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MEMORANDUM

THE WHITE HOUSE

WASHINGTON

Section III

LACK of flexibility to deal with certain unproven
CASES.

* Consultation Prior to publishing list of restricted use

* Define "use" in LAW - Sale, Poss. etc. (Sec 12th 2(g))

Records on Misuse

* Broad Policy Issues of Pesticide Regulation
Cost-Benefit question

Misuse Use

National Consideration to Ag (work)

Environmental Impact Statement

Problem with Major Use



100 10 175

EPA POSITION PAPER ON THE
CERTIFICATION OF PRIVATE APPLICATORS
AS MANDATED BY THE
FEDERAL INSECTICIDE, FUNGICIDE AND RODENTICIDE ACT, AS AMENDED

The Act directs the Administrator of EPA to prescribe certification standards. States may administer the certification program by submitting an approvable State plan to EPA. Standards for certification and regulations on State plans have been finalized.

It is an EPA policy not to develop a Federal certification program. Full reliance is therefore being placed on the States to move forward with responsible and approvable certification programs.

There are a wide range of procedures States can use to certify private applicators. Those procedures we believe acceptable are discussed. A brief discussion on concepts EPA followed in developing this material may be helpful.

- ° Section 4 and the regulations issued thereunder are designed to ensure that restricted use pesticides are used safely and properly and can continue to be available to meet the needs of agricultural production. It was not intended to create a burdensome regulatory framework which works to the detriment of the farmer.
- ° The private applicator is a pragmatic person who will respond positively to well designed, reasonable, and useful programs, but will be offended by approaches designed only to meet administrative requirements.
- ° The historical relationship between the farmer and his Cooperative Extension Service County Agent can be significantly enhanced by training programs which include the safe and proper use of pesticides and which can ensure that farmers meet competency standards. We should, therefore, specifically encourage those ongoing programs that take full advantage of this established relationship.
- ° Certification is a State program. To assist, EPA has attempted to outline an acceptable range of options. Ultimately, however, each State concept for certification will be evaluated along with the other component parts of the State plan. If there are questions as to the acceptability of a State's certification concept, that State should immediately seek an opinion from the appropriate EPA Regional Office.



MAR 27 1975

CERTIFYING PRIVATE APPLICATORS

A State may choose to employ various options to make restricted use pesticides available for use by private applicators. In the Agency's judgment there are three basic variables in the development of an applicator certification program:

- (1) Type of Certification based on the breadth or scope of the authorization which the certification program will confer;
i.e., general certification (covers any restricted pesticides which a private applicator would normally expect to use in the production of his crops), pesticide class certification (covers any restricted pesticides in a specified category of pesticides), crop specific/commodity/site certification (covers any restricted pesticides which are used in the production of a crop or site), single product certification (covers one or more uses of a single product or related product with the same active ingredients and proportions), and single purchase/single use certification (interim or emergency);
- (2) The mechanisms or procedures which will be utilized to determine



competency, e.g., written examinations, oral examinations, written questionnaires, fact finding interviews, self study, and, training.

- (3) The person or persons who will determine competency, e.g.,
employees or officials of the State Lead Agency or cooperating agencies, legally regulated pesticide dealers, or any other legally authorized person.

Acceptable options for each of these variables are discussed below:

Discussion of Types of Certification

The standards of competency for the certification of private applicators as outlined in Sections 171.5 and 171.6 have been written in general terms and are designed to cover a wide range of hazards and problems associated with the use of restricted use pesticides. Hence, they offer States a great deal of flexibility in designing certification programs that fit their needs. A State may decide to implement complete training and/or testing programs and full certification programs prior to October 21, 1976 when certification becomes effective. (Training and written testing are of course, not mandatory-- it is the determination of competency and the certification process that is mandated by the Act and required by EPA Standards). Although full certification is most desirable and probably less expensive in the long



run, it may be necessary for some States to employ "interim" measures to assure the availability of restricted use products to their private applicators for a period after certification goes into effect. There are five types of certification a State may wish to utilize. All comply with the requirements of the standards for private applicator certification [40 CFR 171.5-171.6] , but differ in breadth or scope. The first three types (particularly the general certification) would require the private applicator to apply general principles to specific problems associated with particular products and situations.

There are a wide range of concerns associated with the use of pesticides in general, varying from acute dermal and inhalation hazard (which, under the law, requires classification for use only by or under the supervision of certified applicators) to a wide variety of other hazards both to man and non-target organisms. These include acute and chronic oral toxicity and chronic inhalation and dermal toxicity to man, and effects on domestic and farm animals, pollinating insects, pest parasites and predators, fish, and wildlife.

In recognition of these factors, the first three types of certification require a detailed assessment of applicator competency in terms of practical knowledge regarding the general use and handling of pesticides as outlined in Section 171.5(a)(1)-(5), and 171.6.



The fourth type, single product certification, would be based on specific problems associated with one or more uses of a particular product. Most of the problems associated with a specific product use are identified on the label, and, as a matter of course, appropriate precautionary statements are also included. Thus, single product certification does not require the applicator to be familiar with the general principles governing the safe use of restricted use pesticides, but only with these principles as they relate to a particular product. Because it is narrower in scope, single product certification could result in a high level of competency in handling a particular product.

The Agency regards the fifth type, single purchase/single use, as only a marginally effective way of determining the competence of applicators to use or supervise the use of restricted use pesticides. Accordingly, the fifth type will be acceptable only on an interim basis, i.e. until October 21, 1978. Thereafter it may be used as a mechanism to respond to emergency situations.



