative approaches are also possible.

One approach would be to give the CPSC the discretionary authority to require exporters to secure the permission of the government of the importing country as a condition of export.

As in our proposal for discretionary ban authority, a decision to invoke the permission requirement would be made following a rulemaking or adjudicatory proceeding and would be based upon specific criteria.

The concept of requiring the receiving country's specific approval as a condition of export is also not a new one.

The medical device amendments I mentioned earlier allow HEW to require such approval as an alternative to an outright export ban.

The administration's Drug Regulation Reform Act of 1978 that Don Kennedy discussed this morning contains a similar procedure for the export of new drugs—H.R. 11611 and S. 2755, section 135.

Another approach would be to require exporters to notify the Consumer Product Safety Commission prior to exporting a product that has been found too hazardous for domestic sale.

Such notification should include a description of the product, the anticipated date of shipment, the place from which shipment will occur, the ultimate destination of the product, and the quantity of of the product to be exported.

Upon receipt of such a statement, the Commission would see that the appropriate U.S. agency notifies the government of the receiving country about the intended export and the hazard the product may pose.

It may also be useful to require labeling of the product to inform the importer of the possible hazard.

Again, the concept of requiring notice to the importing country is not new. It has been the subject of much of your discussion this morning.

The Toxic Substances Control Act—15 U.S.C. 2611 (1976)—contains such a requirement for the export of certain toxic substances.

In addition, the House Commerce Committee has included similar language in the Consumer Product Safety Commission's reauthorization legislation which is now pending.

To summarize, Mr. Chairman, the Commission shares your interest in the important and complex issue of hazardous product export.

We believe that in some instances placing restrictions on the export of dangerous consumer products is both consistent with U.S. human rights policy and in the best interests of American consumers.

We urge congressional action on this issue to clarify our legal authority to place restrictions on hazardous exports and to provide greater uniformity in the Federal Government's approach to dealing with the export question.

We appreciate the opportunity to appear here today, and we would be glad to answer any questions that you may have.

Mr. ROSENTHAL. Thank you very, very much.

Your attachments will be made a part of the record without objection.

[The material referred to follows:]

ATTACHMENT

U.S. CONSUMER PRODUCT SAFETY COMMISSION
WASHINGTON, D.C. 20207

Gentlemen:

As you may already be aware, on May 5, 1978, the United States Consumer Product Safety Commission determined that it has authority to prohibit the exportation of TRIS products which are banned hazardous substances under the Federal Hazardous Substance Act (FHSA) (15 U.S.C. 1261 et seq.) and which products or components thereof have ever been sold or offered for sale in domestic commerce. A copy of the Federal Register notice setting forth the Commission's determination is enclosed.

You will also find enclosed a Special Order issued by the Commission to your firm, as well as to a number of other manufacturers of TRIS-treated children's wearing apparel, requesting that your firm provide to the Commission certain information about your TRIS-treated products.

The Commission is aware that many firms to which the Special Order is being directed have cooperated fully with the agency's efforts to remove TRIS products from the marketplace. Hence, to be a recipient of the Special Order should not be construed by a manufacturer as an indication that the Commission has reason to believe that the company is guilty of any wrongdoing.

I would point out for your information, however, that under the Consumer Product Safety Act (CPSA) (15 U.S.C. 2051 et seq.), a failure to comply with the Special Order could subject your firm, as well as individual directors, officers, or agents of the firm, to civil penalties under section 20 of the CPSA (15 U.S.C. 2069), and under certain circumstances to criminal penalties under section 21 of the CPSA (15 U.S.C. 2070).

In addition to the information requested in the Special Order, the Commission is hereby asking all recipients of this letter to inform the Associate Executive Director for Compliance and Enforcement as soon as possible of any shipments of TRIS-treated products which have been made to U. S. possessions or territories or to the Commonwealth of Puerto Rico. The Commission views any such shipment as movement of a banned hazardous substance in interstate commerce, which is a prohibited act under Section 4 of the FHSA (15 U.S.C. 1263). The agency is aware, however, that certain firms may have shipped TRIS-treated products to Puerto Rico or other United States possessions or territories between April 8, 1977 and May 5, 1978 on the mistaken belief that such shipment constituted exportation rather than movement in interstate commerce. The Commission is primarily interested in identifying and locating TRIS products which may yet be in the marketplace of U. S. possessions or territories or the Commonwealth of Puerto Rico, in order that such products can be removed from the distribution chain and the hands of consumers as rapidly as possible.

Should you have questions concerning the information requested by the Special Order or this letter, the name and telephone number of a contact person within the Commission's staff is included in the Order.

Sincerely,

Edwin F. Tinsworth

Edwin F. Tinsworth
Acting Associate Executive Director
for Compliance & Enforcement

Enclosure: (2)

[6355-01]

CONSUMER PRODUCT SAFETY COMMISSION

EXPORTATION OF TRIS-TREATED CHILDREN'S WEARING APPAREL AND OTHER TRIS PRODUCTS

Statement of Policy

AGENCY: Consumer Product Safety Commission.

ACTION: Statement of policy.

SUMMARY: In this notice, the Commission states and discusses its enforcement policy concerning the exportation of certain TRIS products that it believes are banned hazardous substances under the Federal Hazardous Substances Act.

DATES: The policy became effective on May 5, 1978.

FOR FURTHER INFORMATION CONTACT:

Alan Shakin, Office of the General Counsel, Consumer Product Safety Commission, Washington, D.C. 20207, telephone 202-634-7770.

SUPPLEMENTARY INFORMATION:

Background

Since April 1977 the Commission has taken a number of actions concerning the chemical flame retardant TRIS, and certain products containing TRIS, that it believes are "banned hazardous substances" under the Federal Hazardous Substances Act (FHSA, 15 U.S.C. 1261 et seq.). These actions, as well as some litigation that has resulted from them, are discussed in FEDERAL REGISTER notices dated April 8 (42 FR 18850), June 1 (42 Fr 28060), and December 6, 1977 (42 FR 61593 and 61621).

On October 20, 1977 the Commission considered issues relating to the export of the TRIS products that the Commission believes are banned hazardous substances. On May 5, 1978 the Commission reconsidered these issues.

Statement of Policy

The Commission's existing policy, based on its interpretation of the FHSA, is that it has authority to prohibit the export of TRIS products which have ever been sold or offered for sale in domestic commerce and which are banned hazardous substances. For the reasons discussed in the December 6 FEDERAL REGISTER statement of policy, the Commission believes that the TRIS products named in the April 8 and June 1 FEDERAL REGISTER notices are "banned hazardous substances" (in the discussion below, these products will be referred to as "TRIS products").

In addition, the Commission has considered the question of when a TRIS product has been sold or offered for sale in domestic commerce, and is thus within the scope of this export policy. In the Commission's view:

(1) If a TRIS product has been sold or offered for sale in domestic commerce in its present form, it would clearly be within the policy. For example, if a TRIS-treated children's garment had been on the shelf of a retail store and was then recalled, it would be included within the policy. Similarly, if a bolt of TRIS-treated fabric intended for use in children's wearing apparel has been sold in domestic commerce, it would be included within the policy.

(2) If a TRIS product has not been sold or offered for sale in domestic commerce in its present form, it would be within the export policy as long as a component which is a TRIS product has been sold or offered for sale in domestic commerce. For example, even if a TRIS-treated children's garment has never left the factory where it was manufactured, it would be included within the policy if one or more of its components that are banned hazardous substances such as TRIS-treated fabric, have been sold or offered for sale in domestic commerce.

