LORDS OF THE HARVEST: REPUTATION CONCERNS AND REGULATORY APPROVAL OF GENETICALLY MODIFIED ORGANISMS

Abstract

Little is known about what influences regulatory decision making. We posit that regulators’ choices are not simply based on objective information about firms and products, but are also influenced by reputation concerns of the regulators. Focusing empirically on U.S. Department of Agriculture approval of genetically modified organisms, we find that reputation threats from critical stakeholders and regulatory reference actors improve regulatory approval and that the influence of regulatory reference actors increases with firm and product uncertainty. We suggest that these reputation concerns allow firms to influence regulatory decision making. Implications for institutional theory and nonmarket strategy are discussed.

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In 2005, the United States Department of Agriculture (USDA) approved the first perennial genetically modified (GM) crop for market—Monsanto’s Roundup Ready alfalfa. Shortly thereafter, environmental movement organizations and organic farmers filed suit against the USDA, arguing that it had not conducted a complete environmental impact assessment on GM alfalfa. In 2007, a federal district court in California ruled in the plaintiffs’ favor and placed an injunction prohibiting the sale of GM alfalfa until the USDA could conduct a full environmental impact assessment. Monsanto appealed but the U.S. Supreme Court upheld the lower courts’ rulings in 2010.

Six months later, the USDA was once more under fire, this time for approving Monsanto’s Roundup Ready sugar beets. Environmental and organic food activists sued the USDA for not exploring the potential impact of cross-pollination with normal sugar beets before approving the genetically modified organism (GMO).\(^1\) Agreeing with them, a federal judge placed an injunction prohibiting the planting of GM sugar beets until the USDA could carry out a complete environmental impact assessment.

These negative court outcomes pose the question: How could a government agency responsible for protecting the nation’s food supply approve a controversial product without evaluating all of the risks involved? In this paper, we attempt to shed light on this issue by exploring factors that can influence the decision making of regulatory actors.

Although government actors are relevant to business in virtually every sector, the degree of state intervention is particularly high in a number of regulated industries, including biotechnology, telecommunications, electricity, and pharmaceuticals. Regulatory agencies in such industries can dramatically influence firm performance and survival by imposing product

\(^1\) Genetically modified organisms are organisms whose genetic material has been altered using genetic engineering techniques to enhance desired traits such as herbicide resistance, pesticide properties, and nutritional content.
standards and production requirements, approving or disapproving product or service offerings, and changing market entry and exit rules (Henisz & Zelner, 2001; Garcia-Canal & Guillen, 2008). Firms in regulated industries therefore have strong incentives to attempt to influence regulatory decisions to their benefit (Keim & Zeithaml, 1986; Hillman & Hitt, 1999). Yet prior work has remained unclear about whether and how a government regulator’s decisions are substantially shaped by regulated firms.

Management research on business-government relations has generally drawn upon two different—and often competing—conjectures. The first, espoused by organizational sociologists and in particular by early institutionalists, views a government regulator as an external entity that exerts coercive and normative pressures on firms and thereby affects their performance and behavior (Scott, 2008). Under this view, firms are often treated as impotent actors and the state as a stable exogenous force (Meyer & Rowan, 1977; DiMaggio & Powell, 1983). But treating regulatory agencies as exogenous inputs and organizations as unduly constrained actors does not explain why and how firms in the same regulatory environment use influence strategies and gain differential advantages from regulators.

The second view, often guided by the idea of regulatory capture in the political science literature (Bernstein, 1955; Stigler, 1971), has provided a rather different image of government regulators whose actions are significantly affected by the interests of powerful economic and political actors. For example, this view suggests that large established firms can receive favorable treatment from the state, such as regulatory approval and favorable price control and consumer safety measures (Crandall & Flamm, 1989; Carpenter, 2004). While it is worth noting how a handful of established firms can shape regulatory decisions in favor of their commercial interests, this stream of research overlooks whether and how the majority of nonestablished
organizations—such as new ventures—can affect regulatory outcomes. Hence, understanding regulatory decision-making processes while discounting neither the agency of regulated firms nor the self-interest of regulatory agencies seems to be one of the central issues of research on firm performance in regulated environments.

We address these issues by taking the view of regulatory agencies as socio-political actors who have strong concerns about their own bureaucratic autonomy, political longevity, and social identity (Carpenter, 2001; King, Felin, & Whetten, 2010). Our view builds upon the social actor conception of the organization (Coleman, 1982; Whetten, 2006; King, Felin, & Whetten, 2010), which suggests that organizational action is better understood as the product of interaction between an organization and its focal audience. According to this perspective, an organization is an actor within a larger social system and relies on the approval of relevant others, such as primary stakeholders and other opinion makers who can indirectly influence the organization’s reputation. It therefore attempts to cultivate and maintain a favorable conception of itself among target audiences (Whetten & Mackey, 2002; King, Felin, & Whetten, 2010).

