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Regulating Pesticides Under Uncertainty:
Application to Cotton Pest Control Workers

Federal pesticide law requires that economic benefits and environmental hazards including adverse health effects be weighed for thousands of active chemical ingredients already in use. The burdensome nature of this task is compounded by the fact that for many chemicals, the principal concerns are long-term environmental health effects including cancer, mutation, and birth defects. The degree of uncertainty about the magnitude of these chronic health risks is so great as to confound ordinary evaluation procedures. Estimates of human dose-response relationships for known animal carcinogens, for example, can range over many orders of magnitude.

To deal with this wide margin of error, quantitative risk assessment procedures have traditionally built in deep cushions by making "conservative judgments" at each stage of any health risk analysis. Although the intention is protection of human health, an unfortunate result has been to discredit quantitative risk assessment as a source of unbiased health risk information which can meaningfully be weighed against estimated economic benefits.

As far as possible, it is therefore desirable to frame environmental health risks probabilistically, with unbiased rather than conservative point estimates and realistic confidence intervals. This type of formulation has two virtues. First, it becomes meaningful to discuss trade-offs between risks and economic benefits. Second, a variety of health hazards can sensibly be compared, and uniform decision criteria can be applied by regulatory agencies, making possible improvements in both fairness and social efficiency.

The present paper is an application of recent conceptual work in health risk analysis (Crouch and Wilson; Lichtenberg and Zilberman) to the problem of

regulating an agricultural pesticide. Health risk to agricultural pest control workers from the cotton pesticide <u>chlordimeform</u> is represented as a probability density function based on the best available evidence for underlying physical and behavioral parameters. Expected producer benefits from the pesticide are estimated. The optimal regulatory choice is then calculated under three different decision criteria: a standards approach based on traditional conservative risk assessment practices, a safety fixed rule utilizing an explicit confidence interval, and a risk-benefit analysis. In the first two cases, the expected value of economic benefits is maximized subject to a health constraint. In the risk-benefit approach, aggregate trade-offs between economics and health are considered explicitly, and the implied value of a statistical life is calculated under alternative regulatory policies.

I. The Social Decision Problem. The regulatory agency's problem with respect to a chemical pesticide is to choose a set of regulations which will protect human health and the environment without imposing undue economic costs. The appropriate way to balance economic costs with health and environmental considerations is however far from clear.[1]

Consider a policy Z toward a particular chemical, consisting of a set of choices Z_1 through Z_n concerning possible regulatory actions. These actions

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[1] Federal pesticide law on the subject reads as follows: "The Administrator [of EPA] shall register a pesticide if he determines that, when considered with any restrictions imposed...it will perform its intended function without unreasonable adverse effects on the environment...", where "the term 'Unreasonable Adverse Effects on the Environment' means 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" (FIFRA Sec. 5 and Sec. 2).

might include a range of options such as a complete ban, quantity restrictions, safe use regulations, unit taxes, etc.

For an agricultural pesticide used in a relatively small region, per acre profits are

$$\Pi (Z) = p \, \overline{Q} \, [1 - D(Z)] - C(Z),$$

where
$\overline{Q}$ = potential yield (no pest damage)
p = output price, taken as given
$D(Z)$ = % yield damage, a function of pesticide regulations
$C(Z)$ = costs of damage control (including regulatory costs).

Total output is $\overline{Q} \, [1 - D(Z)]$, of which $\overline{Q}$ represents potential output and the damage function D the fraction of this potential which is destroyed by pests. The agency's regulatory choices will influence the level of damage control and hence yield. Potential output $\overline{Q}$ of course depends on the producer's other input choices; we ignore these other inputs in order to concentrate on the damage control problem. The costs of damage control $C(Z)$ also depend on the regulator's decisions. These include unit costs and application costs of the regulated chemical and possible substitutes, and costs imposed by regulation. The latter, such as expenses to cover safety clothing and equipment, are assumed to be passed through to producers by competitive pest control firms.

The economic effect of a total ban, for example, is the difference in per acre profitability with and without the banned chemical, net of the effect of available substitutes. Assuming that profits do not fall sufficiently to bring about crop substitution, the overall economic effect of the policy is $[\Pi (Z) - \Pi (\emptyset)]$ times the number of acres affected, where $\Pi (\emptyset)$ is profit per acre when no regulatory action is taken.

The health effect of policy Z is the reduced incidence of illness (or probability of illness) in population groups which may be exposed. We will be

concerned with chronic effects, viewed epidemiologically as probabilistic events, so that the influence of policy on health is measured in terms of changes in the level of risk to individuals in exposed population groups. Groups are differentiated according to the level of exposure or susceptibility to the chemical under review. The overall health effect of the policy is the totality of individual health risk reductions to persons in the affected groups.

Conservative Standards. Environmental health standards such as 10^{-6} lifetime risk are often suggested as guidelines for acceptable risks to the general population, while somewhat lower levels, such as 10^{-5}, are sometimes considered tolerable for occupational hazards. Policy analysts do not wish to understate health risks. The traditional solution has been to make conservative risk estimates wherever possible, resulting in a kind of worst case portrayal. Current practice in regulatory agencies is to omit explicit reference to the uncertainty around health risk estimates.

Given the conservatism of the risk estimates, health risk standards such as those mentioned above will necessarily be applied not to expected risk but to some type of upper confidence interval. However the informal nature of the conservative judgments used in the traditional risk analysis makes it impossible to know what confidence interval is finally being employed.