A further discussion of each of the five types of certification follows:

(a) General Certification

This system certifies the private applicator to apply any restricted use pesticide which he would normally expect to use in his particular agricultural operations. The knowledge requirements should cover all aspects of the private applicator standards and should be broad enough to test the private applicator's ability to apply general principles to specific problems associated with the restricted use pesticides required for the production and protection of his crops.

(b) Pesticide Class Certification

This system certifies the private applicator to apply any restricted use pesticide in the same class or family. This would include all different pesticide products and all different formulations of a pesticide used for the same purpose, use, or application. Examples include, but are not limited to: preemergence herbicides for vegetable crops, foliar insecticides on corn, rodenticides in fruit orchards, nematicides in fields prior to planting, ground application of fungicides on vegetables, seed treatments for plant diseases, desiccants and defoliants on cotton, and livestock dips for insect control.



Competency determination should reflect the full range of the private applicator standards, but emphasis should be placed on the particular characteristics of the pesticide and on the nature of the application or use.

A private applicator may wish to be certified for only one or two classes under this system. Any applicant who is certified for several classes may find it desirable to apply for general certification.

(c) General Crop/Livestock/Site Certification

This system certifies the private applicator to apply any pesticide as one provided a need for specific application is demonstrated. The applicator would be expected to deal with his agricultural operations. This would include any pesticide products (different pesticide classes, active ingredients, and formulations) used on a specific line or class, designation. Examples include: single crop, such as cotton, corn, apples, or wheat; single site class, such as poultry houses or dairy barns; single livestock line, such as beef cattle, swine, or turkeys; crop classes, such as forage crops or small fruits; site class, such as be or greenhouses; and livestock class, such as poultry.

Competency determination should reflect the full range of the private applicator standards, with emphasis placed on the particular



characteristics of the specific crop or site, or crop/site class concerned and the pests involved.

A private applicator may wish to be certified for a specific crop or site (such as cotton, corn, or beef cattle) or for a crop or site class (such as forage crops, livestock, or small grain crops). Any applicator who desires certification for several commodities, or crops, or sites may find it to his advantage to apply for general certification.

(d) Single Product Certification

This system certifies the private applicator for one or more uses of a single product or related products with the same active ingredient and with a similar formulation and uses. Such a private applicator would be fully certified for all uses indicated on his certification form. These uses will correspond to all appropriate uses for the agricultural area where he will be expected to make pesticide applications.

Certification under this system may be the only type of certification some private applicators will ever need. They can, however, move from this type of certification to certification by class of pesticides, crop/commodity/site, or general certification by demonstrating their competency to use a wider range of restricted use pesticides properly and safely.



(e) Single Purchase/Single Use Certification (Interim/Emergency Program)

This system would authorize the private applicator to make a single purchase for a single use of a restricted use product (or other products of the same formulation) on a one time basis. It represents minimal compliance with the standards (40 CFR 171.5 and 171.6).

It should be emphasized that the single purchase type of certification is acceptable only as an interim or emergency measure. States desiring to initiate the provision as an interim measure should submit in their State plan the procedures they will follow, as well as specific plans for upgrading to full certification on a specific time schedule. In no case should this type be utilized to certify private applicators beyond October 21, 1978. Thereafter it may be used as an emergency provision to accommodate situations such as an unexpected pest problem that requires immediate certification of a previously uncertified private applicator or one whose particular type of certification would not cover the product needed to deal with the outbreak.

Discussion of Mechanisms for Determining Competency

Various mechanisms may be utilized to determine competency of private applicators. It will be the State's option to determine which mechanism or combination of mechanisms best meet the State's and private applicator's needs. The standards for certification of private applicators [171.5(b)] specify that a certification system employ "a written



or oral testing procedure, or such other equivalent system as may be approved as part of a State plan." Some acceptable methods of determining competency of private applicators, including "equivalent systems," are discussed below. The first six methods are appropriate, depending upon design and scope, for general, pesticide class, commodity/crop/site, single product, and single purchase/single use certification.

(a) Written examination (open book or closed book), administered by a public employee designated by the State lead agency.

(b) Oral examinations, administered by a public employee designated by the State lead agency who is knowledgeable in the use of pesticides. The oral examination must be equivalent in scope to a written examination, and a written record is required.

(c) Written questionnaire. This mechanism would be a no-pass/no-fail questionnaire administered by a lead agency designated public employee knowledgeable in pesticides who would discuss individually with the applicator the correct answer(s) to any question(s) incorrectly answered. (The State may use a licensed and regulated dealer who is knowledgeable in the use of pesticides to administer the questionnaire for single purchase/single use certification on an interim/emergency basis). The questionnaire would be submitted to the lead agency, along with a statement by the public employee that he has discussed the incorrectly answered question(s) with the applicator and that he is satisfied that the applicator understands the correct answer(s).



(d) Demonstration (simulated or actual). Combined with one or more of the other mechanisms, this could be a most effective means of demonstrating competency, especially in such areas as calibration of equipment, application technique(s), mixing, etc. Written explanation of how the demonstration was conducted should be provided by the public employee designated by the State lead agency.

(e) Completion of Approved Training. This could be a most effective method of ensuring competency of applicators. It would be necessary, however, for those conducting the training to design measures to assure themselves that those being trained are receiving the information being imparted, e. g., by trainee response to specific questions. In addition, there should be a signed statement by the trainer attesting to the trainee's successful completion of the training.