Any parties who disagree with the Commission's policy, or with its application to particular products, will have ample opportunity to contest it at a hearing in Federal district court, if and when the Commission files enforcement actions against the products of such parties.

Dated: June 9, 1978.

SADYE E. DUNN,
Acting Secretary, Consumer Product Safety Commission.

[FR Doc. 78-16437 Filed 6-13-78; 8:45 am]

[1] The level of restraint has not been adjusted to account for imports after December 31, 1977.

U. S. CONSUMER PRODUCT SAFETY COMMISSION

TRIS-TREATED PRODUCTS

Special Order for Submission of Information

The United States Consumer Product Safety Commission hereby orders those manufacturers of children's sleepwear served with this special order to submit to the Associate Executive Director for Compliance and Enforcement of the Consumer Product Safety Commission no later than July 17, 1978, the information requested below:

1. State the official name, complete address, and telephone number of the principal place of business of the firm.
2. State the place of incorporation if the firm is a corporation.
3. State the name, address, and place of incorporation of the parent corporation, if any.
4. If the firm is not a corporation, describe the legal entity. If a partnership, state the names of all general and limited partners.
5. State the name, address, and telephone number of the firm's registered agent to receive service of process in the jurisdiction of the firm's principal place of business.
6. State the name, address, and telephone number of the firm's registered agent authorized to receive service of process within the District of Columbia, if any.

7. State the names and titles of the principal officers of the firm.

8. List the name and title of each official within the firm who has engaged, is engaging, or will engage in any decisions involving TRIS-treated products on or after May 5, 1978, indicating each official's area of responsibility and the nature of the decision(s) made by each person named.

9. State the number and exact location of all TRIS-treated products that are currently in inventory or otherwise under the firm's control, identifying each product and the quantity thereof by style or other identifiable classification.

10. For every disposition (for example, destruction) of TRIS-treated products which is to be made by the firm after receipt of this Special Order, notify the Associate Executive Director for Compliance and Enforcement at least 15 days before each such disposition is scheduled to occur, stating (1) the intended means of disposition, (2) the intended place of disposition, (3) the time scheduled for disposition, (4) a description as to style or other identifiable classification for each product and the quantity thereof, (5) the name, address and telephone number of the official within the firm who is responsible for accomplishing such disposition, (6) the name, address, and telephone

number of any agent or independent contractor who will accomplish such disposition on behalf of the firm, and (7) identify and describe in complete detail each and every document and entry thereon maintained by or on behalf of the firm which relate to the disposition of the TRIS-treated products described herein, or, in the alternative, submit copies of each such document.

11. For each disposition of TRIS-treated product other than by destruction (for example, exportation) on or after May 5, 1978, but before receipt of this Special Order, state the exact date of each disposition, the name, complete address and telephone number of each receiving party, and the quantity of each product and the identification thereof with specificity as to style or other identifiable classification.

12. For any changes which occur in the firm's inventory of TRIS-treated products after your initial submission of responses or for any other changes in the information furnished in the firm's initial submission of information, provide immediate supplemental responses to reflect all such changes as they occur, until otherwise notified by the Commission. State this information in the same form as your initial response.

Those manufacturers who have any questions about the subject of this Special Order should contact: Ms. Elizabeth Jones, Division of Regulatory Management, CPSC, telephone (301) 492-6400.

32-427 O - 78 - 16

This Special Order is promulgated pursuant to sections 5, 27(b)(1) and 30(d) of the Consumer Product Safety Act, 15 U.S.C. 2054, 2076(b)(1), and 2079(d), and section 11(a) of the Federal Hazardous Substances Act, 15 U.S.C. 1270(a).

By direction of the Commission:

Sheldon D. Butts
Acting Secretary
U. S. Consumer Product
Safety Commission

Dated: 6/14/78

Mr. ROSENTHAL. Under section 27(b)(1) of your act you sent special notice to Tris manufacturers requiring information about present inventories. Have you done anything similar to that to other manufacturers—for example, baby pacifiers or asbestos products?

Ms. KING. No. This is the first instance that the special order has been used for this purpose, dealing specifically with the export question.

Mr. ROSENTHAL. Do you think it would be useful in such a situation as the pacifier situation in which there are exports?

Ms. KING. It very well may be.

Mr. ROSENTHAL. Did the Commission notify any countries since 1976 and 1977 about the banned pacifiers that were being exported?

Ms. KING. I was not a member of the Commission at that time.

Mr. ROSENTHAL. I just wonder if anybody knows the history of that.

Mr. MICHAEL BROWN. I am unaware of such notifications, other than that we did deal with Spain through the State Department. The pacifiers we were banning at that time were products of Spain.

It was a question of exportation back to the country of origin, because the importer was returning the pacifiers to the manufacturer for credit.

Mr. ROSENTHAL. Ms. King, I am not sure I understand what the Commission policy is.

You say that the May 5 decision does not necessarily indicate how CPSC discretion in dealing with exports will be used.

You say that the decision indicates how the Commission is likely to approach the export issue. In other places, you say you are awaiting congressional leadership and action.

In a fourth situation, you say we are all waiting to see what the Peterson group produces.

Is there a Commission policy on exports or isn't there?

Ms. KING. I would like to go back to the statement that we made originally.

Tris is a very unusual situation, because the export question really arose out of the domestic prohibition on the sale of Tris. It came out of an earlier action.

Because of the peculiar nature of that specific hazard, we do not say that our action in this case is the definitive statement of the Commission's overall export policy.

We have not, at this point, adopted a general policy on export. What we are saying is that the criteria that would be considered on a case-by-case basis, as these questions come up, are those that we have weighed and balanced in making the Tris decision.

Mr. ROSENTHAL. Are you going to develop a policy, or are you going to wait for congressional action or the Peterson group or are you going to deal with it on a case-by-case basis?

Ms. KING. For the moment I think we will continue to deal with it on a case-by-case basis.

It may be that in the absence of a national approach to the problem or any clarification by Congress of the statutes, we would develop a general export policy.

It has been under discussion for some time. We thought it was premature for us to develop a general policy when there are many other activities pending on other fronts.

Mr. ROSENTHAL. At least in terms of notification it might not be premature. It is something we were trying to explain to Ms. Blum today.

Take the Tris situation. Did you ask the State Department to notify embassies overseas?

Ms. KING. You will recall at that time the Commission did not have the same position on its authority to control the exports.

I would say that in that case the Commission went further than anybody else has gone.

As a matter of goodwill and good faith, the Commission directly contacted the Department of Commerce and Andrew Young, the U.N. Ambassador. Communications were received by the State Department from Andy Young.

The Commission notified at least four international agencies and directly contacted 17 foreign governments. We are still in contact with various foreign governments on the problem.

In asking the State Department how we should proceed in the notification area, they have urged us—in a very recent situation—to deal directly with the Venezuelan Government.

Mr. ROSENTHAL. What situation is that?

Ms. KING. Tris.

Mr. ROSENTHAL. Did you deal with the Venezuelan Government?

Ms. KING. Yes; we are.

Mr. ROSENTHAL. I am curious. What kind of response do you get from a foreign government in a situation like that?

Ms. KING. In this case, the inquiry came from the Government of Venezuela. I think they contacted CPSC directly.

We contacted the State Department and asked them if they would prefer to handle it. They said no, and advised us to go ahead and continue to deal with Venezuela.

