

A CROSS-DISCIPLINARY¹ APPROACH TO RISK ANALYSIS IN PUBLIC POLICY: WITH APPLICATIONS TO FOOD AND AGRICULTURAL POLICY, FOOD SAFETY, AND AFFIRMATIVE ACTION

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The paper develops a framework to understand the risk trade-offs involved in public policy making. The concepts from statistical hypothesis testing are utilized to assess the risks involved as well as the concept of zero tolerance. It is intended for use by public policy makers, the general citizenry, and students to better understand the risk tradeoff. Examples from drug testing, pesticide residue, the greenhouse effect, affirmative action, and project analysis are employed to illustrate cross-disciplinary nature of the framework. It concludes with a food safety case.

Public policy permeates modern life and impacts all of us. Environmental regulation, prevention of monopoly power in product and resource markets, public health, plant and animal health, and economy-wide policies such as government revenue, taxation and interest rate, as well as public sector projects. One factor all of these have in common is risk, that is, decisions are required without complete information about the present or the future. Public policy making involves the assessing the risks of various courses of action and deciding where to draw the line. For example, safety of the nation's food supply requires weighing the risk and costs of making the standard so high that safe foods are declared unsafe, or too low, which adversely effects health.

Public policy makers, the general citizenry, and students, who will one day be both, need a conceptual framework to understand the tradeoffs. The framework must be cross-disciplinary so that it is applicable to a variety of disciplines, and thus issues.

For several years the principle author has taught statistics. Teaching hypothesis testing, the risks involved, and the trade-off between errors in drawing inferences are essential elements in this field. Because these are difficult concepts for students, examples are employed to illustrate these. The course "California and World Agriculture" includes a section on the role of risk in policy making. After several years of utilizing public policy examples in the statistics course, the author employed the statistical discussion to make concrete the idea of risk tradeoffs involved in the public policy arena.

This paper presents the risk analysis initially employed in the statistics course and modifies it for policy analysis. It first discusses the trade-off between the errors in statistical testing and provides several examples. It then proceeds to analyze the role of zero tolerance. It concludes with a food safety case study. These provide a mechanism to enhance policy makers', the citizenry's, and students' awareness of the role of risk in formulating, implementing, and evaluating public policy.

Conceptual Framework: Risk Tradeoff

The initial step in statistical hypothesis testing is to establish the null and alternate hypothesis: two opposite statements about the actual situation. The American justice system

¹ The article is cross-disciplinary because the method employed in this study is applicable to any discipline.

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provides an example. The null hypothesis is that the person is innocent and the alternative hypothesis is that the individual is guilty. The key criterion for establishing the null is that it is assumed to be the case unless there is overwhelming evidence to not accept the null (and accept the alternative as being true) (This usually lies somewhere between the criteria in a criminal case that the evidence provides proof of guilt "beyond a reasonable doubt" and that of the "preponderance of evidence" in a civil court). In our justice system the suspect is assumed innocent unless proven otherwise. In the justice system the burden of proof is on the prosecution to prove that the suspect is guilty: the defense is not required to prove the client innocent (s/he must only cast doubt on the prosecutor's case). Because hypotheses are tested to aid in deciding on a course of action, an action corresponds to each hypothesis. If the jury rules in favor of innocence, then the course of action is to not incarcerate the individual (usually to "do nothing" or "no action is necessary" in most applications); otherwise the defendant faces a penalty. In severe cases "hanging" is the action.

The development of risk tradeoff commences with the errors that can occur from the testing. There are two possible correct decisions and two incorrect ones. The first incorrect decision is known as the Type I error and occurs when the conclusion is that the null hypothesis is false (the alternate is accepted as being true) when the null hypothesis in reality is true (i.e. should have been accepted as being true). The other is accepting the null to be true (the alternate is false) when it is false (the alternative is true). In either case the acceptance and non-acceptance are the decision alternatives.

In the justice system, the Type I error is to conclude that a person is guilty (the null hypothesis of innocence is false) when that individual is innocent (should have accepted the null). This incorrect decision leads to the hanging of a person who is actually innocent. The Type II error results in the freeing of a guilty person because the jury renders a verdict of innocence (accepts null of innocence) for a defendant who is actually guilty (should have concluded that the null of innocence is false/accepted the alternative hypothesis of guilty).