(f) Self Study. This could consist of the completion of a correspondence course; the study of a manual at home followed by the completion of a written exam, either to be sent to the lead agency or to be completed in the presence of a representative of the State lead agency; utilization of audio-tutorial teaching media, such as video-cassettes, slide/tape presentation(s), followed by an appropriation mechanism to determine competency; and programmed instruction. The latter, programmed instruction, may be especially applicable in some States because (1) it has demonstrated effectiveness in imparting information and knowledge, (2) it does not require the presence of an instructor, (3) it can be used alone or combined with an



examination, and (4) it provides States flexibility in that there are various ways it can be used. Below are three acceptable variations of programmed instruction:

- o Completion at home with a subsequent examination administered by a public employee designated by the State lead agency.
- o Completion in the presence of public employee designated by the State lead agency.
- o Completion at home and returned to a public employee designated by the State lead agency with adequate assurance by the private applicator that he has fully complied with instructions in the course.

The public employee designated by the State lead agency will review the materials submitted and determine the competency of the applicator.

The preceding list is not exhaustive. If a State chooses to use another variation of programmed instruction, EPA will evaluate the acceptability of such a program on an expedited basis.

At the request of several State officials, the Agency is developing programmed instruction materials. These materials will be evaluated using control groups to determine the effectiveness of various programmed instruction approaches. EPA will provide States with the results of these studies as they become available with the hope that they will be helpful to States in determining which programmed instruction technique, if any, would be most suitable. A further discussion of programmed instruction is contained in the appendix.



(g) Fact Finding Interview. This is acceptable only as a mechanism for implementing the interim or emergency program for single purchase/single use authorization. The interviewer must be a public employee knowledgeable in pesticides designated by the lead agency, and must provide written evidence to support the determination of competency.

In most of the above mechanisms for determining the competency of the private applicator, there should be a written record to support that determination. This should include (1) the type of mechanism used, (2) how the determination was made, and (3) a statement by the person determining competency that he is satisfied that the applicator has demonstrated his competency.

Discussion of Who May Determine Competency

A number of options are open for the designation of the individual who determines the competency of the applicator. It will be the State's option to determine which person or persons may serve as the lead agency representative to determine the competency of the private applicator. These options discussed briefly are listed below:

(a) State Lead Agency-Employee. This would be an employee, such as field inspector, of the lead agency.



(b) Cooperating Agency Employee. This would be an employee of a cooperating agency familiar with the certification program and its intended goals.

(c) Dealer. This would be the actual seller of the pesticide product. Because of a potential conflict of interest, if dealers are to participate in the certification process, certain controls are needed. First, dealer administered systems must be limited in scope to the single purchase/single use certification using only the written questionnaire or programmed instruction mechanism. Second, all dealer administered systems must include the following elements: (1) a dealer licensing system, (2) enforcement procedures to ensure that the dealer performs his duties satisfactorily, and (3) provisions for penalties (to include revocation of the dealer's license to sell restricted use pesticides) in the event the dealer fails to carry out his responsibilities. Finally, any dealer administered system in which the dealer must exercise discretion to determine an applicant's competence must include a system of training or other method of determining that the dealer is knowledgeable in the pesticides area.



CERTIFICATION OF PRIVATE APPLICATORS

MECHANISMS FOR DETERMINING COMPETENCY

PERSON DETERMINING COMPETENCY: Licensed Dealer

MECHANISM TYPE OF CERTIFICATION	WRITTEN (Open or Closed Book)	ORAL EXAM	WRITTEN QUESTIONNAIRE	DEMONSTRATION (Actual or Simulated)	TRAINING COURSE (Completion of Approved Training)	SELF-STUDY (Programmed instruction only)	FACT-FINDING INTERVIEW
GENERAL CERTIFICATION	NO	NO	NO	NO	NO	NO	NO
PESTICIDE CLASS CERTIFICATION	NO	NO	NO	NO	NO	NO	NO
CROP/COMMODITY CERTIFICATION	NO	NO	NO	NO	NO	NO	NO
SINGLE PRODUCT	NO	NO	NO	NO	NO	NO	NO
SINGLE PURCHASE/ SINGLE USE	NO	NO	YES interim (un- til Oct. 1978) emergency thereafter	NO	NO	YES interim (until Oct. 1978); emergency thereafter	NO



CERTIFICATION OF PRIVATE APPLICATORS

MECHANISMS FOR DETERMING COMPETENCY

PERSON DETERMINING COMPETENCY: Public Employee Designated by The State Lead Agency

MECHANISM TYPE OF CERTIFICATION	WRITTEN (Open or Closed Book)	ORAL EXAM (1)	WRITTEN QUESTIONNAIRE	DEMONSTRATION (Actual or Simulated) (1) (2)	TRAINING COURSE (Completion of Approved Training) (1)	SELF-STUDY	FACT-FINDING INTERVIEW (1)
GENERAL CERTIFICATION	YES	YES	YES	YES	YES	YES	NO
PESTICIDE CLASS CERTIFICATION	YES	YES	YES	YES	YES	YES	NO
CROP/COMMODITY CERTIFICATION	YES	YES	YES	YES	YES	YES	
SINGLE PRODUCT	YES	YES	YES	YES	YES	YES	NO
SINGLE PURCHASE / SINGLE USE	YES (3)	YES (3)	YES (3)	YES (3)	YES (3)	YES (3)	YES (3)

(1) Written documentation required.

(2) Should be combined with one or more other mechanisms.

(3) Interim (until Oct. 1978); emergency thereafter.