The application of a conventional health risk standard to evaluate alternative environmental health regulations can be expressed as follows: choose a regulatory policy Z which reduces (conservatively estimated) health risk below a pre-established standard S with minimum reduction in economic benefits to producers, i.e.

$$\max_{Z} \Pi(Z) = p\,\overline{Q}\,[1 - D(Z)] - C(Z) \quad \text{s.t.} \quad H_i(Z) \leq S, \text{ for all } i,$$

where H_i is estimated health risk to a person in risk group i, for example pesticide applicators or municipal water consumers.

For policy actions which can be applied continuously, the first order conditions for this problem can be simply stated. For each action Z_s which is imposed at a nonzero level,

$$- p \, \overline{Q} \; \partial D/\partial Z_s - \partial C/\partial Z_s - \theta_i \; \partial H_i/\partial Z_s = 0 \, ,$$

where θ_i is the shadow economic value associated with relaxing the health constraint.

Unfortunately we cannot interpret $\partial H_i/\partial Z_s$, the marginal effect of the policy action on health risk, because we do not know how conservative the risk estimation really is. As a result, the various policy actions available for regulating the chemical in question cannot be efficiently allocated.

Safety-fixed Rules. Recent efforts to rationalize risk assessment procedures have led to the representation of health risk as a random variable rather than a conservative point estimate. The distribution of this random variable summarizes the best available information about the risk, and also expresses the degree of uncertainty about the information. Let the variable R_i, like H_i, represent risk to a randomly selected individual in an at-risk group, except that R_i is a random variable rather than a conservative point estimate. (The health risk R_i to an individual, often called the probability of illness, should not be confused with the distribution $f(R_i)$, which expresses the probability that R_i falls within a given range.)

When risk is represented as a random variable, the standards approach per se is no longer meaningful. Lichtenberg and Zilberman outline a safety rule which takes uncertainty explicitly into account. Regulations are designed to

maximize economic welfare subject to a probabilistic constraint. In our case the appropriate safety rule is the following:

$$\max_{Z} \ \Pi(Z) = p \ \overline{Q} \ [1 - D(Z)] - C(Z)$$

$$\text{s.t. prob } (R_i(Z) \geq S) \leq M \text{ for all } i,$$

where S = health safety standard (e.g. 10^{-6}/lifetime)
         M = safety margin or confidence interval (e.g. .98).

That is, the probability that the random variable R_i representing risk to a randomly selected individual in any exposed group exceeds a standard S shall be less than a stipulated upper confidence level M.

For convenience of notation we assume that a single population group is exposed to the chemical so that individual health risk under policy Z is simply $R(Z)$. Define $R_M(Z)$ as the level of risk which is exceeded with probability $1-M$. The health risk constraint prob $(R(Z) \geq S) \leq M$ can be rewritten as

$$R_M(Z) \leq S.$$

And since health risk is to be approximated as a product of lognormally distributed risk factors, it will be useful to replace this expression with the equivalent constraint on the upper confidence level of log risk, i.e.

$$r_M \leq \ln(S) \ ,$$

where r_M is the level of log risk, $r = \ln(R)$, exceeded with probability $1-M$.

The lagrangian for the safety-fixed problem is then

$$L = p \ \overline{Q} \ [1 - D(Z)] - C(Z) + \lambda \ (\ln(S) - r_M(Z)).$$

Again, if policies can be applied continuously, the first order condition for any policy Z_S which is enacted is

$$- p \ \overline{Q} \ \partial D / \partial Z_S - \partial C / \partial Z_S - \lambda \ \partial r_M / \partial Z_S = 0.$$

That is, choose a level of each policy variable Z_S at which the value of the marginal change in total yield is just offset by the change in pest control

and regulatory costs plus the shadow value λ associated with a marginal reduction in the upper confidence level of log health risk. For each policy action which is employed we require:

$$\lambda = (- p\ \overline{Q}\ \partial D/\partial Z_S - \partial C/\partial Z_S)\ /\ \partial r_M/\partial Z_S\ .$$

That is, the shadow price λ associated with the health risk standard must equal the ratio of marginal net economic benefits to marginal health risk reduction under the policy action.

If R is the product of n lognormally distributed risk factors,

$$R = \prod_{i=1,}^{n} X_i\ ;\quad x_i = \ln X_i \sim N(\mu_i,\ \sigma_i^2),$$

then R will also have the lognormal distribution:

$$r = \ln R = \sum_i \ln (X_i) \sim N(\mu,\ \sigma^2).$$

where

$$\mu = \sum_i \mu_i,$$

$$\sigma^2 = \sum_i \sigma_i^2 + \sum_{i \neq j} \sigma_i\ \sigma_j\ c_{ij}$$

and c_{ij} is the correlation coefficient between factors i and j.

The standard normal variable F_M which is exceeded with probability 1-M is related to r_M by:

$$F_M = (r_M - \mu)\ /\sigma,$$

so the constraint $r_M(Z) \leq \ln(S)$ is equivalent to

$$r_M = \mu + F_M\ \sigma$$

$$= \sum_i \mu_i + F_M\ [\ \sum_i \sigma_i^2 + \sum_{i \neq j} \sigma_i\ \sigma_j\ c_{ij}]^{1/2}$$

$$\leq \ln(S).$$

For the lognormal specification of health risk, the first order condition for each policy action Z_S is then:

$$- p \overline{Q} \, \partial D/\partial Z_S - \partial C/\partial Z_S =$$

$$\lambda [\sum_i \partial \mu_i/\partial Z_S + F_M (\sum_i \sigma_i^2 + \sum_{i \neq j} \sigma_i \sigma_j \, c_{ij})^{-1/2} (\sum_i \partial \sigma_i/\partial Z_S + \sum_{i>j} \sigma_i \partial \sigma_j/\partial Z_S \, c_{ij})] \ .$$

This condition highlights the respective roles of material risk reduction and better information (Lichtenberg and Zilberman). For policies which affect one or more of the factor means μ_i but do not change the variance estimates σ_i^2, yield loss ($p \overline{Q} \, \partial D/\partial Z_S$) under the policy should be just offset by cost savings for chemical inputs (net of regulatory costs) $\partial C/\partial Z_i$, plus the value of increased safety, $\lambda \sum_i \partial \mu_i/\partial Z_S$. For policies which yield better information rather than real risk reduction, i.e. reduce factor variances rather that means, the equivalent condition holds except that the source of the reduction in r_M, the upper confidence interval on risk, is simply better information rather than material improvement in health safety.

