Health Value in Food Safety Surveillance Initiatives

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Selected Paper prepared for presentation at the Southern Agricultural Economics Association Annual Meeting, Mobile, Alabama, February 1-5, 2003

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Abstract

Recognizing the increasing concern about the potential health effects of genetically modified foods, this research provides a framework for economic value of monitoring genetically modified food for their potential long-term human health effects. This is with the view of helping policy makers improve resource allocation decisions in the face of competing public health initiatives. Using a hypothetical population exposed to a hypothetical product, we estimate the health value associated with a post-market surveillance initiative. The analysis indicate that the principal challenge confronting decision makers in the implementation of post-market surveillance initiatives is prioritising products for monitoring given the uncertainty associated with outcomes and effects.

Key Words: Post-market surveillance, genetically modified, health

1. Introduction

Although traditional foods have always presented risks of health effects (e.g., ischemic heart diseases, diabetes and cancer), they have been often been accepted as tolerable by-products to their nutritional benefits. The cost of these health risks has been determined to be significant in Canada (Choi and Pak, 2002) and in the United States (Mokdad et al., 2003). However, the advent of genetically modified (GM) foods has unleashed a renewed interest in the potential effect of food consumption on long-term health, influencing research and policy discussions in many countries. For example, the Royal Society of London (1998) called on the UK government to implement post-market surveillance of GM foods. This led to the Advisory Committee on Novel Foods and Processes (ACNFP), which advises the UK Food Standards Agency, to recommend that the FSA undertake a feasibility study on conducting post-market monitoring of food consumption.

The Royal Society of Canada (2001) also recommended post-market surveillance of GM foods because of the uncertainty of their long-term health effects. The report identified three potential sources of human health risks presented by GM foods: possible creation of novel toxicants, possible shifts in the nutrient content of the food, and the possible creation of novel allergens. The authors of the report note (p. 71) that:

> In fact, there are no validated reports of allergic reactions to currently marketed GM foods as a result of the transgene protein. However, the potential risk for development of toxic or allergic reactions to GM foods will likely increase with advances in the scope and range of genetic modifications, wider acceptance of GM foods, increase in total dietary exposure to novel proteins, introduction of a greater variety of these foods, and more innovative transgenic combinations.

As a result of their concern for the potential human late health effects of GM food products, the Royal Society of Canada, like its counterpart in the UK, recommended the development of post-market surveillance mechanisms for GM foods if there are data to indicate their effectiveness to detect the late health effects among consumers exposed to such products.

Various joint expert panels constituted by the Food and Agriculture Organization and the World Health Organization and the European Union and the United States also made similar allusions to post-market surveillance as a means to minimize the potential effects of new GM foods in human health. For example, EU-US governments' Biotechnology Consultative Forum, which met four times between September and December 2000, considered the issues of traceability and monitoring, among others. It noted that mandatory monitoring was necessary whenever unanswered questions regarding specific health, environmental and/or safety concerns are raised about a new

product approved for marketing as well as when companies wish to make claims for benefits from the use of GM crops or foods. Likewise, the January 2001 joint FAO/WHO consultative meeting argued that monitoring needs to be conducted for both potential beneficial and adverse effects. The panel (p. 35) note that:

> The same problems apply to the detection of potential long-term beneficial health effects. Nevertheless, it was recognised that genetically modified foods intended to produce nutritional effects are under development for use in developed and developing countries. In such cases, a change in nutrient levels in a particular crop plant may impact overall dietary intake and it would be important to monitor changes in nutrient levels in such foods and evaluate their potential effect on nutritional and health status.

Health officials in countries where governments are heeding the calls for post-market surveillance policy initiatives are concerned about the implications of such initiatives on their already constrained budgets in the face of such current problems as foodborne diseases. At the same time, because of potential international trade implications, there is concern about post-market surveillance of these products even in countries where there is no current policy discourse about these initiatives.

