Invited Presentation

Pesticide Regulation and the Rule-making Process

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In previous work (Cropper et al.), we examined the U.S. Environmental Protection Agency's (EPA's) decision to cancel or continue the registration of pesticides that went through its Special Review process between 1975 and 1989. Our focus in that paper was on the final decision (Notice of Final Determination) issued by the EPA at the end of the rule-making process. Specifically, we asked whether this decision could be explained by the reported risks and benefits associated with pesticide use, and by the comments of special-interest groups that were entered in the public docket.

In this paper, we examine more closely the stages of the rule-making process: We seek to explain the *proposed* decision issued by the EPA, and we examine how this decision was modified to arrive at a final decision. In the rule-making process, a proposed decision is issued after the EPA completes its risk-benefit analysis of a pesticide, but before the public is given a chance to comment formally. We wish to see if the proposed decision can be explained by the risks and benefits of pesticide use, as measured at the time of the proposed decision. We also wish to determine whether interest groups that subsequently comment publicly on the regulation appear to exert an influence on the *proposed* decision.

The second set of questions we examine deals with changes that occur between the proposed and final decisions. In the set of pesticide decisions we examine, 39% of the initial decisions to cancel and 16% of the initial decisions to continue pesticide usage were reversed. If the rule-making process works as it is supposed to, reversals should occur because of information entered in the public docket during the official comment period or because of revisions in the EPA's estimates of the risks and benefits of pesticide use. The main question of interest here is whether the final decision can be viewed as a modification of the proposed decision, either by new information or by the comments of special-interest groups, or whether the final decision is rethought in light of all available information, implying that the weights assigned to risks and benefits also change.

A third issue that we examine is what causes the EPA's estimates of risks and benefits to change between the proposed and final decisions. Because there are substantial changes in benefit and, especially, in risk data between the two decisions, and because so many decisions are reversed, one might wonder if the changes in data are prompted by a desire to justify a reversal of the proposed decision. We are happy to report that this does not appear to be the case.

An Overview of the EPA's Pesticide Registration Process

In its 1972 amendments to the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), Congress required the EPA to reregister the approximately 40,000 pesticides previously approved for sale in the United States. In the 1978 amendments to FIFRA, this task was simplified by requiring reregistration of the 600 active ingredients used in all these pesticides, rather than the pesticides themselves.

Reregistration of each active ingredient requires assembling the data necessary to evaluate whether the active ingredient causes "unreasonable adverse effects on the environment" for each use for which the substance is registered. If, in the process of collecting this data, it is determined that the active ingredient poses sufficient risks to humans or animals, the active ingredient is put through a Special Review process. The purpose of the process is to determine whether the risks posed by the active

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Table 1. Active Ingredients in the Pesticide Data Base

Active Ingredient	Year	Number of Food-Use Registrations	Number of Proposed Cancellations	Number of Final Cancellations
DBCP	78	12	1	12
Amitraz	79	2	1	1
Chlorobenzilate	79	3	2	2
Endrin	79	8	4	4
Pronamide	79	4	0	0
Dimethoate	80	25	0	0
Benomyl	82	26	0	0
Diallate	82	10	10	0
Oxyfluorfen	82	3	0	0
Toxaphene	82	11	7	7
Trifluralin	82	25	0	0
EDB	83	18	4	18
Ethalfluralin	83	3	0	0
Lindane	83	8	7	0
Silvex	85	6	6	6
2, 4, 5-T	85	2	2	2
Dicofol	86	4	4	0
Alachlor	87	10	3	0
Captan	89	65	65	44
Totals		245	116	96

ingredient are outweighed by the benefits of its use.

The results of the risk-benefit analyses are published in what are known as Position Documents 2 and 3 (PD 2/3). At the end of PD 2/3, the following regulatory outcomes are considered for each use: (1) cancellation of registration; (2) suspension of registration; (3) continuation of registration, subject to certain restrictions; (4) unrestricted continuation of registration.

