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Streamlining the Risk Analysis Process and Ensuring the Optimal Organizations for Food Safety: The case application to biotechnology of *Fusarium* species

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Abstract

Food safety and security may be improved by using technological innovation. However, hostile consumer reaction to scientific solutions is commonly accompanied. The case analysis of food and environmentally borne *Fusarium* mycotoxins and illnesses is examined to clarify a situation where the biotechnological tools could be utilized. *Fusarium* species cause serious economic hardships. The greatest concern is in diseases like *Fusarium* head blight (FHB) associated with deadly mycotoxins, as well as opportunistic species such as *Fusarium solani* can directly infect humans, causing serious illness. An evaluation of the risk analysis framework critiques and makes suggested solutions in order to effectively manage the use of biotechnology in sensitive situations, as in the case of *Fusarium*.

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1. Introduction

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Technological developments focusing on safeguards against risks presented in everyday life have progressed rapidly over the last 100 years. Currently, a challenge of providing safe food and upholding human welfare is presenting itself with the emergence of a deadly fungal genus, *Fusarium*. This paper presents the use of biotechnology for developing effective control methods aiming to substantially reduce any potential health risks resultant of *Fusarium* species. An overview of concerning issues related to *Fusarium* phytopathogenic diseases, associated mycotoxins, and its recent emergence as human pathogens will be covered. These issues will lend to the emphasized vigilance needed to manage further fungal spread in our environments (Khachatourians and Arora 2001).

Biotechnology techniques present researchers with an efficient means of thwarting this fungal threat, however, serious social hurdles must be overcome before biotech methods may be implemented. This paper takes a focused look at the sociological effects of new technology to combat food safety risks. The risk analysis framework will be assessed in order to create a streamlined approach for biotech products when dealing with serious health threats, such as cancer and various fungal infections, to promote benefits at every stage of production. To streamline the current system we have taken an empirical approach, analyzed previous social science research and created an outline for the best alternatives of communication, analysis and institutional structure.

2. The Scientific Challenge

Ubiquitous genera of fungal plant pathogens have recently emerged as having the ability to cause many destructive diseases. Past fungal disease epidemics have been remedied with easily adapted solutions to provide ample resistance. However, *Fusarium* species fail to follow conventional knowledge about common diseases and their respective system interactions. Highly toxic secondary metabolites called trichothecenes are the most likely candidate for their ominous characteristics. The trichothecenes synthesized show toxicity towards all living cells and substantially increase the disease severity of the syndrome.

The lack of substantial progress and strategies for control from classical plant breeding has influenced the use of modern biological techniques. Novel tools are allowing for genetic resistance to the toxin component of the disease to be found, characterized, and introduced to a plant system for utilization. The role of biotechnology has become integral to finding solutions for *Fusarium* diseases (Dahleen et al. 2001) however; its use is no longer a scientific challenge, but a societal quandary demanding precautions to the unknown.

2.1 Implications to World Agriculture

Fusarium species represent a diverse genus of ubiquitous pathogenic fungi found in vegetables, ornamentals, and cereals. The most destructive disease is *Fusarium* head blight (FHB). Research is finding an ever-broadening host range for *Fusarium* isolates (Urban et al. 2002), but it predominantly affects small grain cereals. In areas with favorable disease development conditions, FHB epidemics reduce seed yield and grain quality of cereal crops. In North America, *Fusarium* species are most prevalent throughout the central states and provinces (McMullen et al. 1997, and Clear and Patrick 2001). Within the past twenty years, producers have noticed increasing *Fusarium* infected crops, particularly wheat, barley and corn. Favorable weather patterns and a reduction in tillage practices are believed to be the main causes for this amplification (Tekauz et al. 2000, and Prom et al. 1999).

As FHB increases in severity throughout much of the world's cereal growing areas the need for control becomes of utmost importance. For instance, barley showed a significant increase in FHB severity, first being identified in Manitoba (Canada) in 1993, and progressed until 1998 when it reached levels equal to highly susceptible wheat (Gilbert et al. 1999). When warm moist weather patterns coincide with flowering and grain-fill stages of plant growth, severe losses occur, making FHB the most destructive fungal disease of wheat and barley in North America (Gilbert and Tekauz 2000, and McCallister 1999) and throughout the world. Research areas such as plant pathology, plant breeding, biotechnology, and agronomy are uniting to develop defense mechanisms against FHB. Cultural changes do not offer a substantial barrier to FHB spread making genetic resistance using intensive molecular methods in variety creation the most desirable management option available (Bai et al. 2000).