Mr. ROSENTHAL. Then what happened in Venezuela after you provided this information?

Mr. MICHAEL BROWN. The Venezuelans inquired of us whether certain garments were banned. They also wanted general information to enable them to identify Tris-treated garments.

The information was supplied to them, and we have received nothing back from that Government as to what they did with this information.

Ms. KING. I understand that the Government of France has banned the importation of Tris products as a result of the communications via OECD and CPSC.

Mr. ROSENTHAL. We want to thank you very much for appearing.

[Statements by Commissioner Barbara H. Franklin and former Chairman John S. Byington follow:]

U.S. CONSUMER PRODUCT SAFETY COMMISSION
WASHINGTON, D.C. 20207

July 12, 1978

Honorable Benjamin S. Rosenthal
Chairman
Subcommittee on Commerce,
Consumer and Monetary Affairs
Committee on Government Operations
House of Representatives
Washington, D. C. 20515

Dear Mr. Chairman:

As an individual member of the CPSC, I wish to offer some views regarding the export of hazardous consumer products.

Whether the export of products found hazardous under U.S. laws can be prohibited as a matter of law, or should be prohibited as a matter of policy, are questions which have been highlighted by the Commission's experience in the case of tris-treated children's sleepwear.

As you know the Commission decided on May 5, 1978, to reverse its earlier position and held that it has authority to prohibit export of tris-treated children's sleepwear. I dissented because I believe that a fair reading of our statute and its legislative history shows that the Commission lacks this authority. (Attached is a full text of the dissenting opinion filed by former Chairman Byington and myself.)

Beyond the issue of statutory authority, there are complex issues of public policy which need discussion and resolution. Among them: Does U.S. prohibition of export of hazardous products in effect set health and safety standards for citizens of other countries? If so, is

this appropriate? Is labeling of such products together with notification to foreign governments a more appropriate means to fulfill our responsibility to those countries? Do other countries have similar obligations to us? Would export prohibition place American producers at a competitive disadvantage in world markets? Would loss of American jobs result? Would the U.S. balance of payments be adversely affected?

Clearly, the question of export -- as pointed out by Ms. Peterson's testimony -- is one that cuts across many laws and agencies. Existing statutes take a variety of approaches. In my view, greater consistency and fairness should be sought in the U.S. government's approach to export.

I would make several suggestions.

First, notification requirements would be desirable. I have supported in the past and continue to support amendments to CPSC's statutes that would require notification to importing governments if products are subject to final bans and standards, or have been determined to pose substantial or imminent product hazards. Consideration could be given to making such requirements uniform government-wide.

Secondly, better mechanisms to ensure more effective, more systematic and more timely international notification are needed. I am aware there are systems now in use, but believe they could be improved.

Finally, public discussion must be an important ingredient in establishing our government's posture regarding export. This issue, with its important ethical and economic implications, requires careful consideration of the views of many segments of the American public who could be affected. I hope further hearings will be held to solicit a wide range of public views.

One final note. We at the Commission should not lose sight of our primary mission -- that of protecting the public

in this country from unreasonable risks of injury and illness associated with consumer products. I question whether we have the collective wisdom, or the resources, to make such determinations for citizens in other parts of the world.

Sincerely,

Barbara Franklin

Barbara Hackman Franklin
Commissioner

Attachment

U.S. CONSUMER PRODUCT SAFETY COMMISSION

WASHINGTON, D.C. 20207

DISSENTING OPINION OF
CHAIRMAN S. JOHN BYINGTON AND
COMMISSIONER BARBARA H. FRANKLIN
IN THE MATTER OF TRIS EXPORT
AUTHORITY

On May 5, 1978, the majority of the Consumer Product Safety Commission (CPSC) voted to reverse its previously established export policy and to hold that the Commission has authority to prohibit exportation of TRIS-treated products which are believed to be banned hazardous substances under the Federal Hazardous Substances Act (FHSA) and which products or components thereof have ever been sold or offered for sale in domestic commerce. A Federal Register Notice has been issued containing the Commission's new statement of policy.

We dissent. We believe that the CPSC does not have the statutory authority to prohibit the export of such products. We continue to support the Commission's previous interpretation that the FHSA does not give the Commission authority to seize or otherwise interfere with the export of any TRIS products that are properly labeled and marked for export, and are actually exported in accordance with Sections 5(b)(3) and 6(a) of the FHSA. This includes products that have been previously sold or offered for sale in domestic commerce and recalled.1/

Our position is based upon: (1) the specific language of the FHSA and related statutes; (2) the legislative histories of the FHSA and related acts; and (3) recent legislation enacted by Congress. Moreover, we believe there are longstanding public policy considerations which support this position.

1/ Provided these same products have not been condemned under § 6(c) of the FHSA.

There appears to be no question that products designated and labeled for export but moving in domestic interstate commerce are included within the FHSA and, therefore, are subject to our jurisdiction. However, in the FHSA, there are specific statutory exemptions for exports in the sections on penalties and seizures. Section 5(b)(3) provides an exemption from penalties for persons who export a properly labeled and packaged product that complies with the laws of the foreign country. /

The plain language of this provision certainly does not prohibit the export of non-complying products. The critical question, particularly as it relates to the TRIS situation, is this: does the owner of a product, once sold or offered for sale in domestic commerce, forever lose the opportunity to obtain an export exemption from FHSA penalties?

The legislative history of this act does not provide a clear answer. The one reference to Section 5(b)(3) in the context of this question is contained in a letter from the House Committee on Legislation to the Committee on Interstate and Foreign Commerce. 2/ The sentence reads:

> Nor would it be a violation (of Section 4 of the FHSA) where there is involved any hazardous substance shipped or delivered for shipment for export, to any foreign country, in a package marked for export and branded in accordance with the specifications of the foreign purchaser and the laws of the foreign country.

2/ S. Rep. No. 1158, 86th Cong., 2d. Sess. 33 (1960)

To us, this indicates Congressional intent to allow for a broad export exclusion, conditioned on appropriate labeling. Moreover, export provisions found in statutes enacted by Congress after the FHSA support this interpretation, and may be used to assist in evaluating Congress' intent under the principle of in pari materia.

Basically, this tenet of statutory interpretation holds that statutes that pertain to the same thing or have the same purpose or object should be construed together as if they were one law. 3/ Moreover, the later act can be regarded as a legislative interpretation of the earlier act in the sense that it helps ascertain the meaning of the words as currently used. 4/

Applying this tenet, since the FHSA was passed, there have been two other statutes enacted by Congress which have the same goal of safety of consumer products in the domestic marketplace and also which address the export question. The Flammable Fabrics Act of 1953 was amended in 1967 5/ to add an export exemption. This provision 6/ permits products that do not comply with our flammability standards to be exported if they are labeled for export. Again, we perceive nothing in the plain language of the statute or in the legislative history that would support a narrow interpretation of the export language.

Our most recent legislative pronouncement on product safety is the Consumer Product Safety Act 7/ enacted in 1972. It contains Section 18 8/ which also allows for the export of non-complying products:

> This Act shall not apply to any consumer product if (1) it can be shown that such product is manufactured, sold, or held for sale for export from the United States..., unless such consumer product is in fact distributed in commerce for use in the United States... (emphasis added)

3/ United States v. Freeman 3 How. 556,564 (1845); Sanford v. Comm'r., 308 U.S. 39, 44 (1939). See 2A Sutherland Statutory Construction § 51.02, at 290 (1973).