Publication of PD 2/3 is followed by a comment period, during which members of the public, including growers, public-interest groups, and registrants, can respond to the proposed regulations. If cancellation or restrictions on use are contemplated, the U.S. Department of Agriculture (USDA) and the EPA's Scientific Advisory Board are asked to review the risk-benefit analyses. Final regulatory decisions, together with the names of commenters, are published in Position Document 4 (PD 4), which becomes law unless a hearing is requested by interested parties.

Between 1975, when the Special Review process was initiated, and 1989, a total of 68 Special Reviews were begun (U.S. Environmental Protection Agency). Of these, 18 ended at the pre–Special Review stage, 37 had been completed by December 1989, and 13 were ongoing. Our study focuses on a subset of the 37 completed reviews, that is, those that both involve pesticides used on food crops and are suspected human carcinogens. We focus on this subset because health risks other than risk of cancer are seldom quantified, which makes a quantitative analysis of regulatory decisions difficult.

The set of cancer-causing food-use pesticides that have gone through Special Review is listed in Table 1. Note that although there are only 19 such pesticides, they were registered for use on a total of 245 crops. What we shall try to explain is the decision to cancel or not cancel each of these uses.[1]

Factors Influencing the Proposed Cancellation Decision

The decision to cancel a pesticide registration is to be made by weighing the benefits of pesticide use against the risks that pesticide use poses to humans and to the environment. We therefore assume that the probability that pesticide i will be proposed for cancellation for use on crop j is an increasing func-

[1] Of the 245 final decisions in our data base, 39% represent cancellations, 4% suspensions of registration for failure to provide data, 5% unrestricted continuations, and 52% continuations with restrictions. The types of restrictions typically imposed consist of measures to protect pesticide mixers and applicators, such as requiring that protective clothing be worn, or replacing human flaggers with mechanical ones. These decisions are to be made by comparing the risks and benefits of the restrictions; however, the position documents typically do not contain enough data to permit an analysis of each restriction. For this reason, we consider only two regulatory outcomes: continuation of registration (with or without restrictions) or cancellation. Suspensions for failure to provide data are grouped with continuations, since registrations are continued as soon as the data are provided.

tion of the vector of risks of pesticide use, $\mathbf{R}_{ij}$, and a decreasing function of the vector of benefits, $\mathbf{B}_{ij}$,

$$(1)\ P(cancel_{ij}) = P(\alpha_1\mathbf{R}_{ij} + \alpha_2\mathbf{B}_{ij} + u_{ij} \geq 0),$$

where α_1 and α_2 are vectors of weights attached to risks and benefits, and u_{ij} is a random error term capturing unmeasured risks and benefits.

For the substances in Table 1, risks include the excess lifetime risk of cancer to pesticide applicators, to mixers of pesticides, and to consumers who ingest pesticide residues on food.[2] These risks are reported as the number of cancer cases per million exposed persons. For example, it is estimated that 70 persons out of every 1 million persons who eat almonds sprayed with benomyl (for 70 years) will develop cancer at some time during their life.

To calculate the total number of cancer cases that are estimated to result from pesticide use, this risk number must be multiplied by the size of the exposed population. For most dietary risks, the entire U.S. population is assumed to be exposed. Since this number is constant for all pesticide/crop combinations, it does not matter whether we use risk per million exposed persons or total number of cancer cases as an independent variable. Although the number of persons who either mix or apply the pesticide in question does vary across pesticide/crop combinations, the size of these populations is rarely reported. We therefore assume that the applicator and mixer populations are constant across all observations.

An additional problem is that risk estimates are sometimes not reported for one of the three groups. In earlier work, we handled this problem by recording a value of zero whenever risk data were missing and then using a dummy variable to indicate that the data were in fact missing. The coefficients of the missing risk dummies were, however, not significantly different from zero, implying that missing risk information is treated as being equivalent to zero risk. In the work reported here, we have, therefore, omitted the missing risk dummy variables.

Pesticides also pose risks to fetuses and may cause genetic mutations. Because these risks are inherently difficult to quantify, we resort to a dummy variable to indicate that a risk may cause adverse reproductive effects. Danger to nontarget animals (fish, birds) is likewise handled by a dummy variable that is equal to one if the pesticide poses risks to marine life.