The social actor conception of the organization is particularly relevant to our study because regulatory relationships are not as simple as prior research on business-government relations suggests with its focus on dyadic exchanges between the regulator and the regulated firm. Rather, many regulatory relations are triadic: Third-party actors, such as social movement organizations and other stakeholder groups, may influence regulatory decision making.

Our central premise is that a government agency has strong incentives to protect its reputation and to further its own interests and independence. Regulatory decisions may therefore not only be based on objective information about the firms and products in question, but may also be affected by third-party audiences, including external stakeholders and reference groups.
who can protect or threaten an agency’s reputation and independence (Skocpol, 1985; Dacin, Goodrich, & Scott, 2002; Carpenter, 2004). In short, we posit that a regulatory agent’s concerns about its reputation ironically create conditions under which regulated firms can influence regulatory decision making even for controversial products. Our paper identifies predictors of such conditions and explains the generation of differential regulatory benefits.

We test this idea in a study of regulatory approval of GMO products by the USDA, which has the responsibility to protect humans, plants, and animals from dangerous genetically modified plants and the power to regulate the development and commercialization of new GMO products. Although GMOs have been extensively studied, regulatory agencies are still unable to completely analyze the significant potential risks and hazards, leaving regulatory decisions about GMO-based products subject to uncertainty.

We view the USDA as a political actor anxious about losing its reputation as a guarantor of the public safety in the agricultural market—a valuable political asset which can be used to generate public support, obtain authority and discretion from politicians, protect the agency from political attack, and recruit and retain valued employees (Carpenter, 2001). USDA decisions may therefore be influenced by the opinions of powerful stakeholders, such as agriculture business associations, that constitute its reputation base.

We also describe the USDA as a social actor concerned about the reputations of the firms it regulates, especially when the qualities of their products are not well known. The USDA relies upon product information, expert scientific opinion, and experimental studies submitted by petitioning organizations to determine a product’s health and environmental risks. But when uncertainty remains, the USDA is also likely to rely upon the evaluations and opinions of regulatory reference groups, such as Food and Drug Administration (FDA), that make similar
regulatory decisions (Merton, 1968).

THEORY AND HYPOTHESES

Regulatory Actors and Reputational Concerns

A stream of research guided by the social actor conception of the organization (Selznick, 1957; Whetten, 2006; King, Felin, & Whetten, 2010) suggests that organizations are not discrete economic entities but social actors that operate in a broader institutional environment that shapes their structural characteristics and core identity traits. The social actor conception of organizations is consistent with institutional perspectives in positing that organizations rely on the approval of relevant stakeholders—including employees, shareholders, media, and other target audiences—in order to obtain resources necessary for survival (Meyer & Rowan, 1977; Oliver, 1991; Delmas & Toffel, 2004; Love & Kraatz, 2009), but it departs from institutional perspectives by viewing the organization as an important source of agency and institutional heterogeneity. For example, the social actor conception emphasizes a variety of interpretations that an organization constructs and enacts about its environment and the efforts that it makes to skillfully cultivate and establish a favorable reputation among target audiences (Whetten & Mackey, 2002). Thus, this approach suggests that organizations are not entirely constrained by the institutional systems; rather, organizations are viewed as endowed with agency and acting in their own interest while reacting to norms, expectations, and other institutional pressures from target audiences.

Viewed from a social actor perspective, a government regulator is not a homogenous systematic institution designed to protect property rights and regulate markets for the benefit of society independent of its own interest—a traditional imagery of the state and its agencies espoused by economic historians and strategy scholars (North, 1990; Carruthers & Ariovich,
2004). Instead, the social actor conception suggests that a governmental regulator will react to target audiences and manage its reputation and identity in a manner that is consistent with its own interests, such as political autonomy and regulatory power. This imagery of government actors is also consistent with some work in political science, which views the state as composed of heterogeneous agencies acting semi-autonomously in pursuit of their own interests (Skocpol, 1982; Evans, Rueschemeyer, & Skocpol, 1985; Carruthers, 1994).

A bureaucratic agency can strengthen its autonomy and power by protecting and strengthening its reputation, defined as a generalized expectation about an actor’s future behavior or performance based on perceptions of past behavior or performance as well as on non-performance-related information, such as ties to exchange partners (Fombrun & Shanley, 1990; Rao, 1994; Podolny & Phillips, 1996; Deephouse & Suchman, 2008). A strong reputation can give a bureaucratic agency policymaking autonomy, discretion, and crucial resources (Carpenter, 2001), whereas a weak reputation can prompt important audiences to question the agency’s competence and legitimacy (Pfeffer & Salancik, 1978), which could in turn lead to loss of resources or authority and even to elimination (Martins, 2005). An agency’s concern for its reputation can therefore motivate it not only to perform its duties well, but also to meet the expectations of the target audiences which are its reputation stakeholders.