Risk Benefit Analysis. Although the safety-fixed rule provides a substantial improvement over the conservative standard by explicitly introducing uncertainty into the decision process and permitting efficient allocation of regulatory actions toward any one chemical, it shares with the standards approach a significant shortcoming. Neither decision rule acknowledges the trade-offs between economic benefits and environmental health risks which are at the heart of pesticide regulation. The law requires that the economic importance of a substance be taken into account in determining the acceptable health risk. For example, we might like to see a requirement that, at least for regulations governing similar materials to which similar population groups are exposed, the choice of regulations should be such that λ, the shadow cost of marginal risk reduction, should be the same. Some type of risk-benefit analysis is required.

Unfortunately, in the context of environmental health and safety regulation, risk benefit analysis usually involves attaching rather arbitrary monetary values to human mortality and illness. One commonly used number is a million dollars per statistical human life, although neither the marketplace evidence for this particular value, nor the conditions under which its use is appropriate, are very clear. Presumably such a criterion is appropriate only for very small individual risks, but how small?

In spite of the difficulties, it is useful to posit a model which is capable of making comparisons across different hazardous materials. For an agricultural pesticide, the unconstrained cost-benefit model might look like the following:

$$\max \quad (p\,\overline{Q}\,[1 - D(Z)] - C(Z))\,A\,Y - V\,R_M(Z)\,N$$

where
A = affected acreage
V = monetary value of statistical life used for the analysis
N - number of persons exposed
Y - number of years exposure.

Economic benefits per acre are multiplied by the relevant acreage. The upper confidence interval on health risk is monetized by multiplying by the value of statistical life (V) and by the size of the exposed group (N). In order to annualize the risk, it is necessary to divide by the number of years exposure (Y) which was assumed in the derivation of R_M. The first order condition is

$$(\,-p\,\overline{Q}\,\,\partial D/\partial Z_S - \partial C/\partial Z_S)\,A - V\,\partial R_M/\partial Z_S\,\,N/Y = 0.$$

The choice of M, the upper confidence level of risk, is of course a policy decision. Expected health risk could be used, but this is inconsistent with the tradition of conservatism with respect to uncertain human health hazards. It should be noted that under a standard or safety fixed rule it is not important whether the economic benefits are regarded as

deterministic or as probabilistic, since benefits or expected benefits are maximized subject to a health constraint. In case of cost benefit analysis the specification of economic benefits may be important, since in evaluating trade-offs we may in principle at least wish to consider confidence intervals on economic benefits as well as health risks.

II. Specifying Health Risk

Effective policy analysis depends on an appropriate delineation of health risk factors, which captures the various policy options and their effects on health risk reduction. So long as all individuals receive low doses, the extra risk R to a randomly selected individual in a population exposed to an average daily dose D of the contaminant for a lifetime can be approximated by

$$R \simeq \beta D,$$

where β is a linearized form of the dose-response relationship known as potency and D is individual average daily dose over a lifetime, normally expressed in milligrams of the chemical per kilogram of bodyweight per day (Crouch et al.).

The uncertainty associated with health risk assessments of this kind enters β and D from a variety of sources. For carcinogens, potency must generally be extrapolated from laboratory animal studies involving high dosages. Following Crouch and Wilson, we treat β as the following product of random variables:

$$\beta = b K E,$$

where b is the animal potency (i.e. linearized dose-response) estimate, again in milligrams of daily exposure per kilogram of bodyweight, K is an interspecies extrapolation factor, and E is a dose extrapolation factor. Potency is essentially a biological fact which cannot be altered by regulatory

policy. It is, however, possible to reduce the variances of b, K, and E by gaining better information.

Dose D may similarly be regarded as a random variable with its own set of underlying risk factors. For example exposure to a pest control worker might be represented as follows:

$$D = a * s * C * v * X * T * A * Y \ / \ (70 \text{ kg} * 70 \text{ years} * 365 \text{ days/year}),$$

where
a = avenue of exposure
s = dermal absorption
C = potential exposure/lb. active ingredient
v = fraction of potential exposure which reaches skin
X = lbs. active ingredient per acre treatment
T = treatments per acre per year
A = acres/year treated by an individual employee
Y = years employed.

Avenue of exposure allows for the fact that pesticide exposure to pest control workers is primarily dermal, rather than oral as it is in the mouse study; dermal absorption is the fraction of material which is absorbed from the surface of the skin; potential exposure is the amount of material reaching clothing and so forth. To express D in mg/kg/day average daily dose we divide as is customary by an average bodyweight, 70 kg, and by average life expectancy in days.

Ideally, the health risk model should be specified using as much behavioral and biological detail as possible in order to highlight potential policy targets. The multiplicative approach is flexible enough to accommodate numerous policy considerations simultaneously, by modeling health risk as a rather open-ended product of random variables, any of which can be subdivided as needed to express greater detail. Some of the factors in the lognormal model may be regarded as statistically independent of each other, and others not. Any non-zero correlations will of course influence the distribution of R and the confidence intervals around health risk estimates. In the present

example, potential regulatory targets include but are not restricted to: 1) the label application rate X, 2) the maximum number of treatments per year T and 3) mandated use of safety clothing and equipment which influences the exposure ratio v.