The benefits of pesticide use should, ideally, be measured as the streams of consumer and producer surpluses that would be lost if the pesticide were banned. In practice, producer surplus is reported more often than consumer surplus, and it is most often reported for the year immediately following cancellation. Our estimate of benefits is therefore lost producer surplus in the year after proposed cancellation, measured in 1986 dollars. When producer benefit data are missing, we record whether banning the pesticide is or is not likely to result in yield losses.[3]

Column 2 of Table 2 presents maximum-likelihood estimates of equation (1), assuming that the error term u_{ij} is independently and identically normally distributed for all pesticide/crop combinations. The results are not very comforting. Although increases in dietary risks significantly increase the likelihood that a pesticide will be proposed for cancellation, risks to applicators—the group receiving the highest per capita dose of pesticides—are not statistically significant. Risks to mixers are statistically significant, but of the wrong sign: an increase in risk of cancer to mixers reduces the chances that a pesticide is proposed for cancellation. It is also surprising that adverse reproductive effects do not increase the likelihood that a pesticide is proposed for cancellation.

There are similar anomalies in the effect of producer benefits on the probability of proposed cancellation. As expected, an increase in producer benefits, when benefits are quantified, reduces the probability of proposed cancellation. The absence of benefit data, however, also decreases the chances of proposed cancellation, even if cancellation of the pesticide will not reduce yields.

Examination of the data suggests that it is two pesticides—DBCP and EDB—that are responsible for these anomalous results. The problem is that both pesticides posed very high risks of cancer to applicators and mixers, and also caused adverse reproductive effects. In the proposed decision, however, the EPA declined to ban DBCP and EDB in most uses (see Table 1). If the EPA had, in fact, initially proposed to ban DBCP and EDB on all crops, the anomalous results in column 2 of Table 2 would disappear. This is illustrated in column 3 of Table 2, in which equation (1) has been reestimated assuming that all uses of EDB and DBCP

[2] The assumptions used by the EPA in calculating these risks are described (and criticized) in Cropper et al. In the analysis reported here, we take the EPA's estimates at face value, on the grounds that these risk estimates are those seen by policymakers.

[3] Means and standard deviations of all risk and benefits variables, at the time of the final decision, are reported in Cropper et al., Table 2. Variable means and standard deviations at the time of the proposed decision are reported in column 1 of Table 2.

Table 2. Probit Results, Proposed and Final Decisions

		Parameter Estimates and t-Statistics[b]				
Variable	Means and Std. Dev.[a]	Proposed Decision	Proposed Decision[c]	Proposed Decision[c]	Final Decision	Final Decision
Intercept	—	0.11	−0.24	−0.52	−0.88	−1.38
		(0.48)	(1.05)	(1.22)	(5.29)	(1.90)
Diet Risk per Million	497.5	0.01	0.55	0.20	—	4.3E-3
Persons	(2570.4)	(2.34)	(3.08)	(1.22)		(2.17)
Applicator Risk per Million	3064.1	1.3E-5	4.1E-4	6.9E-4	—	6.5E-4
Persons	(13553.3)	(0.75)	(3.82)	(4.88)		(2.65)
Mixer Risk per Million	155.4	−0.03	—	—	—	2.9E-3
Persons	(741.7)	(1.84)				(0.19)
Producer Benefits (in	11.14	−0.08	−0.02	−0.02	—	−0.07
millions of 1986 $)	(42.22)	(4.74)	(2.38)	(2.43)		(2.75)
Producer Benefits Missing	0.14	−1.59	−1.32	−1.24	—	−2.40
× Yield Loss	(0.34)	(4.93)	(4.27)	(2.80)		(5.34)
Producer Benefits Missing	0.13	−1.47	−1.24	−0.46	—	−0.68
× No Yield Loss	(0.34)	(4.63)	(3.98)	(0.97)		(1.06)
Reproductive Effects	0.68	−0.17	0.41	−0.30	—	0.50
	(0.47)	(0.76)	(1.82)	(0.81)		(1.29)
Danger to Marine Life	0.52	1.00	0.39	−0.49	—	−0.75
	(0.50)	(4.74)	(1.77)	(1.35)		(1.40)
$X'_4\hat{\beta}_{23}$	—	—	—	—	0.01	—
					(3.63)	
Academics Comment	—	—	—	−1.48	−1.25	−1.85
				(3.22)	(4.88)	(3.50)
Growers Comment	—	—	—	1.46	−1.52	−1.92
				(2.68)	(3.02)	(2.49)
Environmental Groups	—	—	—	2.93	1.63	3.33
Comment				(6.95)	(7.33)	(6.12)
Log-likelihood	—	−108.3	−98.8	−48.7	−105.9	−48.1
% Correctly Predicted	—	80.2	82.2	93.0	78.9	93.4