The benefits of a strong bureaucratic reputation are well illustrated in the USDA’s takeover of federal forest lands (193 million acres) from the Department of the Interior in the early 20th century. At the time, the Interior Department was one of the oldest and largest executive agencies, but it reputation was in shambles due to the mishandling of Civil War veterans’ pensions in the late 19th century and the squandering of Reclamation Act monies. The USDA, though relatively small and young, had already gained such a strong reputation for
science, conservation, and efficiency among influential groups such as the General Federation of Women’s Clubs, the Audubon Society, the Sierra Club, the Grange, and the Progressive Party that when the agency proposed, in 1905, to take over the management of federal forest lands from the Interior Department, even such powerful political opponents as the Speaker of the House of Representatives and the Secretary of the Interior were forced to give way (Carpenter, 2001).

Types of Reputational Concern: Egocentric and Altercentric

In order to understand how target audiences play the role of reputational bases in affecting regulatory decisions, it is useful to adopt the perspective of a focal regulator and distinguish two kinds of reputational concern. The first is its accountability to key audiences that constitute its reputation base and that may, at any time, call upon it to explain and justify its behavior and performance (Scott & Lyman, 1968; Lerner & Tetlock, 1999). This can be labeled “egocentric reputation concern,” since the focal regulator is concerned about its own reputation.

The second concern is for the reputation of regulated firms and products, especially when firm or product uncertainty is high. This can be labeled “altercentric reputation concern,” since the regulator is concerned about the reputations of its alters—the firms and products it regulates. Organizational reputations are often affected by associational ties to prominent collectives such as established religious groups (Baum & Oliver, 1991), customers and stockholders (Elshbach, 2003; Elshbach & Sutton, 1992), and governmental bodies (Sine, David, & Mitsuhashi, 2007). This paper explores how regulatory reference groups serve as potential sources of social influence for the focal regulator’s decision making, especially when the qualities of firms and products under review are very uncertain (cf. Merton, 1968; Podolny, 1994).

The distinction between egocentric and altercentric reputation concerns lays a conceptual
foundation for differentiating the influences of different kinds of external parties on regulatory decisions. The egocentric reputation concern focuses on political sources of influence that trigger a focal regulator’s efforts to gain favorable support from target audiences as its reputation base. In contrast, the altercentric reputation concern focuses on social sources of influence which increase the value of looking to reference groups to reduce the uncertainty of regulated firms and their products. We do not suggest that one concern is more important than the other. We do imply that reputation concerns arise from different sources of external audiences and prompt a regulator’s efforts to resolve such concerns by considering political and social factors in addition to objective information on the products themselves. Insofar as regulators are concerned about their reputations and about external parties as reputational bases, their reputational concerns create conditions under which regulated firms can influence regulatory decision making. The implication is that regulated firms may obtain favorable regulatory outcomes by gaining the support of target audiences (stakeholders and reference groups) that can affect regulatory decision making.

**Reputation Stakeholders and Regulatory Decision Making**

The USDA is responsible for protecting humans, plants, and animals from dangerous genetically modified plants by approving the development and commercialization of new genetically modified food products. The agency can review experimental evidence, yet there are risks (Conner, Glare, & Nap, 2003) which are impossible to fully assess. For example, if genes with herbicide properties from a GMO variety were to horizontally transfer to wild plant varieties, it could foster the growth of indestructible weeds that would not only reduce agricultural yields but might also dismantle an entire ecological system. Genetically modified products can themselves become indestructible species that can invade and take over multiple
ecological populations. For instance, in a mathematical modeling of transgenic fish species, Muir and Howard (2002) concluded that biotech fish with high fitness qualities would dominate local ecologies, leading to the extinction of other marine species. Additionally, the process used to create GMOs may produce hidden and unintended allergens in the new variety. For example, in the process of creating biotech soybeans, Pioneer Hi-Bred spliced genes from Brazilians nuts into soybean plants. Food scientists later found that the altered soybeans produced allergic reactions in people allergic to Brazilian nuts (Nestle, 1996). While standard plant toxicology and field tests try to measure and predict such risks, scientists cannot capture the total impact of GMO genes on every kind of organism (i.e., plant, animal, microbial), including those near the transgenic crop (Hails & Morley, 2005). Even with barren agriculture buffer zones and seed-terminator technology to prevent horizontal and vertical gene flow, significant potential ecological threats remain to be analyzed (Kuvshinov et al., 2001).

Such unresolved risks to the environment and to consumers are a potential threat to the USDA’s egocentric reputation as a guarantor of the public safety in the agricultural market, as vividly exemplified by the recent cases of Monsanto’s Roundup Ready alfalfa and sugar beets. In the absence of decisive evidence for the safety of GMOs, the USDA can request additional field tests of submitted product lines and can spend more time analyzing the results. But a delay can also be costly to an agency’s reputation. For instance, in 1988, when AIDS activists learned that the FDA might delay approval of lifesaving AIDS therapies, they demonstrated at the FDA’s headquarters, forcing the agency to make a sharp change in its policy on AIDS drugs (Carpenter, 2002). Similarly, if well-organized groups of farmers, agro-biotechnology firms, and general consumers want new GMO products, delays in approval could hurt the USDA’s reputation.