4/ Alexander v. Alexandria, 9.U.S. (5 Cranch) 1, 7-8 (1809) (Marshall, J.); United States v. Stewart, 311 U.S. 60, 64-65 (1940); Erlenbaugh v. United States, 409 U.S. 239, 243-44 (1972) (Marshall, J.).

5/ Pub. L. No. 90-189, § 10,81 Stat, 574.

6/ 15 U.S.C. § 1202 (1967).

7/ 15 U.S.C. § 2051 (1972).

8/ 15 U.S.C. § 2067 (1972).

To obtain this exemption, the consumer product or its container, when distributed in commerce, must bear a stamp or label stating that it is intended for export. Here the statutory language specifically acknowledges the reality of the export situation and recognizes the necessity for the seller to move the goods in interstate commerce to deliver them to the port of exit. This is acceptable for non-complying goods if properly labeled. Only if they are labeled and then diverted for actual use in the United States are the goods in violation of the Act. By clarifying that "distribution in commerce" refers only to subsequent (post labeling for export) "actual use" in the United States, it is clear to us that Congress intended to allow the export of non-complying products that had at one point been distributed in commerce and subsequently recalled.

The legislative history of this provision clearly shows that properly marked and labeled products can be exported even though they have been sold in domestic commerce. The House Committee Report 9/ stated that:

> (I)t should be noted that in cases where such product has been distributed in commerce, in order to quality for an exemption, the product... must bear a stamp or label stating that the product is intended for export (emphasis added).

The debate in the House 10/ further supports this interpretation. Mr. Gross asked, "Does this mean products which would otherwise be disqualified under this Consumer Product Safety Act could be exported to foreign countries?" Mr. Staggers, Chairman of the House Committee on Interstate and Foreign Commerce, replied in the affirmative and noted that "we are not trying to make the law for any country. In certain instances certain products might be wrong here, but they might be all right in other countries - we do not know."

When Mr. Gross asked whether this was a double standard, Mr. Moss agreed that it was - one standard for Americans and one for foreign consumers, if their governments establish

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9/ H.R. Rep. No. 92-1153, 92d. Cong., 2d. Sess.

10/ 118 Cong. Rec. H. 85 98-99 (daily ed. Sept. 20, 1972).

standards lower than the United States. Mr. Moss then explained that:

> .... if we deny our manufacturers a right to participate in that market all we are doing is denying them job opportunities because other countries will manufacture and ship into these nations products which conform to their standards.

Thus, the three statutory export provisions, construed together, support the view that Congress intended to create a broad FHSA export exemption.

Congressional legislation favoring broad export exemption has been modified recently. The Toxic Substances Control Act provides for export with labeling plus notice to EPA, who in turn must inform the relevant foreign government(s). S. 2755, the Drug Regulation Reform Act of 1978, echoes this 3-prong approach to exports. A similar notice provision has also been incorporated into the House proposed CPSA amendments although, as a matter of practice, the CPSC already had utilized existing mechanisms, i.e. the World Health Organization and the United Nations, to notify foreign countries of potential TRIS exports.

In our opinion, all the various export provisions seem to be articulating, with varying degrees of precision, a public policy that the United States does not intend to set health and safety standards for the world. Under this policy, our responsibility to other countries is fulfilled by requiring appropriate labeling and notification to foreign countries of impending exports. This allows other countries, based on adequate information, to make their own choices and to establish their own criteria and standards. Moreover, such a public policy does not put American manufacturers at an economic disadvantage in the world market -- by having, for example, CPSC standards required for certain of their exported products, when such is not the case for competing foreign firms. To do otherwise would in effect create an adverse trade hurdle that could have severe economic consequences for our domestic economy without providing any additional health and safety benefits for the American consumer.

Our top priority at CPSC should be to insure that our actions result in increased health and safety protection for the American public. We cannot understand how a narrowly construed export exemption policy will achieve that. Some might argue that it would have a deterent effect on manufacturers, in that they would

be more careful to manufacture safe products if they knew they could not later "export their mistakes". However, we find no basis whatsoever for that reasoning. First there is no evidence that manufacturers make their products with an eye on export safety valves. Second, even if a manufacturer chooses to export patently "unsafe" products, he or she can do so today, even under the majority's interpretation of the FHSA if the goods are not distributed in domestic commerce prior to export. Third, if Congress had deterence in mind, it could have easily expressed that in any of the above Acts or legislative history. However, Congress failed to even hint at this. Therefore, we have no basis whatsoever for implying such an intent to Congress.

Above all, it seems clear to us that the issue of exports cuts across many laws and agencies and that there must be some consistency and fairness in our United States export policy.

Obviously, we do not favor, nor do we encourage laws that endanger the health and well-being of citizens around the world. However, we must conclude that the answer to the critical question posed earlier is: yes, the owner of a product, once sold or offered for sale in domestic commerce, can subsequently export without incurring penalties under the FHSA. After a careful review of all the statutes we administer, we can reach no other conclusion then that Congress intended to permit such export.

Chairman S. John Byington — Date: June 15, 1978

Commissioner Barbara H. Franklin — Date: June 15, 1978

Mr. ROSENTHAL. The subcommittee stands adjourned.

[Whereupon, at 12:20 p.m., the subcommittee adjourned, to reconvene at 10 a.m., Thursday, July 13, 1978.]

U.S. EXPORT OF BANNED PRODUCTS

THURSDAY, JULY 13, 1978

HOUSE OF REPRESENTATIVES,
COMMERCE, CONSUMER,
AND MONETARY AFFAIRS SUBCOMMITTEE,
OF THE COMMITTEE ON GOVERNMENT OPERATIONS,
Washington, D.C.

The subcommittee met, pursuant to recess, at 10 a.m., in room 2247, Rayburn House Office Building, Hon. Benjamin S. Rosenthal (chairman of the subcommittee) presiding.

Present: Representative Benjamin S. Rosenthal.

Also present: Jean S. Perwin, counsel; Eleanor M. Vanyo, assistant clerk; and Henry C. Ruempler, minority professional staff, Committee on Government Operations.

Mr. ROSENTHAL. The subcommittee will be in order.

This morning we continue the hearing on export of banned products.

The first witness is Sharon Ahmad, Director of the Office of International Trade of the Department of State.

We are very pleased to have you here.

I know that you have a prepared statement, and we are anxious to hear it.

STATEMENT OF SHARON E. AHMAD, DIRECTOR, OFFICE OF INTERNATIONAL TRADE, BUREAU OF ECONOMIC AND BUSINESS AFFAIRS, DEPARTMENT OF STATE; ACCOMPANIED BY PAUL H. BLAKEBURN, OFFICE OF EAST-WEST TRADE

Ms. AHMAD. Thank you, Mr. Chairman.

It is a pleasure to be here to meet with this subcommittee and to discuss some of the aspects of U.S. Government policy regarding the export of items which are banned for sale or otherwise restricted in domestic use.

The Department of State recognizes and supports the growing worldwide concern that neither governmental nor private actions should blindly endanger the public health and safety, or the environment.

This concern is increasingly an international one.

In an era of massive movement of goods and services within and between nations, we must recognize the possibility that some items of commerce may be found to present a danger to the public welfare.

It is the right and the duty of national governments to take appropriate measures to protect the health and safety of their populations.

We believe, however, that no country should establish itself as the arbiter of others' health or safety standards.

We believe that individual governments are generally in the best position to establish standards of public health and safety.

To make informed decisions, however, any government needs authoritative and comprehensive information about the risks and benefits attendant with the use of potentially hazardous products.