The purpose of this paper is to present a framework for assessing the health value of post-market surveillance programs with the view of providing public health officials with a decision tool to facilitate effective resource allocation in the face of potential health risks from GM foods. We draw on methods that have been used extensively in health economics in estimating the cost of injury (Cutler and Richardson, 1998) and quality of life effects of diseases (WHO, 2001). Since these methods have been used to address known situations, we have adapted them to account for the uncertainty surrounding potential health risks emanating from exposure to GM foods and embedded

decision criteria within them. The next section provides an overview of post-market surveillance and its application to human health and food. We also present the challenges associated with the implementation of implementing post-market surveillance protocols specifically for a particular class of food products. We note that in spite of these challenges, the decision to implement such policies will ultimately be imposed by administrative fiat (as seen in the case of the EU's GM food traceability legislation (Commission of the European Communities, 2001)), and thus policy makers need to have tools that allow them do the best under the circumstances. We present a test of the framework with a hypothetical population exposed to a hypothetical genetically modified food product.

2. Post-Market Surveillance of Late Health Effects from Food

Post-market surveillance is the process of collecting, collating and analyzing health data associated with particular products after they have been introduced into the marketplace with the view to maximizing their safety and efficacy and minimizing their potential side effects. Post-market surveillance has been used for a long time in the prescription drugs and medical device industries to maximize safety and efficacy as well as to help balance effectiveness against risks and affordability. Because of its success in these industries, proponents of post-market surveillance believe it can address some of the uncertainty surrounding long-term health effects of GM food exposure, which would add another level of safety to existing protocols (Office of Technology Assessment at the German Parliament, 2000).

However, the difficulty of implementing post-market surveillance in the food industry is not lost in the debate. Katzek and Gassen (2000), for example, observe that despite the risks associated with the consumption of novel foods, practical and systematic evaluation of potential negative long-term effects and methodological protocols and legal frameworks do not currently exist. The Canadian Biotechnology Advisory Committee (2001) also observed that there are many difficulties in conducting GM food post-market surveillance, noting that these difficulties are only going to get more complex given the new products in the innovation pipeline. The Royal Society of Canada (2001, p.73), echoed this difficulty by noting the paucity of existing relevant data collection and analysis protocols after recommending the development of mechanisms for after-market surveillance of GM foods incorporating novel proteins. Similarly, the first Joint FAO/WHO Expert Consultation on Food Derived from Biotechnology (2000, p. 32) noted that:

> . . . the issue of long-term effects from the consumption of genetically modified foods and noted that very little is known about the potential long-term effects of any foods. In many cases, this is further confounded by wide genetic variability in the population, such that some individuals may have a greater predisposition to food-related effects. In this context, the Consultation acknowledged that for genetically modified foods, the pre-marketing safety assessment already gives assurance that the food is as safe as its conventional counterpart. Accordingly it was considered that the possibility of long term effects being specifically attributable to genetically modified foods would be highly unlikely. Furthermore, . . . observational epidemiological studies would be unlikely to identify any such effects against a background of undesirable effects of conventional foods.

The EU-US Biotechnology Consultation Forum (2000) also noted that implementing a post-market surveillance on a broad basis is near impossible. Therefore, it advised that "a detailed plan for mandatory monitoring should be established on a case-by-case basis," (p. 12). The Forum also recommended limited licenses as a means "to enforce effectively the obligation to monitor. For this purpose the limitation of the duration of marketing approvals may be an appropriate instrument. For these marketing approvals, continued approval would be based upon the results of the monitoring," (p. 13). However, concerns about the potential hazards of GM foods are motivating certain countries, such as the UK, to assess the feasibility of a post-market surveillance system for food (Elliot, 1999).

3. Description of the Framework

Population health protection resources have been allocated for many years using summary measures of population health, such as quality adjusted life years (QALYs) and disability-adjusted life years (DALYs) (Murray and Lopez, 2001). They have also been used to estimate population health values (Moore et al., 1993) and compare changes in population health values in different periods (Cutler and Richardson, 1998). These summary measures are structured to fall between 0 (death) and 1 (perfect health), with values in between indicating the intensity of living with an undesirable condition.