A bureaucratic agency’s reputation, while largely based on its ability to provide for the
general welfare of the public, may be particularly vulnerable to its central stakeholders (Delmas & Toffel, 2004), the individuals and businesses that are the objects of its services, operations, and functions (Clarkson, 1995; Mitchell, Agle, & Wood, 1997). For example, environmental and conservancy groups and Indian tribes would be important stakeholders for the Interior Department. The USDA’s reputation stakeholders include agribusiness and farmer associations; their dissatisfaction with the agency’s services could put it at risk. Many of these stakeholders reside in the congressional districts of elected officials who sit on the agriculture committees of Congress and who might lobby those legislators overseeing the agency to reduce its autonomy, responsibility, or resources.

Biotechnology firms might encourage agribusiness and farmer associations to endorse a product under review with a statement that the product would improve their business, the environment, or the public’s general welfare. The USDA routinely highlights in its decision reports the approval requests it received from its stakeholders and its concordance with their endorsements. For example, the USDA reported that communication from agriculture trade associations requesting approval of Monsanto’s corn variety #863 “stressed…the advantages to growers in increased yields and crop quality” (APHIS, 2005: 1).

Thus, we argue that powerful stakeholders will use the USDA’s concern for its own reputation (egocentric reputational concern) to affect regulatory decision making in favor of regulated firms. We predict that:

Hypothesis 1: Product approval requests from powerful stakeholders (agriculture trade associations) will increase the rate of product approval by the USDA.

Reference Group Evaluations and Regulatory Decision Making
Given the fundamental uncertainty about the safety of most GMOs, social influence on regulatory decisions is likely to become salient (Podolny, 1994). For two reasons, we focus on regulatory reference groups as sources of such social influence on the USDA. First, a bureaucratic actor’s reputation is based on its effectiveness and efficiency. If a regulatory reference group can make the USDA appear ineffectual or incompetent, the blow to the agency’s reputation could cost it political autonomy and budgetary support. This effect can be particularly compelling when the regulatory reference group is a rival bureaucratic agency and its reputation for analyzing product and process risks is as good or better than that of the USDA. In such cases, USDA officials may feel pressure to conform to the reference group’s opinion out of fear that any perceived inconsistency may indicate that the USDA is incorrect or is failing to perform its duty.

Second, a regulatory reference group’s evaluations of firms and GMO products can provide social cues or symbolic value that affects the reputations of the firms and their GMO products. When the USDA has to make an approval decision and there is high uncertainty surrounding the firm or product, the agency may use the evaluations of its regulatory reference groups as supplementary information in an effort to avoid making a mistake. Prominent reference groups may thus address the agency’s altercentric reputation concerns and thereby affect its approval decisions by providing legitimacy to and nonobservable information about the GMOs under review.

The FDA, for example, does not give regulatory approval for GMO products, but does act as an optional consultant to biotechnology companies on how they should design nutritional labels for their products. It bases its consultation only on nutrition results from tests conducted by the biotechnology company; it does not test the product itself, conduct a comprehensive
scientific review of the data, or examine the product’s environmental risks. The company then receives a consultation memorandum or certificate that describes any nutritional labeling issues that have been raised and resolved. A typical memorandum might confirm that a genetically modified herbicide-resistant tomato can be labeled a tomato on the basis of the company-provided information. A copy of the memorandum is forwarded to the USDA if the firm’s product is currently under review, but none of the memorandum form letters in our dataset contained any information on which the USDA would base its own ruling. Each concluded with the following disclaimer statement:

As you are aware, it is COMPANY X’s continued responsibility to ensure that foods marketed by the firm are safe, wholesome, and in compliance with all applicable legal and regulatory requirements.

The FDA is arguably one of the most powerful regulatory agencies in the world, with the authority not only to regulate all pharmaceutical and food-processing production in the United States, but also to stop the sale of any food, drug, or health product; to fine any food, drug, or health product producer if it violates labeling requirements or if its product is deemed to endanger human health; or even to shut down such a producer’s domestic operations (Carpenter, 2002). Even if FDA consultations have little to do with the product’s risk factors, the agency’s established authority and power can make it difficult for the USDA to ignore its labeling consultations. As one high-ranking official of the USDA’s biotechnology regulatory office explained:

We’re in constant communication with the FDA. We know when a company receives a consultation with the FDA and we have regular conference calls with them. The FDA and USDA rule on different aspects, but we want to make sure that we don’t contradict the FDA. You just don’t want to be in a situation where you make an approval and it’s out there and someone else is not going to approve it. The contradiction may or may not be bad, but we want to judge it as we go.
The USDA is thus likely to avoid any appearance of contradicting the FDA as a regulatory reference group, since doing so could damage its own reputation as an effective and efficient arbiter of food safety. Consultations with the FDA can thus serve as positive signals for regulated firms, leading to favorable regulatory treatment, such as higher product approval rates.