Thus, the Department of State sees a continuing program of information exchange on hazardous products as key to a U.S. national policy in this area.

Such a policy would require from the U.S. side, notification to foreign governments of U.S. domestic regulatory action.

It might also be useful to explore with other governments their views on the need for increased international cooperation in this area.

The U.S. Government has a statutory obligation to inform foreign governments of regulatory actions under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) and the Toxic Substances Control Act (TSCA).

Other notifications have also been made, but they have thus far been at the discretion of the regulatory agencies and we cooperate with them.

We think notifications of regulatory actions on hazardous substances should be mandatory, except in unusual circumstances.

Some have argued that notification by itself is not sufficient; that foreign governments should be required to approve importation of hazardous substances before export is permitted from the United States.

This procedure is in effect for certain of the drugs under the jurisdiction of the Drug Enforcement Administration.

We do not believe that imposition of such a procedure across the board would be advisable. Further, we believe that foreign governments, or some of them, would object—on the grounds that it infringed on their sovereignty—to a U.S. requirement that they approve importation of products determined to be hazardous in use in the United States.

They are also likely to object that approval might absolve the American exporter of any further liability. We think that is an extremely important point.

Foreign purchasers are quite likely to turn to non-U.S. sources of supply if they are faced with a burdensome U.S. unilateral requirement.

Export of items we have banned from domestic commerce has not heretofore caused foreign policy problems; that is, complaints to us from foreign governments.

In all probability, this is partly because some such items have uses other than those prompting our own restrictions, partly because foreign governments are satisfied that their import and domestic regulatory programs are sufficient to carry out any desired actions to protect the public health and safety in their countries, and perhaps partly because some governments can devote few resources to monitoring possible hazards.

Whatever the reasons, as I say, up until now there have been no foreign policy problems caused by this situation.

I mentioned earlier that we see the international exchange of information as key to an effective policy on export of hazardous substances.

I would like to describe existing mechanisms that might be built upon to implement this policy.

Even before the passage of the Toxic Substances Control Act, the Department of State had begun to work on procedures for notification to foreign governments of U.S. regulatory actions and receipt of information on foreign regulatory actions and experience.

We asked the United Nations Environment Program for all relevant information on foreign legislation and regulations relating to chemicals and compiled data on foreign regulatory programs for chemicals, including the names of responsible officials abroad.

We also worked with the Environmental Protection Agency in the development of section 12(b) of the Toxic Substances Control Act, which calls for foreign notification of regulatory actions under that act.

We understand that the Environmental Protection Agency has not yet taken any final action to restrict chemicals under the Toxic Substances Control Act.

The Environmental Protection Agency has, however, announced preliminary action on chlorofluorocarbons and polychlorinated biphenyls.

When final action is taken, we will work closely with the Environmental Protection Agency to notify foreign governments.

Additionally, the United States participates in an information exchange and notification program of the Chemicals Group of the Organization for Economic Cooperation and Development (OECD).

This program anticipates that any Organization for Economic Cooperation and Development member country which takes regulatory action on chemicals will notify other members.

The national contact point for the United States is the Environmental Protection Agency's Office of Toxic Substances, which is responsible for passing on information received to other concerned U.S. Government agencies.

We have participated in the United Nations Environment Program's International Register for Potentially Toxic Chemicals. Part of their programs include information exchanges on chemicals. We expect to participate fully in this endeavor when it becomes operational.

I should note at this point that we are informed that recent French Government action to ban temporarily the importation of Tris-treated children's sleepwear was based on information received through the Organization for Economic Cooperation and Development.

Mr. ROSENTHAL. Have you notified the French Government bilaterally?

Ms. AHMAD. No, sir, we have not.

Mr. ROSENTHAL. Why not?

Ms. AHMAD. We had not notified any government bilaterally, because we had not received the Consumer Product Safety Commission's request to do so.

Mr. ROSENTHAL. They hadn't requested you to do that?

Ms. AHMAD. No, sir.

Mr. ROSENTHAL. They asked you to notify just world organizations?

Ms. AHMAD. They apparently did that themselves. We did not do it directly at the time.

But we have offered ourselves, and we are available as the conduit for such notifications bilaterally or to international organizations.

We did suggest, as early as last summer, through an inquiry received from the Department of Commerce, that this be done. But we have not been requested to do so.

We do understand, however, from an inquiry we made to our Embassy in Paris, that action was taken as a result of the information reecived through the Organization for Economic Cooperation and Development.

Finally, we are contributing to the development of a comprehensive procedure for foreign notification of all domestic regulatory actions in the health and safety areas.

In January of last year, the Department of State established a Subcommittee on Toxic Substances as an integral component of the standing Committee on International Environmental Activities. This was done on the recommendation of the entire Committee on International Environmental Activities, in anticipation of the regulatory actions about to be undertaken in the implementation of the Toxic Substances Control Act.

Notification actions prior to the formation of the Committee on International Environmental Activities and its Subcommittee on Toxic Substances had taken place with regard to the activities of the Environmental Protection Agency in the implementation of the Federal Insecticide, Fungicide, and Rodenticide Act and of the Food and Drug Administration in a number of cases; for example, red dye No. 2.

Part of the activity of the New Subcommittee on Toxic Substances will be to insure timely notification, both bilaterally and multilaterally, of all domestic regulatory actions; for example, banning or restriction of use of chemicals.

The membership of the Subcommittee on Toxic Substances, and of the Committee on International Environmental Activities itself, includes the Environmental Protection Agency, the Consumer Product Safety Commission, and the Food and Drug Administration, as well as the Departments of Agriculture; Commerce; Treasury; the Interior; Health, Education, and Welfare; Transportation; and OSHA.

As you have already heard from Mrs. Peterson, an interagency working group is actively considering the options for a Federal policy in this area. The Department of State is participating in the work of this group which will complete its studies, we expect, by early fall.

We have recommended to the group that the Federal policy should concentrate on a system of notifications of U.S. regulatory action.

Our experience with public health and safety notifications—for example, in the case of leptophos—indicates that foreign governments welcome notification of U.S. regulatory action and are fully prepared to act on this information if they see a need to do so.

We believe, therefore, that additional export control measures, at least across the board, are neither necessary nor desirable.

Foreign governments can protect their own populations and environments, and existing U.S. procedures appear generally sufficient to guard against accidental or deliberate reimportation of hazardous

products into the United States, though this subject may warrant further study, perhaps even on an international basis.

Mr. Chairman, your letter of invitation to testify on this important subject posed a series of specific questions.

While my statement has already dealt in some measure with the thrust of many of these queries, I would like now to respond to each in turn.

First was the question on Department of State procedures for the notification to foreign governments of U.S. agency action.

These have been in effect for many years.

When an agency proposes to inform a foreign government of regulatory action, findings, or scientific information or to request information on foreign experience, the Department of State consults with the agency on the type of action requested and transmits the agency request to all embassies or to those specified by the agency.

Instructions to our posts may be a general request to inform the appropriate unit of the host government of the U.S. action, or a specific request to communicate with a particular ministry or individual.

We are guided by agency wishes in this matter.

Should the host government wish to comment on the action or request additional information, we again serve as the conduit for the communication.

Another question was about the existence of Department of State liaison with agencies such as the Environmental Protection Agency, the Food and Drug Administration, and the Consumer Product Safety Commission for the purpose of disseminating information to foreign governments. That was dealt with, in part, earlier in my statement.