MAR 26 1975

DRAFT EPA REGULATIONS ON
THE REGISTRATION, REREGISTRATION,
AND CLASSIFICATION OF PESTICIDES
UNDER FIFRA, SECTION 3

The household pesticide industry, including the manufacturers and distributors of disinfectants, germicides, sanitizers and insecticides for household, lawn and garden use, are most severely and adversely impacted by the criteria for classification and the data requirements for registration as general use pesticide for domestic applications. Read literally the classification criteria could exclude from the household market 30 to 40% of currently registered disinfectants. The data requirements, particularly the chronic and teratogenic studies, are too costly for the small formulators (almost 50% of CSMA's membership) to withstand.

TESTING REQUIREMENTS

As drafted the regulation will require household pesticides to undergo the following tests: (1) general wildlife testing where a household pesticide may be used for "outdoor application"; (2) chronic feeding studies on two different species of animals for all pesticides used in residences; and (3) teratogenic testing for all pesticides, the use of which may result in significant exposure to female humans. For the ordinary household lawn and garden pesticide the foregoing testing requirements do not appear justified by an environmental or human risk, and each imposes prohibitive costs upon the household pesticide formulator.



(1) Acute and Subacute Toxicity to Wildlife

Outdoor application is defined to include "use that occurs outside enclosed manmade structures" (p. 14) and as such would include many pesticides which otherwise or additionally would fall within the domestic application (p. 11). EPA has indicated that where a household pesticide, such as a lawn and garden insecticide was also intended to be used "outside" the house, that pesticide would fall into both the "domestic" and "outdoor" categories. Thus the applicable registration criteria for such household pesticide would be the outdoor as well as the domestic criteria and the outdoor criteria includes wildlife testing (p. 66-67). Furthermore, a rebuttable presumption against registration will arise with respect to such household pesticide where the acute, oral or subacute dietary LDSO are of a certain level in mamalian and avian feed studies (p. 106) - even though exposure to wildlife from such household pesticides is virtually non-existent.

A lawn and garden insecticide receives infrequent use, resulting in minimal exposure to wildlife, both because the volume of use is low and the area of exposure is usually quite small. Unless the wildlife data is supplied, however, the product will be classified for restricted use and, thereby, effectively eliminated from the household market. These wildlife studies, based upon reliable estimates, will cost from \$5,000 to \$15,000 which must be borne even though the risk of wildlife injury is remote, if not non-existent. This result is unjustified on its face.



The ready solution to this problem is to clarify the definition of "outdoor" applications so as to exclude those products which fall within the broad definition of "domestic."

2. Chronic Feeding Studies.

The regulations establish a rebuttable presumption against registration or in favor of cancellation where a pesticide (including its ingredients, metabolites and degradation products) induces tumors in experimental animals (p. 107). Furthermore, in order to obtain registration a pesticide intended for use in residences, in closed working spaces, or their vicinity, must undergo chronic testing (p. 69). Chronic testing is a multi-generation study on two species of test animals.

Historically, EPA has required chronic feeding studies of only active ingredients, most of which (at least those commonly used) have undergone chronic testing by the basic manufacturer. For CSMA members the prime impact of the regulation is that the formulated product, or pesticide, must now undergo the same chronic test that was previously limited to the active ingredient only. The well-documented cost of chronic testing is \$100,000 plus. The formulator must now bear this cost on each separate formulation or be cancelled.

The chronic testing of the formulated product seems unreasonable for any of a number of reasons:



a. Under present practice active ingredients of pesticides are all tested (and properly so) for chronic effect. Additionally, inert ingredients, at least those exempted from tolerances in agricultural pesticides (40 C.F.R. § 180.1001) are generally regarded by EPA as imposing no significant chronic hazard. Where both inerts and active ingredients are considered to pose no unreasonable chronic toxicity risk, the requirement to test the formulated product appears to have no scientific justification.

Implicit in this requirement is the undocumented assumption that the mixture of well-tested inerts and actives will have some synergistic effect on the formulation and pose a chronic hazard. The across-the-board requirement of chronic testing of the formulated product based upon this assumption appears unreasonable. Some specific finding with regard to a particular formulation should precede the determination to require testing.

b. The level of human exposure (either dermal, inhalation or ingestion) to household pesticides is generally extremely low. For example, it is highly unlikely that a toilet bowl cleaner, a spray disinfectant, or a lawn and garden insecticide results in any significant inhalation or dermal exposure in man and little, if any, ingestion exposure as the result of residues in food. Only where biologically significant exposure can be shown to result from use of a particular household pesticide should a chronic study be required. Even then, for reasons described above, the chronic testing should be required of only the active ingredient.



c. Any chronic feeding study should be limited routinely to a study of the primary active ingredient, as distinct not only from the inert but also the active ingredient which is quantitatively small and relatively innocuous. For example, many solvents and perfumes are now listed as active ingredients because of the policies within the registration division and not the regulations. Chronic toxicity testing of these ingredients is unwarranted by any known risks.

d. If each company were required to subject each household lawn and garden pesticide to chronic testing, the cost would amount to a \$100,000 per pesticide in order to register the product. Approximately 50% of CSMA's members have sales of \$10 million or less (and 25% of this number has sales of \$1 million or less.) A typical company selling 50 household pesticide products with a gross annual sales of \$2 million would be forced to endure a cost of \$5 million in chronic testing in order to keep those 50 pesticides registered and on the market. In other words, it would cost 250% of this company's gross sales in order to keep its product line. The result is disastrous on its face.

e. The rebuttable presumption operates to render presumptively unregistrable or cancelable any pesticide which induces tumors in experimental animals. Not even the Delaney clause of the Food Drug and Cosmetic Act (21 U.S.C. § 348(c)(3)) goes this far since the Delaney clause makes such a finding mandatory only where "cancer" is induced in the feeding animal and the tests



are "appropriate for the evaluation." The rebuttable presumption in the regulations for pesticides is operative even though the test protocols called for highly exaggerated feeding levels, the test animals are not sufficiently comparable to man so as to permit extrapolation of the results, and induced tumors were diagnosed as non-cancerous. The presumption is unreasonable.