Hypothesis 2: Positive signals from regulatory reference groups (FDA consultation) will increase the rate of product approval by the USDA.

Uncertainty and Regulatory Decision Making

As noted, a regulatory reference group can provide a social cue that enhances the reputation of the applicant firm and its product—altercentric reputation, from the USDA’s point of view. Because the FDA is the sole regulatory authority and ultimate gatekeeper for the pharmaceutical industry, that agency’s evaluative capabilities are perceived to be strong. Insofar as the FDA’s ability to discern quality is trusted, other regulatory agents, such as the USDA, are likely to interpret consultations from the FDA as a valid signal for firm and product quality. Thus, when it comes to seeking USDA approval for GMO products, the value of FDA consultations may increase with the uncertainty surrounding both the GMO under review and its producer’s reputation. On the other hand, since agriculture business association requests are based on these groups’ political influence as reputation stakeholders and do not provide social-informational benefits, the value of such requests in seeking USDA approval should be independent of uncertainty about the product or producer.

As theory and research suggest, high uncertainty enhances the importance of social signals, such as consultations, endorsements, and certifications, which provide needed information, symbolic value, and legitimacy (Spence, 1974; Podolny, 1994; Stuart, Hoang, &
Hybels, 1999; Sine, David, & Mitsuhashi, 2007). When there is decisive evidence that a GMO product is safe, the USDA’s regulatory evaluations can be straightforward and are less likely to be based on external signals from other regulatory agents. In the absence of such evidence, the USDA’s approval decisions are more likely to be affected by FDA consultations. We focus on two groups of uncertainty measures: organizational characteristics (failed product petitions and foreign origins) and product characteristics (novelty and confidential business information).

**Firm uncertainty: Failed product petitions and foreign origins.** Biotech firms that have a number of past petition failures with a regulatory actor may acquire a poor reputation with the agency and therefore face longer approval times (Fombrun & Shanley, 1990). For the USDA, a firm’s history of failed product petitions could signal that it is not as comprehensive in its analyses and experimental designs as it should be, compelling the USDA to review that firm’s GMO products with greater scrutiny and adding to the review time. However, if that company consults a prominent third-party bureaucratic actor (e.g., the FDA), the consultation may serve as social information that signals the high (or at least high enough) quality of the GMO product and thus compensates for the negative effect of failed past petitions. Therefore, we predict that a consultation from the FDA will have a stronger positive effect on the USDA’s decision making when the company has a history of product petition failures.

*Hypothesis 3: Positive signals from regulatory reference groups (FDA consultation) will have greater influence on the focal regulatory agency’s (USDA) decision making when a firm has a history of product petition failures.*

Research on international business finds that firms entering foreign countries will almost always face higher costs due to unfamiliarity with the culture or laws, government discrimination
because of differences in regulatory regimes, or not being sufficiently embedded in the country’s information networks (Zaheer, 1995; Zaheer & Mosakowski, 1997). Foreign biotechnology organizations that develop their GMOs in their home countries and then petition the USDA for approval in the United States may face longer approval times, particularly if they develop and test their products under different regulatory supervision than that of the United States.

Confidence in the ability of foreign regulatory agencies to evaluate food safety has been eroded by a number of highly publicized food scares in Europe (Jacob & Hellstrom, 2000; Knowles, Moody, & McEarchen, 2007). For instance, in the early 1980s, tens of thousands of people became sick and over 800 people died in Spain from cooking oil laced with aniline, a toxic industrial chemical. A little over a decade later, British regulatory agencies failed to recognize and contain bovine spongiform encephalopathy—the notorious “mad cow disease”—which infected thousands of cattle and killed nearly 200 people (McNeil, 2006). A few years later, Belgian food regulatory agencies were discovered trying to cover up the leakage of a highly carcinogenic chemical, polychlorinated dibenzo-dioxin, into animal feed; this contamination led to the euthanization of over 7 million chickens and 60,000 pigs. More recently, a British state agency was slow to recognize and report highly infectious foot-and-mouth disease which then spread throughout Britain, threatening animals in continental Europe and leading to the slaughter of over 7 million cattle (Rivers, 2007).

With such failures in mind, the USDA may likely believe that GMOs developed and tested under the auspices of foreign regulatory agencies will not be as safe as those developed and tested under its own scrutiny and will therefore subject these products to longer investigations. However, positive signals from a regulatory reference group may serve as valuable information that may mitigate the negative effects associated with uncertainty about
foreign regulation. Thus, we predict that a consultation from the FDA will have a stronger positive effect on the USDA’s decision making when the company is of non-U.S. origin.