In addition to membership on the standing Committee on International Environmental Activities, the Department of State is in frequent contact with these agencies at the working level. We are always prepared to respond to agency requests for assistance in notification.

You asked about steps taken by the Department of State to inform foreign governments of the dangers of Tris-treated garments which are currently being exported.

As the subcommittee is aware, the Consumer Product Safety Commission Commissioner, Mr. Byington, wrote last summer to Secretary of Commerce Kreps on the subject of Tris exports.

He also wrote to Ambassador Young at the U.S. mission to the United Nations. The mission was asked to inform the World Health Organization.

The mission referred the communication to the Bureau of International Organization Affairs in the Department of State, which forwarded the information to the International Agency for Research on Cancer at Lyon, France.

The agency is a World Health Organization-sponsored unit and expressed its appreciation for the information. It said it would consider taking up the subject at a future meeting of the Agency.

As the Consumer Product Safety Commission had suggested in its memorandum to Secretary Kreps that Tris and Tris-treated products be placed under export controls authorized by the Export Administration Act on foreign policy grounds, the Department of Commerce asked the Department of State for its views on this action.

We responded that we could neither endorse nor recommend the imposition of controls under the foreign policy criteria of the act.

We suggested that the Consumer Product Safety Commission, in consultation with the Department of Commerce, prepare a notification to foreign governments for transmission through the Department and our posts abroad. We have received no response to our suggestion.

Mr. Chairman, just to make sure that the record is clear, I would like to interject at this point that I understand during Monday's hearing there was some misunderstanding on this issue.

It was stated, if we heard correctly, that the Department of State had opposed the notification; and that is not correct.

I would just like to make that clear.

We understand that the information on Tris provided to the Organziation for Economic Cooperation and Development was transmitted directly by the Consumer Product Safety Commission.

Thus, Organization for Economic Cooperation and Development member governments and the World Health Organization have been informed of the U.S. action. Most governments of the world have not received notification directly from the U.S. Government.

You asked about any information the Department of State might have regarding the number of products, chemicals, drugs, or devices banned from domestic consumption which are presently being exported.

The Department of State has no statistical information of this type.

You asked about any information the Department of State might have regarding foreign government interest in receiving information concerning U.S. regulatory action affecting products imported into their countries.

There are several indications that foreign governments welcome notification of U.S. regulatory actions.

As a leading innovator, the United States may be the first to discover undesirable effects for use or misuse of products.

And the United States has more resources to devote to testing and investigation than are available in many countries.

For example, in the case of our notification on Leptophos, 35 countries asked for further information, while 6 indicated that they did not wish future notifications of this type.

We have provided this information to the subcommittee, as requested.

We think this is a convincing demonstration both of the worth of notification and of foreign government's ability and willingness to act to protect their populations.

Mr. Chairman, this concludes my prepared statement. I would now be happy to respond to your questions.

Mr. ROSENTHAL. Thank you very much.

We are going to take a 5-minute recess for a vote and then will reconvene.

[Recess taken.]

Mr. ROSENTHAL. The subcommittee will come back to order.

On Tuesday, the General Accounting Office testified that notification sent to Department of State channels often do not reach the appropriate foreign officials.

First, do you have any comment on that? Second, how can we assure that notice is actually achieved, absent a certification by these governments?

Ms. AHMAD. I have not seen the GAO report. I understand that that statement was made here—that our foreign service posts may not have carried out the instructions that were sent to them.

I cannot comment on that, because I have not seen the actual specific information nor had a chance to look into it.

Mr. ROSENTHAL. For the record, will you obtain a copy of their testimony? If you can't get it, we will send it to you, including the letter that they sent. And, for the record, please comment on it.

Ms. AHMAD. We can certainly do that, sir.

[The material follows:]

The GAO survey of notification procedures and results abroad was useful in pointing out shortcomings. We doubt, however, that one could extrapolate from the survey results to an accurate picture worldwide. We understand that the GAO questioned primarily foreign technical personnel. As the GAO pointed out in its testimony, officials may be reassigned, or have incomplete files regarding U.S. notifications. We think it likely that some notifications - though delivered to foreign governments - did not reach the officials questioned by GAO. Though some governments have designated a particular person or office to receive notifications on pesticides, for example, many have not. In such cases, we have no option but to deliver notifications to the Ministry of Foreign Affairs with the request that they be sent along to the appropriate Ministry or agency. We can see no solution to this problem.

Conversely, though agency-to-agency notification may help to ensure that specialized foreign agencies receive information on U.S. regulatory action, direct technical correspondence is not of the stature of diplomatic exchange. Thus, we think it vital that U.S. regulatory agencies provide to the Department of State material sufficient to permit official government-to-government

notification by diplomatic communication, whether or not the U.S. agency is in touch with counterparts overseas.

We agree with the General Accounting Office conclusion that U.S. notification procedures need improvement. For our part, we intend to revise the standing instructions to the Foreign Service, contained in the Foreign Affairs Manual, to clarify procedures for handling notifications.

With the cooperation of the Enviromental Protection Agency, we will develop a procedure to ensure that notifications are both readable and legible. In the future, we will request confirmation of receipt and delivery. These standards should also apply to notifications by other agencies.

Ms. AHMAD. I would be able to say at this point that we are a large organization, staffed by human beings. We send out instructions to our posts. We fully expect such instructions will be carried out.

In many cases, it is not possible for the foreign service officer and an Embassy to know precisely which officials in the government——

Mr. ROSENTHAL. Then you should send back a letter or notice saying: I don't know what to do. What should I do?

Ms. AHMAD. What I am saying is that he may not know every single official in the government who ought to receive that information but through the Ministry of Foreign Affairs, this can be disseminated.

Beyond that, it is up to the host government to make sure that everyone——

Mr. ROSENTHAL. We understand that. But if the thing stops dead in our Embassies, then we are not serving a useful purpose.

Ms. AHMAD. We were not aware that that had happened.

Mr. ROSENTHAL. Anyway, you will look into this and let us know your views on the subject.

Ms. AHMAD. Certainly.

Mr. ROSENTHAL. Somewhere in your statement you said that you didn't think it was a good idea for return receipts to be required, or some form of acknowledgment for foreign governments. Did you say something like that?

Ms. AHMAD. I am not sure.

Mr. ROSENTHAL. You said: Foreign governments should not be required to approve importation of hazardous substances before export is permitted from the United States.

Then you said: We do not believe that imposition of such a procedure across the board would be advisable.

It seems to me like a very simple task. What can we do to make more efficacious our notification and dissemination of information on important matters such as this?

Ms. AHMAD. We certainly agree with you, Mr. Chairman, that we should do everything we can to improve our notification system. We are the first to admit that it is not perfect.

In fact, in the establishment of the Subcommittee on Toxic Substances earlier this year, we recognized the fact that there is much more to do in this area. We need to be sure we know from within what needs to be notified.

I think the Department of State is fully aware that it needs to make sure that its instructions are carried out by its posts.

But with respect to requiring formal acknowledgments or approvals, and other such requirements across the board, we do have some concerns—not in the intent of the proposal but in the possible effects.

Just to make something clear, Mr. Chairman, I would like to say that I represent the Department of State here this morning.

There are several elements of the Department of State that are concerned with this matter—the Bureau of Oceans and Environmental and Scientific Affairs, which carries out on a day-to-day basis, this kind of activity, and my Bureau which is concerned——

Mr. ROSENTHAL. I don't follow that. What activity do they carry out?