In order to decide whether or not to accept a null hypothesis, it is necessary to decide how much risk one is willing to take in making a wrong decision, that is, the maximum risk of being incorrect that can be tolerated. This is known as the tolerable error. For the Type I error it is α , the Greek letter alpha. The probability of making the Type II error is the Greek letter beta, β . To illustrate, use $\alpha = 10\%$ and $\beta = 20\%$.

As in statistics, the focus is on α . After examining the evidence, one will only conclude that the null hypothesis is false, if the probability of doing so, and being incorrect (i.e., making the Type I error - remember that the Type I error involves a decision that the null hypothesis is false) is within α , the tolerable limit for the Type I error. Employing $\alpha = 10\%$, the jury will only render a guilty verdict (not accept the null of innocence) if the risk of doing so and being incorrect (making the Type I error) is 10% or less. If the probability of hanging an innocent person, α , is too high (above 10% in this example), then the jury renders a verdict of innocence (accepts the null of innocence).

If the verdict is innocent (the null is accepted) the probability remains that a guilty person has been freed (Type II error with a probability of β). No matter what decision is made, the risk that the decision is incorrect always exists.

A tradeoff exists because, in the short run, α can only be reduced (increased) by increasing (reducing) β . For example, in criminal cases assume a person is considered guilty if a minimum of 10 jurors vote so (in actuality a unanimous vote of guilty is needed for conviction - part of the "beyond a reasonable doubt" criterion). If the public decides that too many innocent people are being hanged (α is too high), it changes the requirement to 11 guilty votes. This reduces the probability of hanging innocent people by making it more difficult to convict. However β , the probability of letting a guilty person go free, increases. So α decreases, but β increases.

The risk tradeoff is a short-run phenomenon. Both risks can be reduced in the public policy arena in the longer run as new information and technologies are developed.

Application: Policy Examples

Public Health - Drug Testing: When testing any medicine, whether for humans or for animals, two sets of hypotheses are important. The first is whether or not the drug is effective, and the second is to test whether or not negative side effects accompany its use. The focus here is on the second. The null is that the drug is safe, i.e. it has no side effects, because it is assumed it is safe until shown to be otherwise. The alternative then is that it is safe. The first error is to conclude that the drug is safe when it has negative side effects. In this case the FDA would withhold the (safe) drug from the market. The other risk is to approve a drug that has side effects because the test results lead the researchers to incorrectly conclude that the drug is safe. The reduction of one type of error causes an increase in the other. The decision of where to draw the line is sometimes influenced by public pressure in heavily publicized cases.

In the late 1950s Thalidomide, a fertility drug, was approved for human use. Unfortunately, its use sometimes lead to dramatic birth defects such as children born with hands or feet, but without arms or legs. The outcry over this side effect lead to tightening of testing procedures to make it more difficult to approve a drug and to prevent similar dire consequences in the future. In other words, it reduced β , the probability of marketing an unsafe drug. However in doing so, it increased the probability of α , that a safe drug would be withheld from the market. Thus individuals that could be cured or aided by a safe, new drug would not gain access to it. This was the cost of tightening the requirement for approving a safe drug.

Pesticide Safety: An analogous situation involving food and agricultural policy is that of pesticide residue. The null and alternate hypotheses are:

Ho: Pesticide Residue Is Not A Health Hazard
Ha: Pesticide Residue Is A Health Hazard

The Type I error is incorrectly conclude that pesticide residue is a health hazard while the Type II one is to erroneously conclude that it is safe. For the former, the burden falls on growers as they suffer financial losses when required to withhold a safe product from the market. The public's health is at risk in the latter. In regulating pesticide residue, the policy makers must weigh the risks involved and decide where to set the standard. Too stringent a standard increases the probability of the Type I error and too lax a standard reduces it. Air and water purity standards provide similar examples.

Environmental Regulation - Green House Effect: Another example, which also greatly affects the food and agricultural system, is the controversy over the "greenhouse effect". Because the it is assumed that the effect does not exist unless scientific evidence demonstrates otherwise, the null hypothesis is that it does not exist. The Type I error then is to conclude that the greenhouse effect exists when it actually does not, while the Type II leads to the opposite mistake. The cost of an incorrect conclusion is extremely high, even disastrous in the latter. The Type II error leads global society to not take action to prevent the greenhouse effect when it should. This leads to the destruction of life as we know it on this planet. The opposite error results in fighting a nonexistent greenhouse effect. To prevent the greenhouse effect entails a radical change in our economy and in our living styles, which is also extremely costly. Those that believe in the non-existence of the greenhouse effect focus on lowering β . They believe that more evidence should be gathered before concluding that it exists. Those that believe in the effect argue that to gather more evidence would require more time, and by the time it would be known with a higher probability of accuracy, it would be too late to reverse it. They are arguing then that to wait would increase α .