(3) Teratogenic Studies

The draft regulations require teratogenic studies of all pesticides which may result in significant exposure to female humans (p. 68). A reasonable construction of this language is to include therein all household pesticides, that is, one might reasonably contend that all household pesticides result in significant exposure to female humans. Accordingly, all household pesticides may be required to undergo teratogenic evaluation at what is estimated to cost \$25,000 per test. If every CSMA manufacturer must submit each active ingredient in each household pesticide to a teratogenic evaluation, the cost could approach the gravity of those for chronic testing.

Almost no teratogenic testing of active ingredients (much less the formulated product) has been undertaken by the manufacturers of basic chemicals. Many active ingredients in household pesticides are low-volume items, moreover, which are not sufficiently profitable that the basic manufacturer would find it advantageous to test; the company might rather stop selling altogether than pay for teratogenic testing. The small household lawn and garden manufacturer and distributor will face the loss of these active ingredients or bear the cost of teratogenic testing themselves. The latter



alternative is not financially feasible for the small manufacturer for the same reasons applicable to chronic testing. Since the consequence to the small manufacturer/distributor is being eased out of business, the result will be a concentration in the larger companies more able to endure the cost impact of this testing. Another obvious consequence will be the loss of new and tried household pesticides relied upon by the household.

CSMA again proposes that the teratogenic testing requirement be limited to those situations in which the chemical results in biologically significant exposure to women and where there is some preliminary finding by the administrator that an apparent teratogenic risk exists. The testing requirement should not be imposed across-the-board on all household pesticides.

THE CLASSIFICATION SCHEME

The criteria for determining whether a pesticide will be permitted for general use includes (1) corneal opacity or irritation and (2) skin irritation (p. 112) (¶162.11(d)(1)(i)(D)(E)). Generally neither criterion is appropriate for household disinfectants and surfactants. By CSMC's calculations, 30 to 40% of the currently registered household disinfectants would not qualify for general use domestic application because of their toxicity in these two areas. These pesticides are generally sold in concentrated (as distinct from the use-dilution) form. In concentrated form they can cause corneal and skin irritation - yet they have been safely used



and registered for use in the household. There is no apparent reason for the abrupt removal of these products from the household. Yet unless such disinfectants may be registered for general use (as distinct from restricted use), they are effectively removed from the household market; restricted pesticides cannot be used by the householder. Unless the criteria, therefore, are relaxed for certain types and certain uses of household pesticides, the result will be a 30 to 40% loss of household disinfectants.

The draft regulations do attempt to provide relief where label or labelling may be adequate to reduce such risks to reasonable proportions (p. 117). The provision for adequate warning labels and labelling is no practical relief, however; the possibility of any minor deviation from the label directions causing harm per se makes the labelling inadequate. In other words, the disinfectant which fails to qualify for general use because of its eye or skin irritancy and for which labelling will not prevent injury from a minor deviation, such as splashing the disinfectant in the concentrated form, cannot be registered for general use in domestic application. That is, it can no longer be used in the home.

The solution is to eliminate the "minor deviation" provision and recognize that so long as label directions provide adequate notice so as to reduce, if not prevent the risk of skin or eye irritation, the product should be registered for general use. See Section 126.11(d)(3)(11) (p. 117).





CSMA

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Medical Department

MEDICINE • HEALTH PHYSICS • INDUSTRIAL HYGIENE • TOXICOLOGY

November 14, 1974

VIA AIR MAIL

Mr. Stephen S. Kellner
Director, Legislative and
Regulatory Affairs
CSMA
1001 Connecticut Ave., N.W.
Washington, DC 20036

Dear Steve:

Attached are cost figures just received from Industrial Biotest Laboratories. I hope they will be of some help. Also attached is a reprint of an article from Dr. Johnson of Dow Chemical. Fig. 18 shows some cost figures for toxicology up to 1970 with projected figures for the future. These are now coming true. I am also enclosing another article giving other figures.

If there are any questions, please let me know.

Cordially yours,

H. A. Birnbaum
Product Toxicologist
Medical Department
Toxicology Services

HAB:kc

cc: Mr. A. T. Talcott
Dow Chemical Co.
2030 Dow Center
Midland, MI 48640



The following figures are from Industrial Biotest Laboratories of Northbrook, Illinois. They cover studies as possible per Section 3 of FEPCA and all figures are approximate cost.