Ms. AHMAD. That Bureau is the one that is in direct contact with the domestic agencies and initiates the instructions at the request of the domestic agencies.

Mr. ROSENTHAL. Why do they do that?

Ms. AHMAD. They are our liaison with the regulatory and other agencies that are concerned with this.

Mr. ROSENTHAL. Don't you just have an agency that can transmit messages to a foreign government?

Ms. AHMAD. The Department of State does. This is just a part of our organization that has primary responsibility for this.

Mr. ROSENTHAL. It sounds stupid to me.

Don't you have like a messenger service that can deliver messages?

Ms. AHMAD. To foreign governments?

Mr. ROSENTHAL. Yes.

Ms. AHMAD. We have a very vast communication system, whereby we send cables and airgrams to our Embassies abroad who, in turn, communicate to the governments. Someone within the Department of State has to make sure that these messages are written and are written correctly and have the——

Mr. ROSENTHAL. Can't you just take the message that is delivered to you by the Consumer Product Safety Commission or the Environmental Protection Agency and transmit the message without editorializing on it?

Ms. AHMAD. We do that.

Mr. ROSENTHAL. So you don't need an Einstein to rewrite the messages.

Ms. AHMAD. We do not have Einsteins in our department to rewrite the messages.

Mr. ROSENTHAL. That we know. [Laughter.]

I don't understand.

Who made the decision that the Bureau of Oceans and Environmental and Scientific Affairs would transmit these messages?

Ms. AHMAD. To answer that specifically, I would have to get back to you. But to us, it seems logical.

We have a bureau that recognizes the international interest in environmental and scientific affairs, as well as oceans.

Mr. ROSENTHAL. Do you have an under secretary or assistant secretary for management?

Ms. AHMAD. Yes; we do.

Mr. ROSENTHAL. Who is that?

Ms. AHMAD. Ben Read.

Mr. ROSENTHAL. Is he the one that assigns which bureau does these things?

Ms. AHMAD. He would be the coordinator of that kind of thing; yes.

Mr. ROSENTHAL. We are going to have to call him and find out why you do it this way rather than a more simple way.

Ms. AHMAD. What would be a more simple way? I don't understand.

Mr. ROSENTHAL. I will think out a more simple way. [Laughter.]

Was there anything else that you wanted to say?

Ms. AHMAD. The Bureau in which I work—the Bureau of Economic and Business Affairs—is quite concerned with this general area, from

the point of view of international trade policy and the effects on international trade of what we are doing.

Mr. ROSENTHAL. What do you mean by that?

Ms. AHMAD. I was responding to your point about whether or not we should require a written approval.

Mr. ROSENTHAL. Not necessarily a written approval. A return receipt requested. That's all I want.

All I want to do is to make sure that these messages are being delivered; is that a difficult assignment?

Ms. AHMAD. That can be done by our embassies simply reporting back that they informed such and such——

Mr. ROSENTHAL. What is wrong with doing that?

Ms. AHMAD. Nothing, sir.

Mr. ROSENTHAL. Could you get a little book and say that on the 15th we sent it and on the 18th they told us they got it? Could that be done by two people—or by one person?

Ms. AHMAD. It could be done, or it could be done by the officer delivering it in person and reporting back by cable that he had done so.

Mr. ROSENTHAL. And he wouldn't have to go through this Bureau of Oceans and Environmental and Scientific Affairs and stop wasting their time.

Why are export policy people concerned with this? You said it has an impact.

Ms. AHMAD. Some of the possibilities which the interagency group is considering we do have to scrutinize carefully with respect to the possible burdensome nature which might impede exports of even nonhazardous substances.

Mr. ROSENTHAL. Do you think that it is possible that, for the sake of discussion, there are some drugs that are so inherently dangerous that notification is not necessary—that exports should be banned altogether?

Do you think there is a possibility of that?

Ms. AHMAD. That could be a possibility.

Mr. ROSENTHAL. Has it ever happened yet?

Ms. AHMAD. I'm not aware that it has.

Mr. ROSENTHAL. Like Kepone or dieldrin or any of those things that do lots of damage to people.

Ms. AHMAD. Mr. Chairman, I am not an authority on toxic substances or other hazardous products.

I think it was mentioned here in previous testimony—yesterday and the day before—that you cannot generalize about all of them.

Some that are dangerous in one set of circumstances may not be in another. Some that we might find totally unacceptable here are, in fact, highly desired elsewhere for other reasons.

Mr. ROSENTHAL. Could you give an example?

Ms. AHMAD. The contraceptive that was discussed here yesterday, I believe would be an example.

Mr. ROSENTHAL. That is highly desirable overseas?

Ms. AHMAD. In certain countries, I am told that——

Mr. ROSENTHAL. Why is that?

Ms. AHMAD. Because of its effectiveness as a contraceptive where they feel the needs are so great that the possible risks involved are outweighed by the benefits.

It is a judgment for them to make. I am not saying that I would necessarily agree with it or that the Department of State would not take a position of that nature.

Mr. ROSENTHAL. Does the Department of State keep a list with every embassy of all banned products that are exported?

Ms. AHMAD. No.

Mr. ROSENTHAL. Why not?

Ms. AHMAD. I don't know that we have such a list.

As I mentioned in my testimony, we do not have any statistical information as to what banned products are, in fact, exported. That is not a function our agency would normally carry out.

Mr. ROSENTHAL. How do you know if they are banned or not?

I still don't understand what you do with relation to these hearings.

You are in the message center department?

Ms. AHMAD. No. I am in the Department of State. I am in the Bureau of Economic and Business Affairs.

Mr. ROSENTHAL. What does that have to do with what we are talking about?

Ms. AHMAD. And I am in the International Trade Policy part of the Bureau of Economic and Business Affairs.

Mr. ROSENTHAL. And they have something to do with sending the messages?

Ms. AHMAD. We have only a peripheral interest in the notification process. We are aware of it, and we do cooperate. The primary responsibility is not, however, in my Bureau.

My Bureau's interest is largely in the proposals for export controls or steps short of that.

Mr. ROSENTHAL. You were opposed to export controls.

Ms. AHMAD. Across the board, yes.

Mr. ROSENTHAL. This is not a personal thing, but I am not sure I know why you are here.

Ms. AHMAD. I am here to answer your questions, sir.

Mr. ROSENTHAL. I thought all the Department of State should do would be to transmit these messages.

Ms. AHMAD. Yes; and that we do.

Mr. ROSENTHAL. Rather ineffectively.

Ms. AHMAD. We certainly transmit the messages as effectively as our electronic system permits us. We can only transmit messages which we receive that are directed by the authoritative people who know precisely what it is—not only that such and such an item has been banned but the reasons therefor.

We do believe that foreign governments should be given the fullest possible information about circumstances leading to the action, so that they may take, on a fully informed basis, whatever actions they wish to take.

Mr. ROSENTHAL. We are going to send a letter to Secretary Vance asking Mr. Read to testify to see if we cannot develop a more effective and simple procedure for notification.

It seems to me that that is what should be done, and I guess Mr. Read would be the man to put it together; right—just to send messages?

Ms. AHMAD. We have no problem with sending messages, Mr. Chairman.

Mr. ROSENTHAL. Well, they don't get delivered.

Ms. AHMAD. That has been stated here. I cannot comment on that.

Mr. ROSENTHAL. Why does the Bureau of Oceans and Environmental and Scientific Affairs have to send the messages?

Ms. AHMAD. Does it make any difference to this subcommitttee which office of the Department of State is designated?