If r is the discount rate, Q_t is the quality life indicator, P_t is the socio-economic value in year t and k and T are the beginning and terminal years under consideration, then for each cohort group i, with population, w_t, the present value of the health capital, V_i, is defined as:

$$(1) \qquad V_i = \sum_{t=k}^{T} w_{it} P_{it} Q_{it} (1+r)^{-t}$$

The socio-economic value is a sum of two values: social value, defined to encompass the value that is placed on human life with or without economic activity (Riley, 1993; Miller, 1990), and economic value, defined as the average cohort income. This may be obtained from the tax returns.

The population health capital, V, is the sum of the health capital for all cohort groups, N. We may present this algebraically as follows:

$$(2) \qquad V = \sum_{i}^{N} \sum_{t=k}^{T} w_{it} P_{it} Q_{it} (1+r)^{-t}$$

It has been argued that the effectiveness of pre-market assessment of GM foods minimizes potential adverse effects to a small segment of the population (FAO/WHO, 2001; Donaldson and May, 1999). However, beneficial effects of GM foods may be over a wider proportion of the population. Therefore, we assume in this framework that only a fraction of each cohort population, α_i, will develop a health condition, d, upon exposure to a particular GM food. We can define the health capital of each cohort after exposure as the sum of the health capital of those with condition d and those without. Algebraically, this is:

$$(3) \qquad V_{id} = \alpha V_j + (1-\alpha) V_l \qquad l \neq j$$

where l is the unaffected population and j is the affected population in each cohort, i.e.:

$$(4) \qquad V_{id} = \left(\sum_{t=k}^{T} c_{dt} \sum_{j=1}^{J} w_{jt} P_{jt} Q_{jt} (1+r)^{-t}\right) + \left(\sum_{t=k}^{T} \sum_{l=1}^{L} w_{it} P_{it} Q_{it} (1+r)^{-t}\right)$$
$$\text{where } J/N = \alpha \text{ and } L/N = (1-\alpha)$$

where the probability that condition d will result from the exposure is c_{dt} and P_{jt} and Q_{jt} are the value and quality of life indicators associated with condition d. All other

variables are as defined. The expected population health capital resulting from GM food exposure, V_G, is expressed algebraically as follows:

$$(5) \qquad V_G = \sum_{i}^{N} V_{id}$$

The implementation of a post-market surveillance of potential human late health effects of GM foods is expected to alter the proportion of the population developing condition *d*, and its effects on health capital. Thus, we can modify Equation (4) to reflect the effect of the intervention thus:

$$(6) \qquad V_i^m = (\sum_{t=k}^{T} w_{jt}^m \sum_{j=1}^{J} c_{dt}^m P_{jt} Q_{dt}^m (1+r)^{-t}) + (\sum_{t=k}^{T} w_{it} \sum_{l=1}^{L} P_{it} Q_{it} (1+r)^{-t})$$

where the superscript *m* indicates the effect of the intervention and the equivalent population health capital is expressed algebraically as:

$$(7) \qquad V_M = \sum_{i}^{N} V_{mi}$$

The economic value of post-market surveillance, V_S, is the difference between health capital with the intervention, V_M, and without the intervention, V_G. That is:

$$(8) \qquad V_S = V_M - V_G$$

A decision to implement a post-market surveillance system for particular conditions may be made on the relationship between V_S and the cost of implementing the system, C_S. If $V_S/C_S > 1$, then the surveillance system creates more value than it costs, supporting its implementation, *ceteris paribus*. If we are comparing two situations, 1 and 2, and $V_1/C_1 > V_2/C_2$, then resources may be allocated to reflect the relative surveillance value-cost ratios. If resources are constrained, such that $C_1+C_2 > C$ available resources, then Situation 1 will be ranked over Situation 2 given the preceding condition.

In the development of the foregoing framework, we have assumed that the variables are not only measurable but that they are also accessible. The challenges of obtaining the changes in socio-economic values as a result of exposure to GM foods may be difficult to overcome because of causative effects of other variables such as education and training as well as experience on the job. Therefore, it may become imperative for policy makers to ensure that cohort group samples assembled for the purpose of post-market surveillance are structured to be randomized on the population. This will help capture the differences in the value of variables determined by other effects other than the exposure to GM foods to be captured and separated.