ACUTE

Oral LD ₅₀ (rodent & non-rodent)	\$2,500
Dermal LD ₅₀	\$500
Skin and eye irritation	\$350

SUBACUTE

90 day rat	\$9,000
90 day dog	\$13,000
Dermal	\$8,000 - \$9,000

TERATOGENIC

Rat	\$5,000
Rabbit	\$7,000
3-generation reproduction	\$25,000

MUTAGENIC

Dominant lethal	\$5,000
Host mediated	\$7,500
Cytogenetic	\$10,000 - \$15,000

CHRONIC TOXICITY (2 YR)

Rat	\$50,000
Dog	\$50,000

CARCINOGENIC

Mouse	\$35,000 - \$40,000
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Test	Mean Cost (M\$)*
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Minimum requirements

Acute	18.4
Subacute	100.5
Metabolism, rat and dog	29.8
Reproduction, rat	35.4
Teratology, rat	10.4
Chronic feeding, rat and dog	155.3
Total --	349.8+

Additional tests

Subacute	13.2
Teratology, second species	10.0
Human metabolism	21.1
Mutagenesis	17.2
Human toxicology	50.0
Chronic feeding, metabolite	155.3
Total --	275.8

*Thousands of dollars

+Minimum time required for completion, 48 months

SUMMARY OF COST/TIME ESTIMATES FOR TOXICITY TESTING



THE WHITE HOUSE
WASHINGTON

Date: April 7, 1975

MEMO TO: NORM ROSS

FROM: JOHN VICKERMAN

J

For your information _____

Please handle _____

Per your request _____

Per our conversation.

Many thanks.



4-8

American Farm Bureau Federation



WASHINGTON OFFICE
425 13TH STREET, N.W.
WASHINGTON, D. C. 20000
AREA CODE 202 - 638-631
CABLE ADDRESS: AMFARMBU

March 25, 1975

Mr. John Vickerman
The White House
Washington, DC 20500

*They want to meet
with Mr. Vickerman*

Dear Mr. Vickerman:

The American Farm Bureau Federation supported passage of the amended FIFRA (October, 1972) and has monitored its implementation because of our recognition of the merit of a reasonable and effective pesticide program designed to prevent misuse. We have worked formally and informally with EPA, expressing the views of farmers. Other organizations and individuals have voiced similar opinions. Our concern is that the implementation of the Act is not attempting to prevent misuse as a primary goal but rather to authorize comprehensive regulation of use. This over-regulation is not within the intent of the law, is not justified by accident statistics, and is not likely to be productive. EPA actions in the past few months have increased our concern.

EPA published the final regulations for certification of applicators of restricted use pesticides on October 9, 1974, one year after the legally mandated date. Those regulations, authorized by Sec. 4(a) of the Act, required that private applicator competency be determined by "written or oral testing procedure, or such other equivalent system as may be approved as a part of a state plan." (40 CFR 171.15) Such regulations disregard the intent of the Senate report which accompanied the amended FIFRA. This report said that in some cases only the signing of a poison or pesticide register would be required, while in other cases the purchaser or user might be required to certify that he has read the instructions and will apply it in accordance with such instructions. In other cases, general or seasonal licenses, permits, or similar forms of approval might be required.

EPA proposed regulations for registration, reregistration, and classification on October 16, 1974, allowing a 30-day comment on a technical and complicated proposal. Numerous requests for an extended comment period were denied. The agency cited the urgency of time as the basis for not granting the extension. The final regulations have not been published yet. As a part of that proposal, EPA proposed to limit the sale of restricted use products to certified applicators or their representatives. The Act requires no such intervention in commerce. Many commercial applicators never purchase pesticides but rely upon the farmer to buy and deliver the product to the applicator at the time of use. Under the EPA scheme the farmer would need to be certified to continue this common business practice, even though he does not use the product himself. Further, it is a common practice in agriculture to purchase in advance of the use season to secure "early order" discounts and insure supply.



The same EPA proposal contained the proposed classification scheme. It is a widely held industry view that many products will be required, because of the nature of the proposal, to be classified for restricted use. EPA denies this and insists that no more than 10 percent of all pesticide uses will be restricted. The latest list I have seen is 34 percent restricted (tentative). The Senate report said: "...few pesticides which are now registered would be classified for restricted use." The more products EPA restricts, the greater the number of applicators that will need to be certified. EPA's latest estimate indicates that over 2 1/2 million private applicators will need certification.

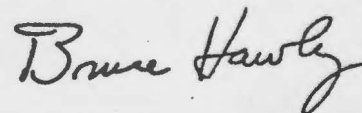
Private applicators may be certified by the states. This must be done by the states in accordance with the EPA regulations for certification (October 9, 1974). The mechanism used by the states will be in accordance with EPA regulations for state plans. (March 12, 1975) At this time EPA has not given a clear definition of what constitutes an acceptable minimum state program for the certification of private applicators. The regulations are vague and subject to many interpretations. AFBF has called on EPA, in a letter to Mr. Train, to permit the signing of a register at the time of purchase as an acceptable minimum upon which states may build. We have not received a formal response to our request.

Because of the number of products likely to be restricted, the large number of farmers therefore needing certification, and the small number of agriculturally related instances of misuse, we feel it is imperative that EPA publicly embrace an acceptable minimum program. Such action would (1) permit the states to structure their own programs, as many states have done years ago; (2) create minimum interference with agriculture, as we continue to produce adequate quantities of healthful food and fiber; and (3) impose a minimum financial burden on the states, which must fund the certification programs.

I believe that many of the views expressed above are shared by other members of the Pesticide Users Conference of which I am serving as chairman. A list of members of the PUC is enclosed.

It would be helpful to us and to the Conference to meet with you at your convenience, to permit the members of the group to share their concerns with you. I hope that such a meeting can be arranged promptly.

Sincerely,



Bruce Hawley
Assistant to the Director
Government Relations

Enclosure



January 1975

PESTICIDES USERS CONFERENCE

Washington, D. C.