III. Empirical Results: Cancer Risk and Economic Effects of Selected Policies

Health Effects. Estimates of the potency and exposure factors for chlordimeform cancer risk to three groups of cotton pest control operators in Imperial Valley are shown in Table 1. The data available from EPA (1986) fall into two categories: those estimates which appear to be deliberately conservative and those which do not. These two types are listed in Table 1 as "conservative" and "unbiased" respectively. For risk factors (5) dermal absorption and (6) the ratio of actual to potential exposure, only a single estimate is available, which was used in both columns. Factors (2), (3), and (4) were not addressed by EPA; we return to them shortly.

The complete multiplicative risk model for pest control workers presented in the previous section has to be simplified to conform with the available data by collapsing the variables C, X, T, and A into a single annual potential exposure variable, Factor 8, for each occupational group. This representation of the data removes from consideration some interesting policy options, such as limitations on the number of acres treated by a single employee in a year.

To find estimated risk in milligrams per kilogram of bodyweight per day, we divide the product of the factor estimates by average life expectancy, 70 years * 365 days per year. The resulting figures are shown at the bottom of Table 1. The difference between unbiased and conservative risk estimates is extreme. For example the range of annual exposure estimates available for

mixers-loaders is much greater than the range of estimates available for pilots. As a result, even though unbiased risk estimates for the two groups differ by only a factor of about two, conservative estimates differ by a factor of thirty.

The traditional approach to the data in Table 1 would be to use the conservative risk estimates in mg/kg/day as the basis for policy decisions. The values for all three groups, but especially that for mixers-loaders--1.7 * 10^{-2} or nearly one in sixty--would almost certainly be considered unacceptable risks requiring some type of regulatory response.

Table 2 shows the risk assessment derived from the multiplicative lognormal model. For each factor this distribution is assigned a mean equal to the log of the "unbiased" estimate in Table 1. The standard deviations are determined by assuming that the log of the "conservative" estimate for each factor is an upper .98 confidence level.

For Factors (2) and (3), which were not addressed by EPA, values for μ_i and σ_i were borrowed from Zeise et al. The interspecies factor (2) has a median value of unity because a fundamental assumption of most health risk analysis is that health effects to different species are the same when exposure is measured in mg/kg/day. The value 1.5 for the standard deviation of this variable is based on comparative laboratory studies for different species.

The low dose extrapolation factor (3) depends on the choice of statistical model. The One-Hit, Multistage, and Weibull models are all commonly used. There is little evidence in favor of one or the other, and the choice of model is considered largely subjective. Crouch et al. note that if low-dose linearity is afforded even a one-third probability of being correct,

then health risk estimates will differ from those of the one-hit model by at most a factor of seven, a small amount in the world of risk assessment. We follow them in utilizing the one-hit model as if it were certain. The log of this factor is therefore given zero mean and variance.

For Factor (4) no estimates were available, even though there is reason to believe that differences in the avenue of exposure, for instance dermal as opposed to dietary, may be important (Crump). One would like to have available a continuous variable analog to the "fifty-fifty ignorance" so often resorted to with discrete distributions. We use zero variance for the log of Factor (4), but it is obvious that such assumptions lead to "nonconservative" health risk assessments and should be avoided.

The lognormal risk assessment for each occupational group is shown at the bottom of Table 2. Mean log risk (μ) is the sum of the factor means, -14.47 for mixers-loaders, -13.27 for pilots, and -17.18 for flaggers. On the assumption that the risk factors are statistically independent, the standard deviation of log risk (σ) is calculated as the square root of the sum of the σ_i. Because of the skewness of the lognormal distribution, $\exp(\mu)$ represents median risk (R_{med}) rather than mean risk. Mean risk ($\overline{R}$) and the 98% upper confidence level of risk (R_{98}) are related to R_{med} by the following expressions:

$$\overline{R} = R_{med} * e^{(\sigma^2/2)} \; ; \; R_{98} = R_{med} * e^{(2\sigma)}$$

(Crouch et al.).

It is interesting to compare the traditional conservative risk estimates from Table 1 with the .98 upper confidence levels in Table 2. The estimated risk to pilots is similar in the two cases, $1.8 * 10^{-4}$ as opposed to $3.4 * 10^{-4}$. However the risk to mixers-loaders is 1 1/2 orders of magnitude lower

under the lognormal analysis, and the risk to flaggers is 2 1/2 orders of magnitude lower. These results occur in spite of the inherent conservatism of the lognormal distribution, and in spite of the fact that an important additional risk factor (Factor 2) has been included only in the lognormal analysis. This large difference between the conservative and lognormal estimates, which occurs only for risk estimates with high variance in one or more risk factors, shows how a series of nonspecific conservative assumptions can become compounded in the traditional style of analysis into a hyper-conservative final risk assessment.

Economic Costs of Selected Regulations. The four regulatory actions which will be considered are a) a ban, b) a reduced label dose, c) limitations on the number of treatments per acre per year, and d) required use of special safety clothing and equipment. The relevant model of per acre profitability is then the following:

$$\max_{X,T,v} \quad \Pi = p\ \overline{Q}\ [1 - D(X, T] - (w_X X + w_T + C(v))\ T$$

where X is the label dose, T the number of applications per season, v the required safety clothing and equipment, and C(v) the additional cost per application associated with v.

The evaluation of action a) compares profits with and without the material, allowing for chemical substitution. Both yields and costs will normally be affected. Action b) sets a maximum on X, and action c) does the same to T. Under action d) the unit cost of application goes up to cover pest control operator costs. We note that policies which combine actions b) through d) are possible.