4. Framework Implementation

Although there is currently no evidence of GM foods causing any health condition in humans, suppose for the sake of argument, that exposing Canada's population to a particular GM food results in a condition *d*. Suppose also that the proportion of the population that is affected, α, and the socio-economic effects of the condition are, as expected, uncertain a priori. Population health protection officials may simulate the health value of the GM food surveillance under alternative plausible values for all the uncertain or unknown variables – α, the probability of condition d occurring, c_{dt}, discount rate, r, socio-economic impact on affected populations, P_{dt} and survival rates, s_{dt}.

For base reference value, we draw from a number of sources: WHO for QALY estimates, Canada Customs and Revenue Agency (CCRA) for economic value by cohort group, Health Canada for survival tables, and the health economics literature for other parameters necessary for the implementation of the framework. For example, the WHO's

Global Burden of Disease (2000) has detailed and extensive data on disability adjusted life years (DALYs) for 109 disease conditions and more than 500 sequelae for North America and the six other WHO regions reported by cohort groups. The CCRA reports average income by cohorts and Health Canada has data on survival rate data by cohorts while Miller (1990) has estimated the social value of an anonymous person as $75,580 (Canadian). The most common discount rate used by health economists is 3 percent (Choi and Pak, 2000), and it is used here to run the different scenarios. It was assumed in all the simulations that the expected lifespan for each cohort is 85 years.

5. Results and Discussion

We assessed the value of post-market surveillance of a negative effect resulting from exposing the Canadian population as it existed in 2001 to a particular GM food under six exposure and post-market surveillance scenarios, plus the base (pre-exposure) scenario (Table 1). The scenarios were based on plausible values for the proportion of the population that is affected and the economic and social impacts of the exposure as well as discount rates and the cohorts that are affected. The post-market surveillance scenarios included these in addition to the time it took for information emanating from the surveillance to be collected, analyzed, causality established and amelioration policy implemented to address the observed condition, *d*, affecting the identified population segment. We have structured the scenarios to illustrate the potential effects of the different variables on the health value of the exposure and the health value of post-market surveillance. For example, in Scenario 2, we assume that 10 percent of all cohorts are affected by the condition. The condition leads to a 15 percent reduction in economic

income (sickness resulting in lower productivity) and 20 percent reduction in social value (e.g., inability to support for friends, family and community). For surveillance effect scenarios, SE3, e.g., assumes that the surveillance response time – i.e. time between starting a surveillance system and implementing an amelioration policy – is five years, and leads to 4 percent of affected population cohorts from Scenario S3 becoming free of the condition (i.e., 1 percent do not fully recover) and economic and social values increase to 95 percent of pre-condition values. We assume that surveillance results in the restoration of Q-index to its base value.

Table 1: Description of Scenarios

Principal Scenarios	Affected Population	Economic Value Effect	Social Value Effect	Surveillance Response Time	Q Index
Base	-	100%	100%	-	Q_{BASE}
S1	10%	90%	90%	-	Q^1
S2	7%	85%	80%	-	Q^2
S3	5%	80%	75%	-	Q^3
S4	5%	80%	80%	-	Q^3
Surveillance Effect					
SE1	3%	95%	95%	10 years	Q_{BASE}
SE2	3%	95%	99%	10 years	Q_{BASE}
SE3	1%	95%	95%	5 years	Q_{BASE}
SE4	1%	95%	90%	5 years	Q_{BASE}

The total and per capita health capital for the different cohorts are presented in Table 2. It shows that the lifetime health capital for someone born in 2001 over a potential lifespan of 85 years is about $2.92 million. This is similar to value of life estimated by the US FDA and the EPA (Riley, 1993). For someone who is 80 years in 2001, the remaining potential life health value is estimated as $543,841. The total potential health value for people born in 2001 is $4,470 billion compared to $5,566 billion for people 35 years in 2001.