AMERICAN AGRIBUSINESS ASSOCIATION, INC.
Suite 928, International Club Bldg.
1800 K Street, N.W.
Washington, D. C. 20006
872-8666
Mr. Frank Frazier

AMERICAN ASSOCIATION OF NURSERYMEN
230 Southern Building
Washington, D. C. 20005
737-4060
Mr. Ray Brush
Mr. Leo Donahue

AMERICAN FARM BUREAU FEDERATION
425-13th Street, N.W.
Washington, D. C. 20004
638-6315
Mr. Bruce Hawley
Mr. John C. Datt

AMERICAN FROZEN FOOD INSTITUTE
919-18th Street, N.W.
Washington, D. C. 20006
296-4080
Mr. Michael F. Brown

AMERICAN NATIONAL CATTLEMEN'S ASSN.
Suite 1015
National Press Building
Washington, D. C. 20004
347-0228
Mr. Bill McMillan

AMERICAN PULPWOOD ASSOCIATION
1619 Massachusetts Avenue, N.W.
Washington, D. C. 20036
265-0670
Mr. J. Edwin Moore, Forester

AMERICAN SEED TRADE ASSOCIATION
1030-15th Street, N.W.
Washington, D. C. 20005
223-4080
Mr. Robert J. Falasca
Mr. Harold Loden, Exec. V.P.

AMERICAN SOYBEAN ASSOCIATION
6434 Lakeview Drive
Falls Church, Va. 22041
941-1466
William Kling, Wash. Rep.

AMERICAN VETERINARY MEDICAL ASSN.
1522 K Street, N.W.
Washington, D. C. 20005
659-2040
Dr. Frank A. Todd

ANIMAL HEALTH INSTITUTE
1030-15th Street, N.W.
Washington, D. C. 20005
296-0787
Mr. Fritz Kessinger

Representing Animal Health Institute
HERCULES INCORPORATED
1800 K Street, N.W.
Washington, D. C. 20006
223-8590
Mr. Jerome J. Breiter

CHAMBER OF COMMERCE OF THE USA
1615 H Street, N.W.
Washington, D. C. 20006
659-6000
Mr. E. Clinton Stokes
Senior Associate - Agriculture

CORN REFINERS ASSOCIATION, INC.
1001 Connecticut Avenue, N.W.
Washington, D. C. 20036
~~628-7634~~ 331-1634
Mr. Robert C. Liebenow, President

EVAPORATED MILK ASSOCIATION
910-17th Street, N.W.
Washington, D. C. 20006
223-6820
Dr. J. C. Flake

FARM & INDUSTRIAL EQUIPMENT INSTITUTE
H. D. Hudson Manufacturing Co.
Suite 819, 1625 I Street, N.W.
Washington, D. C. 20006
~~638-4245~~ 331-1245
Dr. Ray Treichler

INTERNATIONAL APPLE INSTITUTE
2430 Pennsylvania Avenue, N.W.
Washington, D. C. 20037
833-9150
Fred W. Burrows

INTERNATIONAL ASSOCIATION OF ICE
CREAM MANUFACTURERS & MILK INDUSTRY
FOUNDATION

910-17th Street, N.W., Suite 1105
Washington, D. C. 20006
296-4250

Mr. Austin T. Rhoads

INTERNATIONAL SHADE TREE CONFERENCE
Asplundh Tree Expert Co.

505 York Road
Jenkintown, Pennsylvania 19046
(215) Turner 7-2500

Mr. Hyland R. Johns, V.P.

DONALD LERCH & CO., INC.

1101-17th Street, N.W., Suite 808
Washington, D. C. 20036
466-2804

Mr. Don Lerch

J. J. MAUGET COMPANY

Box 3422
Burbank, California 91504

Mr. Dale Dodds

NATIONAL AGRICULTURAL AVIATION ASSN.
1101-17th Street, N.W.

Suite 808
Washington, D. C. 20036
223-2822

Mr. Farrell Higbee

NATIONAL AGRICULTURAL CHEMICALS ASSN.
1155-15th Street, N.W.

Washington, D. C. 20005
296-1585

Mr. Parke C. Brinkley, President
Dr. Jack D. Early, Vice President
Dr. William L. Hollis, Science
Coordinator

NATIONAL ARBORIST ASSOCIATION, INC.

3537 Stratford Road
Wantagh, New York 11793
(516) 221-3082

Mr. Robert Felix, Exec. Sec'y

Representing National Arborist Assoc.
Guardian Tree Experts, Inc.

12401 Parklawn Drive
Rockville, Maryland 20852

Mr. Walter Money

NATIONAL ASSOCIATION OF STATE DEPTS. OF
AGRICULTURE

1616 H Street, N.W.
Washington, D. C. 20006
628-1566

Mr. Wm. Stanwood Cath, Exec. Sec'y

NATIONAL ASSOCIATION OF STATE UNIVERSITIES
AND LAND-GRANT COLLEGES

1 Du Pont Circle, Suite 710
Washington, D. C. 20036
293-7120

Mr. Russell C. McGregor

NATIONAL ASSOCIATION OF WHEAT GROWERS
1030-15th Street, N.W., Suite 10006

Washington, D. C. 20005
659-1533

Mr. Carl Schwensen

NATIONAL BROILER COUNCIL

1155-15th Street, N.W.
Washington, D. C. 20005
296-2622

Mr. R. Wunderle

NATIONAL CANNERS ASSOCIATION
1133-20th Street, N.W.

Washington, D. C. 20036
331-5967

Dr. Edwin A. Crosby, Director
Agricultural and Environmental Affairs

NATIONAL CLUB ASSOCIATION
1129-20th Street, N.W.