Social Policy - Affirmative Action: Utilizing the above to analyze the affirmative action controversy further demonstrates its true cross-disciplinary nature. There are many elements

in the affirmative action controversy and this covers just one element. It occurs when a person who is a minority, either ethnic or gender, seeks employment. The hypotheses are

Ho: A Minority Is Not Qualified

Ha: A Minority is Qualified

The burden of proof is on the individual to show that s/he is qualified and thus the alternative hypothesis. The Type I error is that the individual is incorrectly judged to be qualified and the Type II is that a qualified individual is judged to not be qualified. Because the second error was occurring too much, either through explicit or implicit discrimination, affirmative action was instituted to counter this social injustice. Doing so unavoidably increases the occurrence of the first error. Many of the opponents of affirmative action believe that this is prevalent enough to warrant eliminating affirmative action (Note that there are a variety of reasons why affirmative action is supported or opposed.) Although the passage of Proposition 209 will decrease the probability that an unqualified minority will be hired, it will increase the probability that a qualified minority will not. A thorough analysis of this element of the issue requires empirical measures of the two probabilities.

Generic: The next example is generic in that it is applicable to any public policy or any public or private sector undertaking.

Ho: Do Not Undertake a Project or Policy

Ha: Undertake a Project or Policy

Analysis of errors and tradeoffs are left to the reader. Examples include environmental projects or any project with environmental consequences, developing and marketing a new product, expanding operational capacity, development projects in less developed countries, and infrastructural development such as road, communication, water or irrigation systems.

Conceptual Framework: Zero Risk Tolerance

Tolerable risk is the minimum acceptable risk for making a decision. As the tolerable level approaches zero, the hypothetical cost of doing so increases at an increasing rate, and approaches the zero tolerance level asymptotically (approaches, but never equals zero). It can alternatively represent the cost of the Type II error as tolerance for the Type I error approaches zero, or for the Type I as the Type II approaches zero.

The follow case study illustrates both the trade-off in α and β and the use of zero tolerable error.

Case Study: Food Safety

The complex issues associated with food safety concerns are becoming increasingly important in a dynamic world. The introduction of new and improved agricultural chemicals and the technological improvements made in the detection of "carcinogenic" materials in our food supply have made the topic of food safety a more complicated one.

In response to increasing concern about food safety a provision was included in the Food Additives Amendment of 1958 that became known as the Delaney Clause. It stated that "no additive shall be deemed to be safe if found to induce cancer when ingested by man or animal, or if it is found after tests that are appropriate for the evaluation of the safety of food additives, to induce cancer in man or animal" (Knutson et. al., 1995, p. 410-411).

At the center of the debate involving food safety lies the question, "Should the Delaney Clause be reformed to take into account the technological advancements made in the last forty years or should the Delaney Clause stand solid as the best form of defense against unsafe food?"

Currently, there are four basic levels of tolerance used to differentiate the risks associated with food safety. The first, and most severe, is *zero tolerance*, which advocates that "...products should be completely devoid of...harmful substances that have been directly or indirectly added to the food supply" (Knutson et. al., 1995, p. 410). The second, and less drastic label is of *negligible* or *de minimus risk*. "The de minimus tolerance option suggests that extremely small risk (products containing one part per million, meaning a product cannot cause more than one additional death per one million people) can be ignored" (Knutson et. al., 1995, p. 412). Because of the unworkable nature of the Delaney Clause, the FDA adopted de minimus tolerance for enforcement of Delaney issues involving food additives. The *no significant risk* classification is the third tolerance level associated with food safety. This classification is given to those products containing one part per one hundred thousand and allows a higher level of risk than the FDA permits. Lastly, "the *risk-benefit* approach requires that a pesticide must accomplish its intended effect without '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" (Knutson et. al., 1995, p. 412).

Reform advocates argue that developments in chemical residue detection warrant changes in the Delaney Clause. In addition, the Delaney Clause ignores what supporters of its reform say are essential issues concerning the substitution of one risk for another and the agricultural benefits rendered from the use of chemicals. When the Delaney Clause was established, scientists had only "crude risk-assessment techniques at their disposal" (Snow, 1995, p. 11B) therefore only allowing the detecting of chemical residues in parts per thousand. Today, however, scientists can detect those same substances in parts per billion, trillion and beyond" ("Congress Sets Sights on Delaney Reform", 1995, p. 2). These technological advancements pose a large problem in the enforcement of the Delaney Clause.