Figure 1 shows the estimated lost health value per capita under the defined scenarios in Table 1. Conducting the analysis under per capita conditions eliminates the mortality effects of the scenarios embedded in the Q-index. The figure shows that the highest losses occurred for all cohort groups under S2 while the least losses occurred under S1. Cohort 7 experienced the highest per capita losses under all scenarios. The per capita health value loss for Cohort 7 ranged from $34,735 under S1 to $44,615 under S2. The order of the per capita health loss may be explained by the fact it has the highest remaining life total value (i.e., the product of total remaining life and average remaining life social and economic value). On the other hand, Cohort 17 had the least losses under all scenarios because they had the lowest remaining life total value. We would have expected that health value loss under S3 would be lower than S2 given the higher economic and social impacts as well as higher Q-index under the latter. However, it seems that the fact that a lower proportion of the population was affected by the condition under S3 made the difference.

A summary of the total population remaining lifetime health values under the alternative scenarios and interventions is presented in Table 3. It shows that the total health value prior to exposure for the population is about $57,000 billion. This is the present value of the current population of the country over the next 85 years, discounted at 3 percent. The strictness of our present population assumption limits the analysis to particular population cohorts. It has also assumed static current life tables and Q-indices, i.e., making room for no medical and other improvements that increase life expectancies and quality of life beyond what they are today. The health value lost is the difference between the total health value under each scenario and the value under the base scenario.

Thus, Scenario S2 exhibited a higher loss ($816 billion) than all other scenarios, same as was found under the per capita analysis. The value of the post-market surveillance system was highest under SE3 and lowest under SE1. What is interesting is that while we expected scenarios with higher health value losses to yield higher surveillance values, we found that the relationship is not that straight forward. The recovered value ratio is the proportion of health value loss under each scenario or condition that is recovered by the post-market surveillance system. In our examples, we found that S3 presented the highest recovered value ratio of about 69 percent, while S1 presented the lowest, less than 50 percent. We also find that the recovered value ratios for the shorter surveillance response time scenarios were higher than those for the longer surveillance response time scenarios.