2.1.1 Economic Disparities from FHB

Economic hardships are due mainly to the low quality, shriveled grain from *Fusarium* damaged kernels (FDK) contaminated by mycotoxins (Watkins et al. 2001, and Salas et al. 1997). *Fusarium* mycotoxins are harmful to human beings and animals alike, having the ability to cause feed refusal, high rates of abortion, hemorrhages, various severe illnesses and even death (Walker et al. 2001 and D'Mello et al. 1999). Mycotoxins produced by FHB causing species include deoxynivalenol (DON), nivalenol (NIV), T-2 toxin, zearalenone (ZEA), fumonisins and their derivatives (Atanassov et al. 1994). The interacting factors determining the negative effects of FHB or scab on production and marketing include visibly blighted heads in the field, noticeable *Fusarium* damaged kernels, the incidence of infected kernels, and most importantly mycotoxin levels contained within the grain (Watkins et al. 2001).

FHB has been recorded as causing significant monetary and yield losses throughout South America, Europe, Asia, North America (Bai and Shaner 1994) and recently in

Australia (Nicoll 2002). In North America this quickly emerging disease has been documented as causing severe epidemics in twenty-six states (McMullen et al. 1997) and four provinces (Clear and Patrick, 2001 and Ward and Sayler 2000). Recently the United States Department of Agriculture ranked FHB as the worst plant disease to appear since the 1950's (Wood et al. 1999). The most significant losses have been reported in the US during the 1990's where an estimated \$3 billion US had been lost to the agriculture industry as a result of FHB epidemics (Windels 2000). In Canada, during the same period, Ontario and Quebec producers lost approximately \$220 million US, and Manitoba lost \$300 million US between 1993 and 1998 (McMullen et al. 1997).

2.2 Implications to Human Health

Trichothecene mycotoxins cause serious negative effects to living organisms at low concentrations (Khachatourians 1990, and Kimura et al. 2001). Mycotoxins in foods are tightly regulated in the world market, with detection of 1 part per million being sufficient for shipment refusal. However, in parts of the world where food scarcity is reality, foodstuffs contaminated with these toxins are still consumed (Lugauskas and Stakeniene 2002). Food poisoning in this case causes ill effects and can lead to forms of cancer and potentially death.

The most recent threat encountered by *Fusarium* species is their emergence as a serious human opportunistic fungal pathogen in immunocompromised hosts and infectious ability in healthy individuals (Musa et al. 2000). Human infections from *Fusarium* have been well documented since their presence was established approximately two decades ago as a major cause of fungal keratitis, an unforgiving eye disease. Human infection is made possible by the creation of cyclosporinA (CsA), a strong immunosuppressant that handicaps human defense mechanisms, and heat-tolerance, permitting deep tissue infection (Balakrishnan and Pandey 1996). Resistance to antifungal drug therapy further limits treatment possibilities (Sugiura et al. 1999) and the potential of mycotoxin production shown by Raza et al. (1994) is most alarming. In cases where detection of *Fusarium* infection was not quick, treatment administration was commonly ineffective and lead to death (Sugiura et al. 1999).

2.3 Biotechnology: A 21st Century Solution

The potential threats of *Fusarium* species are extremely diverse and have the potential to inflict great losses to human welfare through disease epidemics and are now responsible for health and safety threats. The interest must therefore be centered towards finding a solution to stop further *Fusarium* spread throughout the environment (Khachatourians and Arora 2001). Classical plant breeding has provided plant varieties that include partial resistance to this fungal menace.

However, in light of the possible consequences, the authors suggest that biotechnology be used to genetically engineer highly resistant plant lines and suppress FHB causing strains as well as species capable of causing human disease.

Recent progress has uncovered resistance mechanisms originating from various *Fusarium* species, yeasts, and plants. To utilize these valuable sources of resistance during production, a social hurdle entailing the practice of plant genetic engineering must be overcome. It becomes integral in circumstances with serious health implications that the unsubstantiated risks of using genetic engineering are greatly outweighed by its effectiveness. Through taking advantage of genetic characteristics present in other organisms, it is now possible to more quickly and efficiently prevent further hardships.

The need for streamlining specific case-by-case uses of biotechnology becomes of utmost importance to suppress situations entailing further outbreaks of *Fusarium* related diseases. Upon weighing the arguments against biotechnology use and the implications that *Fusarium* imparts to our well being, food safety, and security, it becomes clear that a solution is needed without delay. Potential health and environmental threats suggested by biotechnology critics become insignificant when compared to the multidimensional threats present with a variety of *Fusarium* diseases. Our suggestion is that the problem be identified, followed by what tools may be utilized to find a viable solution. In the case of *Fusarium* diseases, the limited options would encourage a proactive stance for the use of biotechnology.