Advocates of Delaney reform also point out that the benefits rendered from the use of chemicals are not included in the assessment and enforcement of the Delaney Clause. The "zero" risk standard "...does not allow an assessment of any possible agricultural benefits from the use of pesticides" ("The Delaney Clause Effects on Pesticide Policy", 1995, p. 1). In addition, the strict enforcement of the Delaney Clause could also "...force farmers to abandon innovative biological control programs because they would have to replace targeted products, which they use in small amounts, with higher doses of less effective chemicals" ("Congress Sets Sights on Delaney Reform", 1995, p. 1). In this situation, the elimination of one risk (a product targeted by the Delaney Clause, only used in small amounts) would be placed with another (a chemical, used in higher doses) without any possible benefits from the original chemical impacting the decision. Finally, the strict enforcement of the Delaney Clause has a definite negative impact on American farmers. It is problematic whether American farmers can compete on the world market if they are forced to comply with an impossible standard that no other country in the world has even considered.

Opponents of reform argue that although America has the "safest food supply" in the world, it should continue to be improved: "...that because Delaney reduces risks associated with carcinogenic pesticide chemicals, it should not be modified" ("The Delaney Clause Effects on Pesticide Policy", 1995, p. 1). Also, modifying the Delaney Clause based on government adult intake standards neglects a child or seniors' ability to fight such pathogens therefore posing food safety concerns to large portions of our society. As Mike Espy, former Secretary of Agriculture, pointed out the "lesson is that when it comes to food safety, just being better isn't enough; that when it comes to protecting human lives, the status quo isn't acceptable; that when a child's death could have been avoided but wasn't, business as usual is not an option" (p. 91).

Although the EPA has never fully applied the Delaney Clause the Natural Resources Defense Council recently sued the EPA and won, instructing the EPA to enforce strict compliance of the Delaney Clause. This will require the EPA to "...ban uses of 38 different pesticide active ingredients" (Fumento, 1995, p. A2).

After examining arguments presented by advocates of Delaney reform, I (secondary author) believe that the “negligible risk” standard proposed in H.R. 1627 represents the best “workable” solution. The Delaney Clause ignores the “scientific maxim that the ‘dose makes the poison’ and treats the presence of all chemicals the same, regardless of if they show up in ten parts per thousand or one part per trillion” (“Congress Sets Sights on Delaney Reform”, 1995, p. 2).

Compromise Solution: In order for a “workable” and safe solution to take place, a compromise must be reached. Perhaps the best solution for food safety concerns is to determine and set an amount of chemical residue that is to be allowed. This could be a measurement such as one part per million or one part per trillion and could be updated in the Farm Bill every five years as new technologies change the possible detection levels and new studies show the effects of chemical residue levels on food safety. In order for this to occur, new methods of testing need to be developed, that accurately reflect the long- and short-term effects of chemical residues on children, adults, and the elderly. Through testing methods that accurately reflect the effects of chemical residues on humans and the ability for those results to alter the set amount of residues allowed on our food, the American public can be assured that their food is and will continue to be as safe as it can be.

Summary and Conclusions

In summary, making decisions involves risk because they must be made with incomplete information, either about the future, or currently what is the actual situation. Employing a situation with only two opposite hypothesis about the actual situation (or the future) and two decision alternatives, two correct and two incorrect decisions are possible. Hypothesis testing, the basis for further discussion, focuses on the risk of making an incorrect decision, especially on the probability of incorrectly not accepting a null hypothesis that is true (the Type I error). The null hypothesis is only not accepted if the risk of doing so incorrectly is within a tolerable limit. Decision making under risk also involves a tradeoff between the two possible errors: in the short run the risk of one type of error can only be reduced by increasing the probability of making the other type of error. Public policy, as does individual decision making involves weighing, usually implicitly, the two errors. As society attempts to reach zero tolerable error, the cost of doing so increases.

Final Note: The authors are compiling a list of situations from a variety of disciplines in which risk tradeoffs are applicable. We would appreciate any examples that the members of the campus community use or of which they are aware. We would also appreciate it if the examples included the risk trade-offs and the courses of action that each would entail. Please send them to the authors at the Department of Food Marketing and Agribusiness Management and Agricultural Education, Building 2, Room 215; e-mail jmweidman; or call Jim Weidman at 2079.

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