Figure 1: Per Capita Health Value Loss by Cohorts for Different Scenarios

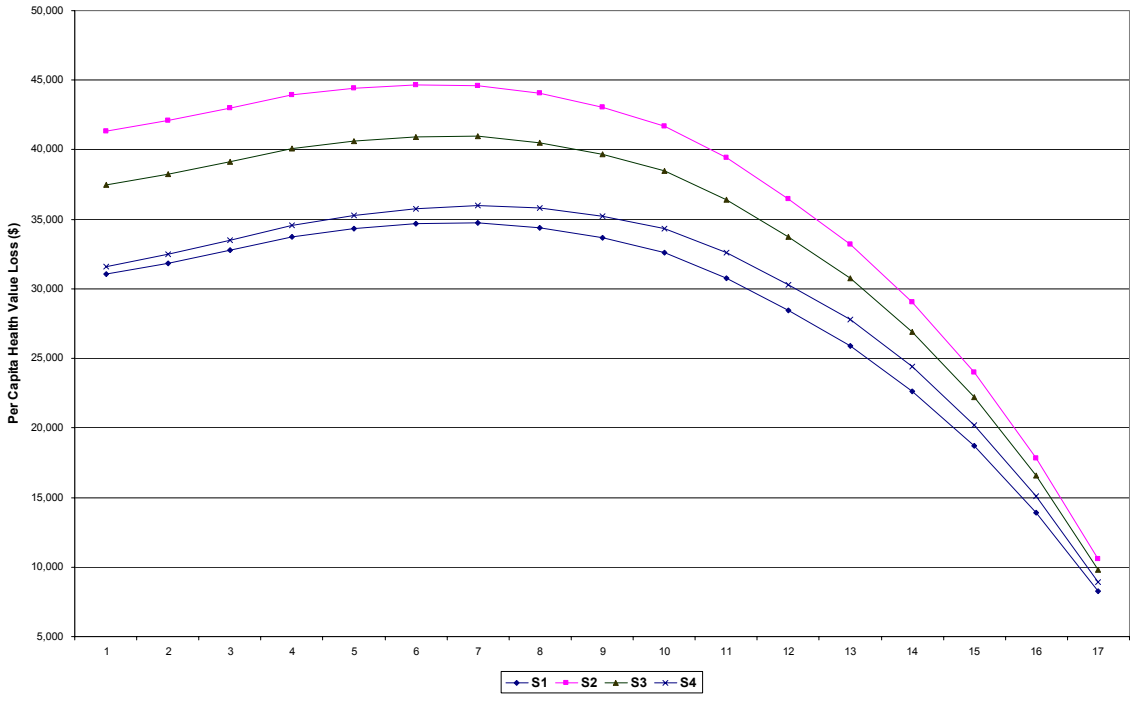

Table 2: Total Population and Per Capita Remaining Lifetime Health Capital by Cohort

Cohort Group	Age in 2001	Remaining Health Value/Person ($M)	Total Remaining Lifetime Health Value ($B)
1	0-4	2.92	4,601.56
2	5-9	2.96	5,227.00
3	10-14	3.02	5,343.62
4	15-19	3.08	5,338.16
5	20-24	3.09	5,281.93
6	25-29	3.08	5,107.28
7	30-34	3.03	5,172.94
8	35-39	2.94	5,565.87
9	40-44	2.80	4,997.30
10	45-49	2.63	3,859.30
11	50-54	2.42	2,816.48
12	55-59	2.18	1,673.50
13	60-64	1.91	951.11
14	65-69	1.62	542.80
15	70-74	1.30	274.03
16	75-79	0.94	103.15
17	80+	0.54	38.72

Different conditions can be ranked by their corresponding post-market surveillance intervention values. Thus, if we thought of the preceding four scenarios as four different conditions emanating from exposure to four different GM food products, we can rank them in ascending value order to decide which condition would produce the highest value. The implementation of each of the surveillance programs may have different costs depending on the population and the required data. Policy makers can subject their value rankings to the costs involved in implementing surveillance programs for each of the conditions. The highest value to cost ratio offers policy makers the decision choice.

Table 3: Total Remaining Lifetime Health Values by Scenarios

Scenario	Total Health Value ($B)	Health Value Loss ($B)	Surveillance Value ($B)	Recovered Value Ratio
Base	56,894.75	-	-	
S1	56,207.16	687.59	-	48%
S2	56,078.18	816.57	-	60%
S3	56,148.40	746.35	-	69%
S4	56,247.88	646.87	-	67%
SE1	56,537.04	357.71	329.87	-
SE2	56,565.74	329.01	487.56	-
SE3	56,663.50	231.25	515.10	-
SE4	56,678.37	216.38	430.49	-

6. Conclusion

This paper is a response to the increasing interest in post-market surveillance of potential human late health effects of GM foods. Although there is currently no adverse incidence of human health that can be attributed to the GM foods, many governments are concerned about its potential. This suggests that those calling for post-market surveillance may gain increasing audience in policy corridors. There is, therefore, a need to anticipate the potential decisions that could arise when the time comes. It is for this reason that we have developed this framework. It is simple and flexible, but requires policy makers to have very a clear definition of the conditions they want to put under surveillance. Without this clear definition, it is impossible to draw on the databanks, such as the WHO's Global Burden of Disease, to facilitate effective decision-making. Also, without a clear definition of what it is that needs to be monitored, significant value of the post-market surveillance system will be lost collecting data and conducting analyses that do not address issues of relevance.

The value of post-market surveillance protocols in total may end up being significantly greater than the estimate for the health value alone as presented in this paper. For example, when the framework is extended to incorporate other government policies surrounding food safety and trade as well as chain of custody for food products, and not just GM food, we can expect the value of post-market surveillance to increase. Hence, this research provides a stepping stone for thinking about how to model the complex issues embedded in post-market surveillance of food as well as ensuring that policy makers have the right perspective on the issues when it comes time for them to make resource allocation decisions vis-à-vis population health.

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