Because crop ecosystems and pest management problems are very complex, estimating net economic benefits from the use of any single chemical can be

surprisingly difficult. In the case of chlordimeform, three different types of economic benefits have been claimed. The first is that chlordimeform is useful in the region primarily for killing the larvae of Heliothis virescens, in particular by acting synergistically with synthetic pyrethroids. The second claim is that its main value lies in slowing the development of H. virescens resistance to the pyrethroids. A third view is that the chemical is primarily a yield-enhancing agent rather than a pesticide.

For whatever reasons, chlordimeform does not appear to have been used in the Imperial region for direct yield enhancement, as is shown by the timing of applications. Since resistance retardation is unproven, the best estimate of economic benefits is 5% improvement in yield due to improved pest control (Carlson). This estimate for North and South Carolina, Mississippi and Louisiana is consistent with field tests by H. Reynolds in the Imperial Valley which showed yield benefits of 3%, 4% and 10% for three different seasons.

The net per-acre effect of a pesticide ban (expected to be negative) is then

$$.05 \ p_c \ Y - p_{cdf}$$

where p_c is the price of cotton, Y the yield in pounds and p_{cdf} the cost of a standard number of treatments. For example using an average 1978-80 price of $.74/lb. for cotton (Burrows et al.), 1979-83 average yield of 1285 lbs. lint (Imperial County Extension) and application cost of $1.50/acre times six treatments (Carlson), the expected value of chlordimeform per acre is

$$.74 * 1285 *.05 - \$1.50 * 6 = \$48 - \$9 = \$39,$$

assuming application occurs along with other materials so there are no extra costs to administer it.

The estimated cost of action a), a ban, is then $39/acre per year. The cost of action b), a reduced dose, is apparently zero, since tests by Reynolds show no yield improvement from 1/4 lb. as opposed to 1/8 lb. of material per acre-treatment. The effect of action c) cannot be determined because the constraint imposed in California (eight treatments per year) was not binding; most growers applied only about six. The cost of action d) can be inferred from the $10 surcharge per load of chlordimeform (or about $3 per acre for six treatments) charged by some pest control operators in response to California's stringent safety requirements.

Trade-offs Under Regulation. These cost estimates for producers under the four possible regulatory actions suggest an efficient policy frontier consisting of only three regulatory possibilities: Policy I, a reduced label dose only; Policy II, a reduced dose together with required safety clothing and equipment; and Policy III, a complete ban. This frontier, plus two inefficient policy choices, is depicted in Figure 1, which shows the lognormal R_{98} estimates for mixers-loaders, the group of greatest concern. We assume that reducing the label dose by 1/2 reduces exposure by 1/2, and that safety clothing and equipment reduce exposure by a factor of 3.6, as in the EPA analysis. Then adoption of these two actions together (Policy II) reduces excess cancer risk from chlordimeform exposure by a factor of 7.2, as shown.

Figure 2 shows the trade-offs under alternative regulatory policies for both the nonspecific conservative risk estimate and the lognormal R_{98}. Under Policy I, risk to mixers-loaders is reduced by 1/2 at zero cost to producers, and by an additional factor of 3.6 at a cost of $3/acre. The resulting level of risk under conservative estimation, $2 * 10^{-3}$, still exceeds the 10^{-5} per lifetime or 10^{-5} per year ($7 * 10^{-4}$ per lifetime) which has been proposed for

occupational exposures (Crouch and Wilson). To meet the standard, the chemical would have to be banned (Policy III), at a total cost to producers of $39 per acre.

Under the lognormal risk analysis, Policy II reduces risk to $1 * 10^{-4}$ per lifetime. This value might be considered marginally acceptable, under the weaker occupational criterion. If so, the safety rule could be satisfied with producer costs of $3 per acre.

Finally we consider aggregate trade-offs under risk-benefit analysis. For this purpose, per acre losses are multiplied by the relevant acreage, and health risks for all groups are included and multiplied by the number in each group. Remembering that with both the traditional and the lognormal models we are dealing in very conservative health risk estimates, the minimum value of a statistical life implied by enacting a particular policy is determined by the following expression:

$$V \leq L * A * Y / \sum_i (N_i * H_i)$$

where L = reduction in per acre profits
       A = acreage affected by policy
       Y = year of employment assumed in health risk assessment
       H_i = health risk reduction to a person in group i (.98 confidence level)
       N_i = number of persons in group i.

Table 3 shows the values of the relevant variables. Since the reduced dose (1) can be undertaken with no costs to producers, it should of course be employed. The minimum value of a conservatively estimated statistical life which justifies the adoption of a stronger measure, Policy II, is for R_{98}:

$$V_2 = \frac{(\$3 * 32,000 * 10)}{(33 * (4-1)*10^{-4} + 35 * (9-3)*10^{-5} + 54 * (3-.7)*10^{-5}) / 3.6}$$

$$= \$70 \text{ million.}$$

For Policy III, a ban, the implied value of life is, again using R_{98},

$$V_3 = \frac{(\$39 * 32{,}000 * 10)}{(33 * 4 * 10^{-4} + 35 * 9 * 10^{-5} + 54 * 3 * 10^{-5})}$$

$$= \$653 \text{ million.}$$

When traditional conservative risk estimates are used instead of the lognormal, the value of life estimates are of course much smaller, $4 million and $40 million respectively, because the upper confidence level on health risk, although nonspecific, is considerably higher. The comparison is shown in Figure 3. It is noteworthy that all of the value of life estimates, even those representing only the adoption of safety gear, are much higher than the $1 million often employed.