[a]Standard deviations are in parentheses. These descriptive statistics were calculated from data available at the time of the proposed decision and for only those observations where data were not missing.
[b]t-statistics are in parentheses.
[c]With EDB and DBCP assumed to be banned at the time of the proposed decision.

were banned at the time of the proposed decision. There is, in fact, some justification for making this assumption. Immediately after its proposed decision on DBCP, the EPA ordered an emergency suspension of DBCP on all crops. The EPA also ordered an emergency suspension of EDB on all crops between the proposed and final EDB decisions.[4] All uses of EDB and DBCP were banned in the final decisions.

Treating all uses of EDB and DBCP as banned significantly increases the magnitude of the effects of dietary risk and applicator risk in the proposed decision.[5] In interpreting these coefficients, one must remember that the population of persons exposed to dietary risks is much larger than the population of pesticide applicators. Using the coefficient on producer benefits to convert the dietary and applicator risks to implied values per cancer case avoided yields an implied value of $9 million (1986$) for consumers and $72 million (1986$) for pesticide applicators.[6] Treating EDB and DBCP as initially banned also reverses the sign on reproductive effects and renders it statistically significant at the 5% level.

One question of interest is whether groups such as grower organizations or environmental advocacy groups exert any influence on the EPA's proposed decisions. Because contact between the EPA and special-interest groups was not a matter of public record until 1985, it is difficult to establish whether any interaction between interest groups and the EPA occurred prior to the proposed deci-

[4] We have anecdotal evidence that the EPA considered ordering an emergency suspension of all EDB uses in October 1977, three years before the proposed decision on EDB.

[5] Mixer risk must be dropped from the equation when all uses of EDB and DBCP are treated as banned, because a pesticide is always banned whenever mixer risk is positive. The coefficient of mixer risk therefore approaches infinity.

[6] The details of this calculation are described in the appendix to Cropper et al.

sion. It is, however, possible to see whether special-interest groups that lodged comments in the public docket following the proposed decision appear to have influenced that decision. To examine this, we include in equation (1) intervener dummy variables equal to 1 if any member of the group in question lodged comments during the public comment period. Since these comments were made after the proposed decision, the only reason for including them in the proposed decision equation is because they are *suggestive* of activities that may have occurred before the proposed decision was issued. The fact that subsequent comments by environmental advocacy groups increase the changes of a proposed cancellation suggests that these groups may have exerted some influence on the proposed decision. The positive sign on comments by grower organizations, however, suggests reverse causality: a proposed ban induces grower organizations to comment.

Why Do Pesticide Decisions Change?

The models presented in the previous section do a fairly good job of explaining the EPA's proposed decision to ban or not to ban a pesticide. What is notable, however, is how many proposed decisions are reversed at the end of the public comment period. If we treat EDB and DBCP as initially banned, all reversals are in one direction: decisions to initially ban a pesticide are reversed to allow the pesticide to be used. Indeed, 45 of the 116 proposed decisions to ban a pesticide were reversed. Why did this occur?

One explanation may be revealed in Table 3, which describes the changes that occurred in risk and benefit information between the proposed and final decisions. Fully one-half of the estimates of dietary risk changed between the two decisions, as did 29% of the estimates of applicator risk and 21% of the estimates of producer benefits. If changes in information alone could explain reversals of decisions, one would expect the model in column 3 of Table 2 to provide good predictions of the final decision, assuming that the values of the independent variables were updated to reflect new information. (We label this predictor $X_4'\hat{\beta}_{23}$, since it uses weights from the PD 2/3 model, but values of the independent variables from PD 4.) This model, however, correctly predicts only 63% of final decisions.