Washington, D. C. 20036
466-8424

Mr. Gerard F. Hurley, Exec. Dir.

NATIONAL COTTON COUNCIL OF AMERICA
1030-15th Street, Suite 700

Washington, D. C. 20005
833-2943

Mr. Phil Burnette, Asst. Wash. Rep.

NATIONAL COUNCIL OF AGRICULTURAL EMPLOYEES
1425 H Street, N.W.

Washington, D. C. 20005
628-8650

Mr. Perry Ellsworth

NATIONAL COUNCIL OF FARMER COOPERATIVES
1129-20th Street, N.W.

Washington, D. C. 20036
659-1525

Mr. Paul S. Weller, Director of

NATIONAL FARMERS UNION
1012-14th Street, N.W.
Washington, D. C. 20005
628-9774

Mr. Reuben Johnson, Director
Legislative Services

NATIONAL FOREST PRODUCTS ASSOCIATION
1619 Mass. Avenue, N.W.
Washington, D. C. 20036
332-1050

Mr. Bruce Grefrath

NATIONAL GRAIN AND FEED ASSOCIATION
500 Foger Building
725-15th Street, N.W.
Washington, D. C. 20005
783-2024

Mr. Harvey L. Kiser

NATIONAL MILK PRODUCERS FEDERATION
30 F Street, N.W.
Washington, D. C. 20001
393-8151

Mr. John B. Adams

NATIONAL PEACH COUNCIL
P. O. Box 1085
Martinsburg, West Virginia 25401
(204) 267-6024
Mr. Robert K. Phillips, Secretary-Mgr.

NATIONAL PEST CONTROL ASSOCIATION, INC.
Tyson's International Building
8150 Leesburg Pike, Suite 600
Vienna, Virginia 22180
(703) 790-8300

Mr. Richard L. Eldredge
Dr. Philip J. Spear, Senior
Director of Research

POULTRY AND EGG INSTITUTE OF AMERICA
425-13th Street, N.W.
Washington, D. C. 20004
347-3991

Mr. Lee Campbell, Washington Rep.

SOCIETY OF AMERICAN FLORISTS
901 North Washington Street
Alexandria, Virginia 22314
836-8700

John H. Blake III
Harry Russ

UNITED FRESH FRUIT & VEGETABLE ASSN.
1019-19th Street, N.W.
Washington, D. C. 20036
293-9210

Mr. Durward Seals, Sec'y
Mr. Bernard J. Imming, Exec. V.P.

U. S. BEET SUGAR ASSOCIATION
1156-15th Street, N.W.
Washington, D. C. 20005
296-4820

Mr. David Carter, Exec. V.P.

WYE TREE EXPERTS
Box 6
Wye Mills, Maryland 21679
Dr. Turp Garrett

Legal Counsels:

Mr. L. Alton Denslow (NATIONAL GRANGE)
531 Washington Bldg.
Washington, D. C.
737-0727

SELLERS, CONNOR & CUNEO (NACA)
1626 K Street, N.W.
Washington, D. C. 20006
783-0600
Mr. Robert Ackerly

COVINGTON & BURLING (NCA)
888 Sixteenth Street, N.W.
Washington, D. C. 20006
293-3300
Mr. H. Edward Dunkelberger

CHEMICAL SPECIALTIES MANUFACTURERS
ASSOCIATION
1001 Connecticut Avenue, N.W.
Washington, D. C. 20036
872-8110
Ralph Engel
Executive Director

NATIONAL GRANGE
1616 H Street, NW
Washington, DC



Additional people to be cleared for 10 a.m. meeting,
Room 305 Norman Ross, Chairing

MICHIELI, Ron

KELLNER, STEVE

COREY, FRED

GRANT, J. D.

HALL, JOHN

OLSON, JACK

~~SEARS, DUDWARD~~

BROWN, JAMES

Monnette, David



THE WHITE HOUSE
WASHINGTON

Date: Tuesday

MEMO TO: Norm Ross

FROM: JOHN VICKERMAN

For your information _____

Please handle _____

Per your request _____

These people want an
audience with someone
on the staff - Can
you meet with them?

JVB

~~DRAFT~~



American Farm Bureau Federation

WASHINGTON OFFICE
425 13TH STREET, N.W.
WASHINGTON, D. C. 20004
AREA CODE 202 - 638 - 6315
CABLE ADDRESS: AMFARMBUR

March 25, 1975

Mr. John Vickerman
The White House
Washington, DC 20500

*Room 305 - 10:00 May 2 -
He is sending me the list of
25 people -*

Dear Mr. Vickerman:

The American Farm Bureau Federation supported passage of the amended FIFRA (October, 1972) and has monitored its implementation because of our recognition of the merit of a reasonable and effective pesticide program designed to prevent misuse. We have worked formally and informally with EPA, expressing the views of farmers. Other organizations and individuals have voiced similar opinions. Our concern is that the implementation of the Act is not attempting to prevent misuse as a primary goal but rather to authorize comprehensive regulation of use. This over-regulation is not within the intent of the law, is not justified by accident statistics, and is not likely to be productive. EPA actions in the past few months have increased our concern.

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According to the charter of the Pesticide Users Conference, I cannot and am not speaking on behalf of the members of PUC. However, I believe many of the members share views similar to those expressed here. As the chairman of PUC, I therefore request that you meet with the Pesticide Users Conference, at your convenience, to permit the members of the group to share their concerns with you.

Attached is a list of the members of PUC.

Sincerely,

Bruce Hawley
Assistant to the Director
Government Relations

Attachment