Conclusions. The three decision criteria considered all lead to different policy recommendations under commonly used rules of thumb: an occupational health risk standard of 10^{-5} per year and $1 million for the value of preserving a statistical human life. The conservative standard suggests that chlordimeform should be banned. The safety-fixed rule indicates that it could be used if safety clothing and equipment were employed. The risk-benefit model implies that no regulatory action is required.

The most appropriate decision rule is by no means clear. The multiplicative lognormal risk assessment technique, with corresponding safety-fixed rule, offer a substantial improvement over current regulatory practice, which utilizes nonspecific conservative risk assessment and informal weighing of trade-offs between health risks and economic costs. An explicit characterization of the evidence concerning health risk, including the uncertainty associated with the evidence, permits more appropriate targeting of regulatory actions.

We should note that even though the value of life approach is attractive in permitting regulatory comparisons among various pesticides, it cannot stand

alone but requires some type of safety rule as well, since lives, or significant fractions of lives, cannot be traded. A value such as $1 million per statistical life, which may be acceptable for evaluating social trade-offs when risks are small—say, under one in ten million—clearly becomes unacceptable for risks on the order of one in a thousand or one in a hundred. The ideal decision rule therefore appears to be some combination of the risk-benefit and safety-fixed approaches, permitting trade-offs between economic benefits and aggregate health risks, but only so long as risks to individuals remain below acceptable threshold levels.

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Table 1
Estimated Risk Factors*

	Unbiased Estimate	Conservative Estimate
Potency Factors		
1) Animal Potency	.041	1.0
2) Interspecies Extrapolation	–	–
3) Dose Extrapolation	–	–
Exposure Factors		
4) Avenue of Exposure	–	–
5) Dermal Absorption	.3	.3
6) Actual/Potential Exposure	1.0	1.0
7) Years Employed	10.0	40.0
8) Potential Exposure(mg/kg/year)		
Mixers/Loaders	.11	37.1
Pilots	.36	.72
Flaggers	.0072	2.16
Product of Risk Factors 1-8		
Mixers/Loaders	.0133	444.96
Pilots	.0443	8.64
Flaggers	.0009	25.92
Estimated Risk in mg/kg/day		
(= Product of Risk Factors / (365*70)		
Mixers/Loaders	5.2E-07	1.7E-02
Pilots	1.7E-06	3.4E-04
Flaggers	3.5E-08	1.0E-03

* Assumes No Regulatory Action.

Sources: EPA (1986) and Zeise et al. (1982). See appendix for details.

Table 2
Lognormal Risk Assessment

	μ_i	σ_i
Potency Elements		
1 Animal Potency	-3.19	1.60
2 Interspecies Extrap	.00	1.50
3 Dose Extrap	.00	.00
Exposure Elements		
4 Avenue of Exposure	-.00	-
5 Dermal Absorption	-1.20	.00
6 Actual/Potential Exp	.00	.00
7 Years Employed	2.30	.69
8 Potential Exposure		
Mixers/Loaders	-2.23	2.92
Pilots	-1.02	.35
Flaggers	-4.93	2.85

	μ	σ	R Med	R Mean	R .98
Mixers/Loaders	-14.47	3.72	5.2E-07	5.2E-04	8.8E-04
Pilots	-13.27	2.32	1.7E-06	2.6E-05	1.8E-04
Flaggers	-17.18	3.66	3.5E-08	2.8E-05	5.3E-05

Sources: EPA (1986) except standard deviations of Factors 2 and 3 which are from Crouch et al. (1983). See Appendix for details.

Table 3

Trade-offs Between Agricultural Profits and Applicator Health Risks

	Conservative Risk			Risk .98			Cost / Acre
	Mixers	Pilots	Flaggers	Mixers	Pilots	Flaggers	
No Policy	2E-02	3E-04	1E-03	9E-04	2E-04	5E-05	$0
Reduced Dose	9E-03	2E-04	5E-04	4E-04	9E-05	3E-05	$0
Safety Gear	5E-03	9E-05	3E-04	2E-04	5E-05	1E-05	$3
Dose and Gear	2E-03	5E-05	1E-04	1E-04	3E-05	7E-06	$3
Ban Chemical	0	0	0	0	0	0	$39

Minimum Value of Aggregate Statistical Life Implied by Enacting Policy:

Policy 1 (Reduced Dose)

$0

Policy 2 (Reduced dose and Required Safety Gear)

Conservative	$4,240,647
Lognormal	$69,589,591

Policy 3 (Ban Chemical)

Conservative	$39,814,963
Lognormal	$653,368,934

Notes: It is assumed that the ratio of applicators to treated acres
    remains roughly constant. Our figures are based on California tests.
    where 33 mixers/loaders, 35 pilots, and 54 flaggers were exposed in
    treating 32,000 acres (CDFA HS-1064, 1982).
        The Implied Value of Life is Calculated as Cost per Acre * Acres
    Treated * Years Employment / Sum of Individual Health Risk Reductions.