Another factor that should matter is the comments of special-interest groups. Intervener dummy variables, together with the predicted value of the decision, $X_4'\hat{\beta}_{23}$, are used in column 5 of Table 2 to explain the final decision. Even adding commenters to the equation does not produce a model that predicts very well: The model in column 5 predicts only 79% of the final decisions correctly.

This suggests that commenters and changes in risk and benefit estimates alone cannot explain the final decision. What must be happening is that the weights attached to risks and benefits change the proposed and final decisions. This hypothesis is examined by estimating a model that allows the weights attached to risks and benefits in the final decision to differ from the weights used in the proposed decision.

This model, which appears in column 6 of Table 2, clearly outperforms the naive model of column 5: it predicts 93% of the proposed decisions correctly. Moreover, a test of the null hypothesis that the weights on risks and benefits in the final decision (column 6) are identical to those in the proposed decision (column 3) can be rejected at the 5% level.

What is interesting is not simply that the weights change, but also the direction in which they change. In column 6, the implied value per cancer case avoided is only $21,000 (1986$) for dietary risks and $35 million (1986$) for applicator risks, a sharp decline when compared to the values implied by the proposed decision. This, however, does not seem surprising. After subjecting a pesticide to Special Review, it would, perhaps, seem surprising if the EPA was not disposed to ban it. Anecdotal evidence about the influence wielded by environmental groups at the EPA during the period studied lends support to this hypothesis. The final decision, on the other hand, reflects the outcome

Table 3. Change in Risk and Benefit Data between Proposed and Final Decisions

Percent of Observations Where:	Diet Risks	Applicator Risks	Mixer Risks	Producer Benefits
There is no change in information	49.6%	71.1%	93.0%	78.9%
Data that is originally missing is known	11.6%	14.0%	7.0%	4.6%
Data that is originally known is considered missing	0.0%	0.8%	0.0%	8.3%
Values are increased	12.4%	8.7%	0.0%	4.5%
Values are decreased	26.4%	5.4%	0.0%	3.7%

of a political process in which those who may be hurt by the regulation have an opportunity to be heard. Sensitivity to such groups may explain the increased weight given costs relative to benefits in reaching a final decision.

Why Do Risk and Benefit Estimates Change?

A final issue that we address is what causes risk and benefit information to change between the proposed and final decisions. Although changes in information do not appear to be the main factor explaining reversals of decisions, it would be disturbing if information was altered to justify a reversal of decision. To test the hypothesis that information did not change randomly, we regressed the difference between the PD 4 and the PD 2/3 values of each risk variable on commenter dummies and a variable equal to 1 if there was no change in decision between PD 2/3 and PD 4 and equal to 0 if the PD 2/3 decision to ban the pesticide was reversed at the PD 4 stage. (A similar regression was run for the change in producer benefits.)

No systematic pattern emerges from the change in data regressions. Commenter dummies are often significant, but of the wrong sign. The change in decision variable is never significant at conventional levels.

Conclusions

In our earlier work, we were encouraged by the fact that the EPA appears to have balanced the risks of pesticide use against the benefits in reaching a final decision to cancel or continue a pesticide. The results reported here are similarly encouraging. Risks and benefits appear to be balanced in reaching a proposed decision, although the initially high values placed on small risk reductions decline by the time a final decision is issued. Moreover, the large number of changes that occur in risk and benefit estimates between the two decisions cannot be systematically explained either by the intervention of special-interest groups or by the desire to justify a change in decision. These results suggest that the rule-making process works.

This is not to suggest that pesticide decisions could not be improved upon. We emphasize that the estimates of risks and benefits used in our study are those reported by the agency in its position documents. The limitations of these estimates are well known. Moreover, the practice of evaluating pesticides one at a time introduces the possibility that a suboptimal decision may be made, compared to a world in which a class of substitutes is considered simultaneously. These, however, are matters that the agency appears to be attempting to remedy.

References

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