Mr. ROSENTHAL. I would just like to find out who is doing it, and how much it is costing, and how efficient it is, and how fast it is working, and things like that.

Ms. AHMAD. We can get back to you, if you like, on the specifics that you just mentioned.

Mr. ROSENTHAL. Thank you very much. We appreciate your testimony.

Ms. AHMAD. Thank you, Mr. Chairman.

Mr. ROSENTHAL. Our next witness is Mr. Rauer Meyer, Director of the Office of Export Administration, Department of Commerce.

Mr. Meyer, we are pleased to have you here. Please proceed.

STATEMENT OF RAUER H. MEYER, DIRECTOR, OFFICE OF EXPORT ADMINISTRATION, BUREAU OF TRADE REGULATION, U.S. DEPARTMENT OF COMMERCE; ACCOMPANIED BY DANIEL E. COOK, ASSISTANT TO THE DIRECTOR, POLICY PLANNING DIVISION

Mr. MEYER. Thank you, Mr. Chairman.

I welcome the opportunity to appear on behalf of the Department of Commerce to discuss U.S. policy regarding exports of items banned for domestic use by U.S. regulatory agencies.

The Department of Commerce recognizes the need for the U.S. export policy to reflect adequately the hazards that certain products present to human health and safety.

At the same time we believe that the policy must strike a balance between the sometime competing concerns of protecting the individual on the one hand and on the other hand of limiting the potential economic burdens that certain restrictive export policies may cause.

To insure this balance, the Department of Commerce, which is currently heading an interagency effort to develop new export expansion measures, is working closely with the Working Group on Hazardous Substances Export Policy.

Such cooperation, we hope, will insure consistency between the administration's announced policy of encouraging exports and its efforts to develop a consistent and effective policy regarding exports of hazardous substances.

The subcommittee has asked whether the Department of Commerce has authority to control exports of items banned for domestic use by other Government agencies; and if not, why not.

The Department of Commerce's authority to exercise control over exports stems from the Export Administration Act of 1969, as amended.

The act states that it is the policy of the United States to use export controls for three primary purposes: National security, foreign policy, and short supply—that is, to protect the economy from an excessive drain of scarce commodities.

To achieve these policies, the act authorizes the imposition of controls on exports.

At the same time, however, it states that neither the act nor regulations issued under the act may "be construed to require authority or permission to export, except where required to effect the policies set forth in this act."

Thus, the Department of Commerce has no authority to restrict exports of banned commodities, unless such restrictions are necessary to further the aforementioned policies.

Two of the policy objectives—national security and short supply—are clearly irrelevant to the issue of hazardous product controls and cannot justify controls over exports of hazardous substances.

The remaining policy objective, the furtherance of foreign policy, is the only potential basis in the act for restricting exports of such commodities.

This policy provision calls for use of export controls "to further significantly the foreign policy of the United States and to fulfill its international responsibilities."

In considering whether export controls are necessary in any particular circumstance for foreign policy reasons, we consult, of course, with the Department of State, as the statute generally obligates us to do.

The Department of Commerce has been asked by a regulatory agency for assistance in controlling the export of a banned item on only one occasion.

In June of 1977, the chairman of the Consumer Product Safety Commission requested Secretary Kreps to control exports of Tris and Tris-treated garments. The stated principal objective of the request was to gain information on exports, rather than to prohibit them.

In that instance, we sought the foreign policy guidance of the Department of State and were advised that controls on Tris and Tris-treated garments were not necessary to further significantly the foreign policy of the United States.

In short, under those circumstances, we lacked the statutory authority to control exports in the case of Tris-treated garments.

The extent to which banned products are actually exported is by and large difficult to establish.

I can tell you that in the first 4 months of this year, 11 million pounds of DDT were exported from the United States to 20 foreign countries, according to the Bureau of Census statistics.

But DDT is unique in that it is identified by a single schedule B classification for statistical reporting purposes. It is the only commodity in that schedule B classification, and thus it is relatively easy to determine the volume of exports.

Most banned products, however, are not as exclusively classified by Census.

A prime example of the difficulty relates to garments treated with Tris which would appear in different variations under a number of classifications.

There are numerous entries in schedule B describing various garments in detail. My understanding is that the only garments actually banned are children's sleepwear.

Schedule B has 16 entries for sleepwear. The entries describe the sleepwear being exported as men's, boys', women's, girls', and infants'; as made of cotton, wool, manmade, or other fibers; as knit or not knit.

The categories do not identify whether the sleepwear being exported is children's sleepwear treated with Tris.

The problem would be the same with most other banned products.

When the Consumer Product Safety Commission bans particular models or types of toys, appliances, or other merchandise, for example, those products are buried in a schedule B category that includes similar, but not banned, products.

When the banned item is a component in a finished product that is not itself banned, the problem is compounded.

To identify banned products in export statistics would, therefore, require extensive changes in the basic reporting reference, as well as increased statistical reporting time and costs.

Even if it were feasible to devise a way to place banned products in distinct reporting categories, the reliability of the export information would be questionable.

Most banned products cannot be distinguished easily from similar products that are not banned. Exporters on whom we would be solely dependent for assignment of the proper schedule B number would, in many instances, find it very difficult to make accurate judgments.

This concludes my statement, Mr. Chairman.

I would be pleased to answer your questions.

Mr. ROSENTHAL. Mr. Meyer, should the Export Administration Act be amended to include export controls on banned products?

Mr. MEYER. That, it seems to me, is a judgment that the administration would have to make on the basis of what the working group on hazardous substances export policy would——

Mr. ROSENTHAL. Does the working group have that matter under consideration?

Mr. MEYER. That general topic is one of the matters they are looking at.

Mr. ROSENTHAL. Does the Department of Commerce have a position that they are espousing within the working group?

Mr. MEYER. At this particular point in time, I don't think the working group has come to any focus on this subject.

My opening remarks, I think, emphasized the need to strike a balance between protecting the individual on the one hand and limiting the potential economic burdens on the other.

Where consideration by this working group would come out, in terms of striking that balance, I cannot say at this time.

Mr. ROSENTHAL. We assume that if there was statutory authority or mandate to restrict exports of banned products, it would be used with a great degree of caution and prudence.

Anybody who had the authority to do that would take into account all the economic and safety considerations.

Mr. MEYER. I would think that one of the basic questions that the working group would address would be the question of whether notification of foreign governments is adequate and appropriate or whether it is inadequate and statutory controls should be imposed.

Mr. ROSENTHAL. Aside from Tris, how many times have you asked the Department of State for foreign policy comments?

Mr. MEYER. We do that fairly often but not in this area.
Mr. ROSENTHAL. In other types of areas?
Mr. MEYER. Oh, yes.
Mr. ROSENTHAL. Like national security areas?
Mr. MEYER. No. On foreign policy concerns.
Mr. ROSENTHAL. Are you a member of the working group yourself?
Mr. MEYER. I am not; Commerce is represented.
Mr. ROSENTHAL. Who is the Department of Commerce representative?
Mr. MEYER. I am not sure. We would have to supply that to you.
Mr. ROSENTHAL. Would you please?
[The material referred to follows:]

Lawrence Lasoff, Special Assistant to the Assistant Secretary for Industry and Trade Administration.

Mr. ROSENTHAL. Thank you very much.
The subcommittee stands adjourned.
[Whereupon, at 10:50 a.m., the subcommittee adjourned, to reconvene subject to the call of the Chair.]

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