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Trade-Offs Between Agricultural Profits and Health Risk Reduction
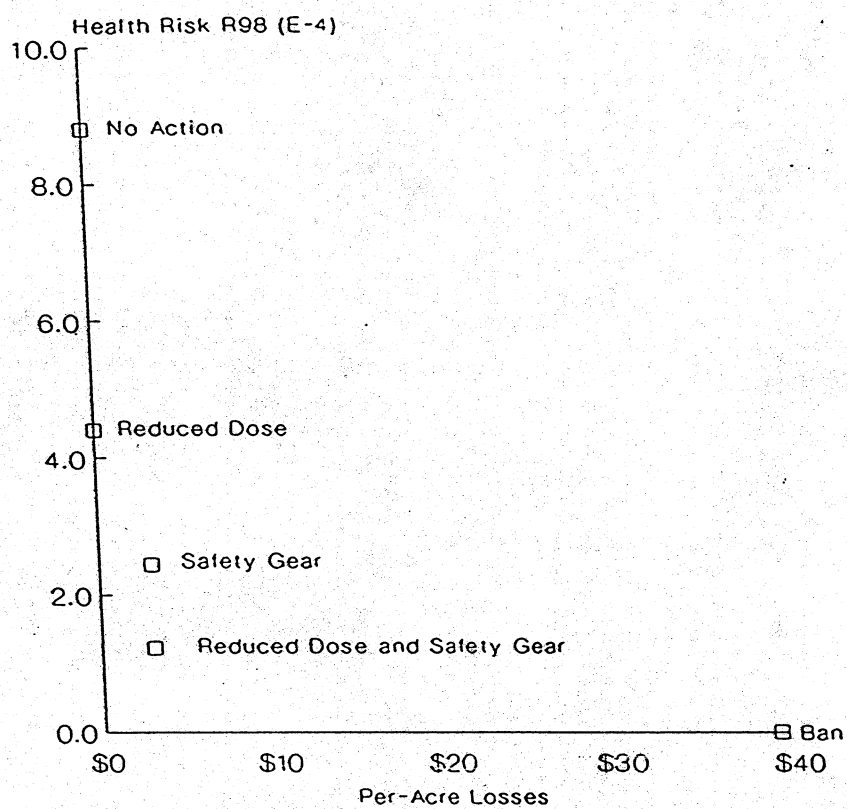
Health Risk R98 (E-4)

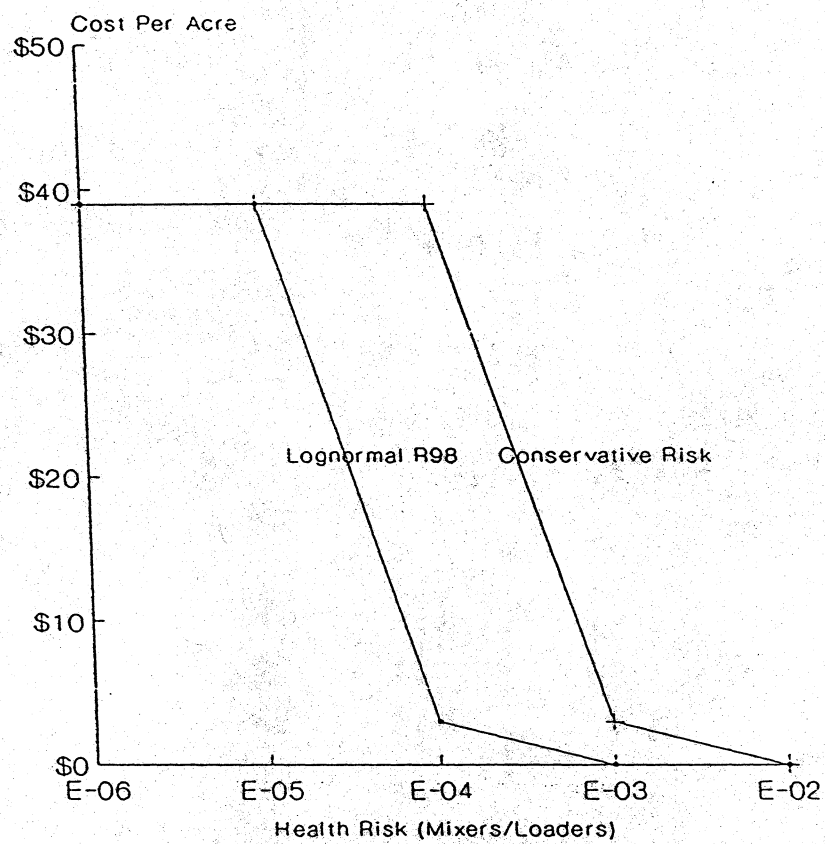Figure 1

Conservative and Lognormal Risk

Figure 2

Value of Aggregate Statistical Life
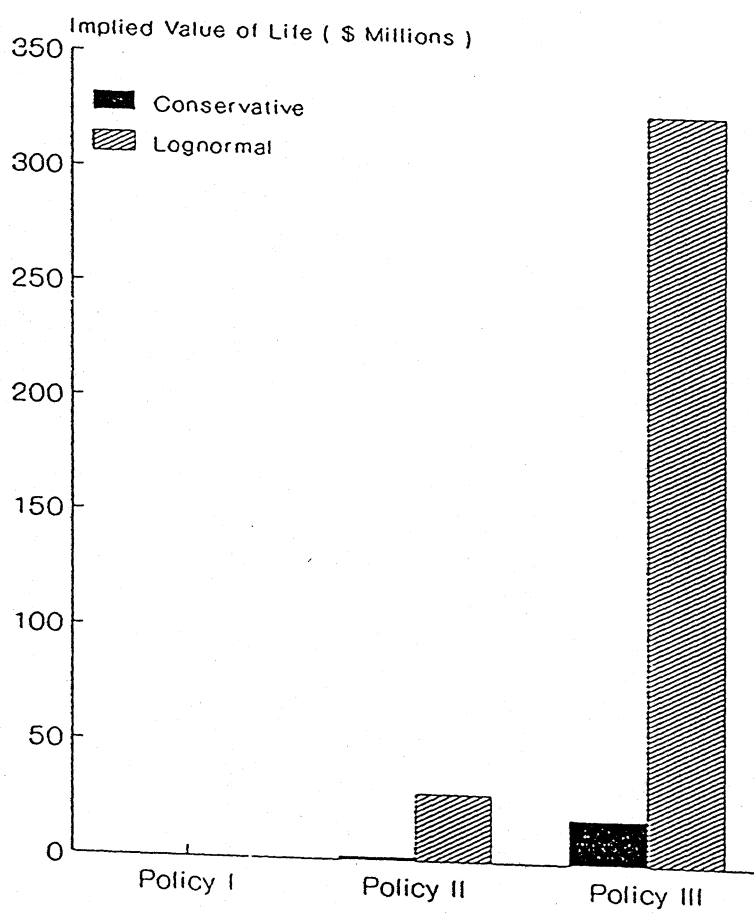For Conservative and Lognormal Estimates

Figure 3

APPENDIX

The following notes describe aspects of the dose-response and exposure estimates used in the health risk assessments.