*Hypothesis 4: Positive signals from regulatory reference groups (FDA consultation) will have greater influence on the focal regulatory agency’s (USDA) decision making when a firm is of non-U.S. origin.*

**Product uncertainty: Novelty and confidential business information.** GMO products that involve novel components and technologies, such as new transgenic procedures, are at greater risk in regulatory review for two reasons. First, the regulatory agent must develop new evaluation procedures and techniques, which will require more time. Second, new technologies are often viewed with more skepticism (Sine, Haveman, & Tolbert, 2005). However, positive signals from a regulatory reference group can serve as reliable information that supplements product review by the focal regulator (USDA). Thus, we predict that a consultation from the FDA will have a stronger positive effect on the USDA’s decision making when the company uses novel technology for the GMO product under review.

*Hypothesis 5: Positive signals from regulatory reference groups (FDA consultation) will have greater influence on the focal regulatory agency’s (USDA) decision making when a firm’s product is novel.*

Agro-biotech firms submitting petitions for GMO product approval are allowed to withhold or redact confidential business information (USDA, 1996). However, to the extent that the petition provides less data and information to the regulatory actor as well as to outside scientists who offer opinions about the product’s potential risks, the product review is likely to
be delayed. On the other hand, consultation with a prominent third-party bureaucratic actor (e.g., the FDA) may serve as supplementary information about the product’s quality and thus mitigate the negative impact on approval time. Therefore we predict that:

_Hypothesis 6: Positive signals from regulatory reference groups (FDA consultation) will have greater influence on the focal regulatory agency’s (USDA) decision making when a firm’s product petition contains confidential business information._

**CONTEXTUAL BACKGROUND**

**Genetically Modified Organisms**

Genetically-modified organisms are plant or non-plant organisms whose genetic material has been altered using genetic engineering techniques to enhance desired traits such as herbicide resistance, pesticide properties, or nutritional content. The first successful genetically modified product to come to market was Calgene’s Flavr Savr tomato in 1992. Scientists at the California-based company discovered polygalacturonase, an enzyme that induced softening in tomatoes. By creating an antisense gene that regulated polygalacturonase production and inserting it into the tomatoes’ cells, Calgene scientists stopped almost all polygalacturonase production. The results were astonishing: Treated red tomatoes could sit on the shelf many weeks longer than normal tomatoes and not soften or spoil. Other agro-chemical and seed companies followed thereafter with their own commercial GMOs, beginning with Monsanto, which in 1993, introduced the first herbicide-resistant plant—Roundup Ready soybeans. In 1995, Monsanto would again surprise the biotechnology community with the introduction of the first plant with internal pesticide properties; the company had isolated a gene within the bacterium _Bacillus thuringiensis_ (Bt) that produced a protein which dissolved the digestive tracts of caterpillars and other insect larvae.
Over the next 12 years, agriculture biotechnology companies would commercialize favorable traits for 19 plant varieties; these were rapidly adopted by farmers, who could profit nicely from larger yields. By the end of 2006, 61% of the corn and 89% of the soybeans grown in the United States were GMO varieties and nearly 70% of all supermarket products in the United States had some GMO content (IFIC, 2007).

**Regulation and the Petition Process**

While these genetically modified plants were being developed and tested in plots around the globe, opposition arose among food-safety and environmental organizations (Weber, Thomas, & Rao, 2009). Anti-GMO activists claimed that bioengineering posed “as serious a threat to the existence of life on the planet as the bomb itself” by poisoning humanity with non-tested food and by “reducing life to its smallest components” rendering it “worthless” (Charles, 2001: 26). In 1986, under pressure from anti-GMO groups, the FDA, the Environmental Protection Agency (EPA), and the USDA adopted the “Coordinated Framework for the Regulation of Biotechnology” to regulate GMOs. Under this framework, the USDA would ensure the environmental safety of all GMO crops and the EPA would regulate substances with pesticide properties. The FDA would act only as an optional consultant to affirm food nutritional labeling; companies would not be required to consult the FDA or, if they did, to follow its recommendations.

Organizations submitting GMO product petitions to the USDA must describe the genetic transformation and its potential environmental consequences and demonstrate that the new plant variety poses no environmental threat (APHIS, 1996). Petitioning organizations must address

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2 If GM food contains a plant-incorporated protectant (PIP), it is subject to review by the EPA 90 days prior to commercialization. In our study, EPA approval for GMOs with PIPs was sought only after USDA approval.
criteria including the breeding history of the transgenic plant population; comparisons of growth
habits, life-spans, vegetative vigor, and pollen parameters; compatibility with wild species; and
consequences of gene flow to other species. The USDA’s Animal and Plant Health Inspection
Service employs about 15 scientists trained in plant biology, entomology, plant pathology,
genetics, plant breeding, and molecular biology to review the petitions. Once the USDA is
satisfied with the information, it prepares an environmental document for public comment. After
considering the comments, it publishes a response and submits a determination of whether or not
it grants nonregulated status. If the petition is approved and the product becomes deregulated, the
USDA no longer has regulatory control over the GMO and the product becomes a normal
commodity item which can be mixed with and exchanged for other plant products.