3. The Social Challenge

A formal risk analysis framework effectively managed risks in many parts of our economy and society in the past, but due to newly introduced technologies, such as biotechnology, there are increasing problems emerging within the process of risk analysis. The testing of this process through the development and commercialization of biotech products is a result of three major activities: (1) a number of regulatory bans on genetically modified organisms; (2) a large amount of negative consumer response; and as a result (3) decreased market acceptance. Biotechnology has become a dirty word in food development and trade. Because of this negative perception of biotech techniques, action must be taken to properly inform the public and effectively regulate the risk analysis process.

The reason for intensive combating of negative perception towards biotechnology is that, in contrast to the fears of many, there are actually great benefits of utilizing this technology and potentially even greater risks posed by not using it. Further, losing this valuable technology could have a significant effect on a number of developed and developing countries. In particular, the technology has great potential to minimize the level of risk of *Fusarium* mycotoxins within the

environment and food system. The utilization of biotechnology techniques is expected to greatly reduce the amount of *Fusarium* species in crops.

3.1 Risk Analysis Framework

Science and policy are two different ways of legitimizing risk and of producing and defining usable knowledge. The use of techniques – knowledge – to diminish the risks imposed by *Fusarium* species is critical as the resulting economic, human and animal health, and environmental benefits are remarkable. The levels of risks imposed by a technology are evaluated through the Risk Analysis Framework (RAF), which involves three constructs or stages: risk assessment; risk management; and risk communication.

The first stage of the RAF is risk assessment. This process is largely conducted by academic, government and industry experts, as well as expert panels. The Codex Alimentarius Commission (1999), hereafter referred to as Codex, defines risk assessment as “a scientifically based process consisting of the following steps: (i) hazard identification, (ii) hazard characterization, (iii) exposure assessment, and (iv) risk characterization.” In short this stage conducts a scientific analysis where hazard is quantified.

The second stage, risk management, responds to the market and takes into consideration the aspect of exposure to a technology. Codex defines risk management as “the process, distinct from risk assessment, of weighing policy alternatives, in consultation with all interested parties, considering risk assessment and other factors relevant for the health protection of consumers and for the promotion of fair trade practices, and, if needed, selecting appropriate prevention and control options.” The management of risk requires knowledge of a broad spectrum of food systems and safety, and includes management of all downstream entities.

The final stage of the RAF is risk communication, which is safety oriented, and is the most difficult stage to undertake both efficiently and effectively. It is defined by Codex as “the interactive exchange of information and opinions throughout the risk analysis process concerning risk, risk-related factors and risk perception, among risk assessors, risk managers, consumers, industry, the academic community and other interested parties, including the explanation of risk assessment findings and the basis of risk management decisions.” Therefore, in a sense, risk communication is also all encompassing.

As stated earlier, the risk analysis framework has worked well for society over a wide range of situations but now is being tested by GMOs. Mycotoxins, as a result of *Fusarium* species, present a number of risks and dangers to the food safety system.

It is imperative that the RAF involve all aspects of risk, this includes societal views, human and animal health, and the environment. The following two sections include a critique of the present RAF, as well as presents solutions to the illustrated problems of the framework.

3.2 The Critiques

There are four critiques of the RAF that emerge with the application of biotechnology products. These critiques are largely interrelated, as the risk analysis process should be more fluid, as opposed to three disconnected stages.

First, there are transparency issues that need to be addressed within and between the different stages of risk analysis, which will add to the fluidity of the process. There is a large amount of difficulty involved in accessing information within the RAF and a limited amount of participation between stages. All stages must have a clear understanding of the legitimate factors that need to be taken into consideration. Presently, science is the key element, but economic impacts and sociological implications must also be delineated in concordance with the analysis. With an increase of transparency throughout the RAF, it is believed that the level of acceptance for new technologies would greatly increase (Reksnes 1998). This is not to say that with an increase of knowledge that acceptance will be greater, but it is the increased transparency of the analytic process that will increase the credibility of the system.

The second weakness of the RAF process is the lack of quantifiable risk of biotech products. This becomes an issue as risk perceptions vary widely and must be taken into consideration. Public risk perception may cause the total calculation of risk to increase dramatically, but if it is not taken into consideration then the approximate value of risk may be misleading. Evaluating the use of biotechnology techniques versus the negative implications associated with *Fusarium* species clearly outlines the human, animal, and environmental benefits of subsequent utilization. As a result the perceived risks of biotech or genetic engineering will decrease as direct human benefit is realized. The most difficult facet of measurement is quantifying risk perception, or 'outrage' (Sandman 1994). If risk perception is not considered, the application of science and technologies that are not favorable to the public may be commercialized. It is not only the calculated value of risk that should be of concern but also the extent of the perceived risk that is critical to its measurement. Therefore, with new technologies, a method must be utilized that takes into account the public perceptions of risk. Failing to take these perceptions into consideration and only quantifying based on physical harm makes the analysis socially incomplete (Fritzsche 1999).