Dose-Response. The linear animal potency approximation at low doses, b, can be derived from any of the common risk assessment models. For the one-hit model expressed in the manner of Crouch et al., this can be seen from the McLaurin Series for $\phi(x) = e^x$:

$$\phi(x) = \phi(0) + x \, \phi'(0) + x^2 \, \phi''(0)/2! + x^3 \, \phi'''(0)/3! + \ldots$$

$$= e^0 + e0 \, x + e^0 \, x^2/2! + \ldots$$

$$= 1 + x + x/2! + \ldots \quad .$$

which implies that the one-hit model can be approximated at low doses as:

$$\text{Risk} = 1 - (1 - \alpha) \exp[- b \, D / (1 - \alpha)]$$

$$\simeq 1 - (1 - \alpha)(1 - b \, D / (1 - \alpha))$$

$$= \alpha + b \, D$$

where D is dose. The risk at zero dose is α, so b times D represents "extra risk" due to the hazardous substance. The linearized extra risk b is known as the carcinogenic potency, representing excess lifetime cancer incidence in a population caused by an average daily dose. The approximation works as long as all individual doses in the population are small. The usual assumption is that if D is expressed in mg per kilogram of bodyweight per day lifetime average exposure, then b is roughly independent of species.

Chlordimeform animal potency data are based on a typical ingestion study of four groups of mice--a control group plus groups at three feeding concentrations. The standard statistical models for quantitative health risk

assessment—the One-Hit, Multistage, and Weibull models—have been fitted to these data by Crump. The choice among these various statistical models is considered somewhat arbitrary. We use the parameters fitted by the One-Hit model

$$\text{prob(tumor)} = 1 - \exp(- q_0 - q_1 \, f),$$

where f is the feeding dose received by the mice in milligrams per kilogram per day. The median animal potency estimate is derived as follows: use Crump's one-hit estimate of risk with the highest dose omitted, so

$$\text{risk} = 1 - \exp(- q_0 - q_1 * \text{dose})$$

$$= 1 - \exp(-.015 - .02 * \text{dose})$$

where dose has been converted from ppm in diet to mg/kg of bodyweight, using Crump's assumed equivalence 1 ppm = .1 mg/kg.

To linearize this for low doses, we require

$$1 - \alpha = \exp(- q_0)$$

so
$$\alpha = 1 - \exp(-q_0)$$

and
$$b \,/\, (1 - \alpha) = q_1$$

or
$$b = (1 - \alpha) \, q_1$$

$$= q_1 * \exp(- q_0).$$

In our case
$$\alpha = 1 - \exp(-.015) = .019$$

and
$$\beta = .042 * \exp(-.015) = 4.1 * 10^{-2}.$$

We note that if the highest dose were included b would have a similar value, $3.4 * 10^{-2}$.

Estimates of the animal potency factor b will in general vary significantly from one group of test animals to another, in part because of small sample size. The interspecies extrapolation factor K is only poorly understood, although it has been studied in general through comparisons of

identical tests on different animals, such as mice and rats. The high to low-dose extrapolation factor E is subject to the greatest controversy, the primary issue being whether to extrapolate linearly downward, or utilize some type of sublinear model implying a threshold effect in the dose-response relationship.

Exposure Factors. Dermal absorption is estimated by EPA to be .3. The agency provides no information on which to base a variance estimate. It is possible that .3 is a conservative estimate which should be treated as an upper confidence interval, but this is not specified.

Factor 6, the ratio of actual to potential exposure, reflects the effectiveness of safety clothing in preventing pesticide from reaching the skin. The EPA estimates that safety clothing and equipment reduce this value by 1/3.6 or 72%. Again, no evidence is available for assigning a variance to the log variable.

For annual exposure to the two occupational groups, the following procedure was used. The median or "unbiased" values are based on field tests undertaken by the Worker Health and Safety Division of the California Department of Food and Agriculture (CDFA). The CDFA measurements suggest annual exposure of .03 mg/kg for mixers-loaders, and .1 mg/kg for pilots, when safety equipment and clothing are used. Multiplying by 3.6, the EPA factor for the absence of safety clothing and equipment gives the figures in Table 1.

EPA estimates were taken to be "conservative". These figures were 10.3 mg/kg for mixers-loaders and .2 mg/kg for pilots, when safety clothing and equipment were used. Multiplying by 3.6 for the absence of such gear gives values of 37.1 and .72 respectively. These conservative estimates are assumed to lie two standard deviations to the right of log mean values. Thus the

standard deviation of the log variable for mixers-loaders, for example, must be 2.92, so that two standard deviations out we obtain a risk of $\exp((-2.23 + 2 * 2.92)) = 37.1$.

Factor 7, years of employment, is handled in similar fashion. A lower figure, 10 years employment, used both by Crump and by the manufacturers, is taken as a median value, while the conservative EPA figure of 40 years is assumed to lie two standard deviations of the log variable above the median.