METHODS

Data and Measures

In this study, we focus on factors that lead to USDA approval (deregulated status) of
GMOs. Our sample consists of all GMO petitions for approval starting in June 1992, when the
first such petition was submitted, through December 31, 2007 when the most recent data for our
analysis were available. During this time, 113 product petitions from 29 companies were
submitted, 73 (65%) of which gained approval.

Dependent variable. Our dependent variable is GMO approval events by the USDA. We
use an event-history analysis rather than a logistic analysis because it maximizes the use of
available information (such as time to approval) and is the standard approach for research on a
similar phenomenon, pharmaceutical approval (Carpenter, 2002). Data on petitions for approval
come from the USDA’s Animal and Plant Health Inspection Service. This dataset contains
information on the organizations making the request, the species or crops in question, the date
the request was received by the USDA, the start and end dates of the Federal Register comment period, the dates of the dispositions issued to the applicant, the status of the request, whether the application contains confidential business information, and the phenotype categories and genotypes (donors and gene designations) of the material in question.

**Predictor variables.** Our predictor variables are product endorsements by agricultural trade associations and consultations with the FDA prior to a USDA decision. About 34% of the petitions received agriculture association endorsements and about 35% received a completed FDA consultation memorandum prior to USDA decision. We included dummy variables, *agriculture business association product endorsements* and *FDA consultation*, indicating that the USDA received agriculture business association letters endorsing the product and that it received the FDA memorandum letter. We read all FDA consultation memorandums and found them to be a standard form letter declaring the GMO nutritional labeling acceptable.

To test Hypotheses 3 through 6, we created a dummy variable indicating whether or not the petitioning firm was located outside of the United States (*foreign company*) and then interacted it with *FDA consultation*. We also created a count variable of the number of failed petitions and interacted it with *FDA consultation*.

At the product level, we asserted that an FDA consultation would mitigate the negative impact of GMO petitions which involved the use of novel technology (new transgenic events) or which contained confidential business information. If the genetic transformation used to create a GMO is fundamentally different from that of a previously approved article, the USDA annotates this in the Federal Register, allowing us to differentiate between radically new transgenic events.

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3 We conducted a logistic analysis to determine if any characteristics of firms or GMOs would make some organizations more likely to engage in FDA consultations than others. We found that companies that had many patents but few patent citations and that had GMOs with product quality trait transformations were more likely than other companies to consult with the FDA.
and incremental gene transformations. We therefore measured the use of *novel technology* by including a dummy variable indicating whether or not there had been such an annotation in the Federal Registrar and interacting that dummy with *FDA consultation*. We also created a dummy variable indicating whether or not a petition contains *confidential business information*, as indicated in the USDA’s registry of GMO petitions, and interacted that dummy with *FDA consultation*.

---Insert Figure 1 about here---

**Firm-level control variables.** Given that larger firms are more likely to command both greater resources (Aldrich & Auster, 1986) and greater power to affect regulatory decisions (Stigler, 1971; Carpenter, 2004), we controlled for *organizational size*, using the number of employees. We also controlled for a firm’s technological prestige by using *patent citation* relationships (Stuart, 1998). An organization filing a patent often lists prior inventions dealing with similar issues to demonstrate how its current application differs. A citation by another organization signals implicit acknowledgement of the importance of the cited organization’s patent. Thus, firms that receive more citations for their agricultural biotechnology patents should enjoy higher organizational status in the agricultural biotechnology domain. We define technological prestige as:

\[
D_{it} = \sum_j C_{jit} / L_t
\]

where \(D_{it}\) is the prestige of firm i at time t, \(C_{jit}\) is coded as 1 when a patent of firm j cited a patent of firm i during time interval t, and \(L_t\) is the total number of patents citations to all agricultural biotechnology organizations during the interval t. Because product lifecycles in the agricultural biotechnology realm are similar to those in the larger biotechnology domain, \(D_{it}\) was computed over a five-year moving window (Stuart, 1998).
Product-level control variables. We included a variable that measured public acceptance of the GMO. When the USDA is deciding whether to deregulate a GMO, it publishes a notice in the Federal Register notifying the public of the company’s petition and providing a 60-day period in which members of the public can voice their opinions to the USDA. A large number of positive public comments may motivate the USDA to approve the GMO in order to maintain or even strengthen its reputation for providing for the public welfare and acting in accordance to what the citizenry feels is right. We obtained a tally of positive public comments from the Federal Register.

When USDA scientists are trying to surmise whether a GMO created from extensively studied technologies presents a hazard to the environment, studies of similar gene transformations published in the scientific journals may reduce the agency’s uncertainty. We examined the cumulative scientific evidence concerning a GMO, as measured by the number of published scientific journal articles. Using the Institute for Scientific Information bibliographic software, we searched for articles in scientific journals on each reported gene transformation used to create a GMO and summed those articles over time in order to create a variable that captured all articles published on a gene transformation by year. In many cases, more than one gene transformation was used to create a GMO.