Third, there is a lack of continuation of risk management after the risk has been assessed. Scientists must continue to participate in this process to ensure suitable application of the technology. Some argue that there is often disregard by the

developers of technology and that technology is released into the environment with no regard for how they may be independently “rearranged” (Winner 1977). Therefore the consideration of both scientific and socially constructed aspects of risk will more aptly determine the effect on society and the environment (Sandman 1994). As a result this supports the management of the hazard throughout the implementation of the technology (Sandman 1999).

Fourth, the underlying shortcoming of the risk analysis process is that risk communication should be continuous and not simply one stage of the process. There are barriers to communication on a number of levels. For example, everyone has slightly different, if not completely different perceptions of technology, which includes a lack of understanding of the science, making it more difficult to understand the technology (Reksnes 1998). Further, there is also a lack of communication between the different levels of the RAF. For example, one of the key problems with risk management is that there is a lack of communication from the risk assessment process to the management stage, with the result that technologies may not be properly managed. Communication is ultimately the key to obtaining trust from the public that must include all that are impacted or potentially impacted by the technology.

In brief, communication is also becoming more significant with the reduction of society’s trust in government regulatory systems. As well, there is a significant amount of disagreement among governments in the risk management stage.

3.3 Solutions

As outlined previously, the overriding issue of the present risk analysis framework is the lack of effective communication. Risk communication should be utilized in order to form consensus regarding technologies and depress argumentative debate. The formation of a consensus on a new technology is very difficult; by focusing on *Fusarium* species and evaluating the overall benefits to the food system through the utilization of biotechnology, the final opinion of the resolution is more likely to be positive and based on the benefits that will be realized while communicating potential risks. The utilization of biotechnology decreases the risks in the food system resulting in unified consent to the uncertainties.

The risk communication stage must be viewed as a process, as opposed to simply a stage, and must start from the beginning of the RAF, making it a more integrated process. In addition, risk analysis itself must remain transparent throughout the three analytical stages.

With the support of a strong policy framework satisfied producers and consumers are more likely to readily accept new technologies. The present negative perception of genetically modified foods is a result of a failure due to a lack of communication, largely by the public actors (Leiss 1999). In contrast, it may be a failure of the

market actors due to a lack of communication within the system (Phillips and Corkindale forthcoming).

Using the European Union's reaction to GM products as an example, one can see that while risk management itself was conducted and managed properly, it was the public issues that were neglected. Public opinion is crucial in the commercialization and distribution of products that are developed by new science and technology. Therefore, this would mean that risk issue management would also become a part of the RAF through the communication process, ensuring that perceptions are considered.

The change that will have the most significant results within the RAF is to streamline communication between stages and actors. Increasing communication between risk assessment and risk management will ensure that there is quality management of new technology. Between assessment and communication an increase in transparency will foster insight to society and promote proper communication of the possible exposure to society.

There are a number of systems of the risk analysis framework that may be considered. Between Canada, the United States and the European Union each stage of the risk analysis framework is managed somewhat differently. For example in the EU risk communication and risk assessment are merged in the public sector via the new European Food Safety Agency, while in Canada and the US risk assessment is left in the public sector and in Canada, in particular, there is no clear lead on risk communication. Risk management is, for the most part, conducted by the private sector in the US with some state responsibility in Canada, and largely in the public sector in the EU. This brings into consideration the question, what role does each institution play as a tool of assessing, managing and communicating risks?

There are clearly public, private, and collective institutions engaged in the RAF and multiple permutations of their roles and responsibilities but no clear model or analysis that demonstrates the optimal design or structure of an RAF. There are two possible general approaches to seeking optimal structures. First, examine national systems or conducted comparative national analyses in an effort to seek best practices. Alternatively, one could look to the international stage where there are presently nine international institutions and a number of regional organizations focusing on the international food system to ensure safety but also to promote trade – IPPC, OIE, Codex, FAO, WHO, WTO, OECD, BSP and various bilateral processes. Given the critical factor that influences legitimacy and value of the RAF is risk communication, there may not be one single approach that works for all products, markets, nations.

4. Conclusion

Fusarium species are prevalent across the globe and the management of this disease will not only decrease the costs of agriculture crop production and marketing but also save lives. The toxins produced by this species are highly stable and testing is both expensive and tedious. There is evidence that the advancement of biotechnology techniques could decrease the infection of plants, humans, animals, and the environment but that the RAF will need to be adjusted to increase communication both throughout the process, as well as to the public. This will be necessary in order for the new biotech related crops to be accepted.

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