The greater the number of field tests a firm conducts on a GMO it has developed, the greater the positive effect they should have on USDA approval by providing the agency with more information with which to determine health and environmental safety. We included a variable for the number of field tests conducted on a GMO and a variable for the number of years it was under examination (GMO testing time). Organizations that develop GMOs containing plant-incorporated protectants (pesticides) are required to go through a product review process
with the Environmental Protection Agency. Although EPA reviews take place after USDA petition approval, we controlled for the requirement for future *EPA oversight* by including a dummy variable (1 for EPA oversight and 0 otherwise). Because too many GMO petition submissions can produce a “traffic jam,” slowing down the regulatory approval process, we controlled for the total number of petitions under review at any given time (*density*). Finally, because there may be more uncertainty about certain types of trait transformations, we controlled for five types of *phenotype categories* classified by the USDA: agronomic properties, herbicide resistance, product quality, virus resistance, and other. (Petitions can include more than one phenotype transformation.)

**Analysis**

We employed an event-history analysis to investigate the effects of stakeholder requests and consultations with the FDA on the rate of petition approval by the USDA. We used a Cox proportional hazards model because, unlike parametric regression models, it does not require assumptions regarding the shape of the baseline hazard, lending it greater flexibility. The hazard rate is given as

$$ h_i(t) = h_0(t) \exp (\beta' \chi) $$

where $h_0(t)$ is the baseline hazard function and $\beta' \chi$ are the covariates and unknown regression parameters. We used maximum likelihood estimation and the Huber-White-sandwich estimator of variance, which clusters observations on organizations, to produce robust standard errors that account for uncontrolled firm-level characteristics. Some of our interaction variables, such as $FDA \times Foreign\ company$ and $FDA \times Confidential\ business\ information$, were highly correlated, which can lead to inflated standard errors and unstable regression coefficients. We used a Gram-Schmidt procedure to partial out the common variance between the highly correlated variables.
(Cohen & Cohen, 1983; Saville & Wood, 1991). We then tested for multicollinearity and found that all variance-inflation factors in the event-history analysis were less than 3.42 and that the majority were less than 1.94, indicating an acceptable level of multicollinearity (Afifi, Clark, & May, 2004).

**RESULTS**

Descriptive statistics and bivariate correlations are provided in Table 1 and the results of the Cox hazard model predicting the rate of GMO product approval are provided in Table 2. The theoretical model for our arguments is located in Figure 1.

---Insert Table 1 and Table 2 about here---

In Table 2, the first model shows the effects of the control variables only; the second adds stakeholder product approval requests; the third adds positive signals from regulatory reference groups (*FDA consultation*); the fourth includes the interaction between FDA consultation and companies with failed petitions; the fifth adds the interaction between FDA consultation and companies of non-U.S. origin; the sixth includes the interaction between FDA consultation and novel technology; the seventh includes the interaction between FDA consultation and confidential business information and—to exemplify our assumption that the value of the stakeholder requests should be largely independent of uncertainty because they do not provide any social-informational benefits—interactions with stakeholders requesting GMO approval; the eighth model adds the interaction between USDA stakeholders and companies with failed petitions; the ninth includes the interaction between USDA stakeholders and companies of non-U.S. origin; the tenth includes the interaction between USDA stakeholders and petitions containing novel technology; and the eleventh shows the interaction between USDA stakeholders and petitions with confidential business information.
Several of the control variables had a significant effect on product approval rates. The petition approval rate was lower for companies with a history of failed product submissions. It was also lower for foreign companies, suggesting that GMOs developed and tested under non-U.S. standards may be suspected of lower quality. Novel technology, confidential business information, and virus-resistant phenotypes also reduced approval rates.

All six of our hypotheses were supported. Our results provide strong support for Hypothesis 1, which predicted that approval requests from USDA stakeholders (agribusiness associations) would increase the rate of regulatory approval. Model 3, for example, shows that a product endorsement from an agribusiness association increases GMO product approval by a factor of 1.96. Consistent with Hypothesis 2, the significant positive effects of FDA consultations indicates that a positive signal from a prominent reference group increases the rate of regulatory approval. Model 3 shows that an FDA consultation increases GMO product approval by a factor of 4.42.

Hypotheses 3 through 6 suggested that the value of FDA consultations may increase with the uncertainty surrounding a GMO product and its producer, while the value of agriculture business association requests should be independent of such uncertainty. Models 4 through 7 generally support these hypotheses. Interaction terms for uncertainty measures and USDA stakeholders are not significant, with the exception of failed petitions in Model 8, while interaction terms for uncertainty and FDA consultations are positive and significant. Hypothesis 3 predicted that the positive effect of an endorsement from a prominent reference group would be greater if a firm had a history of failed petitions. Consistent with this hypothesis, Model 4 shows that an FDA consultation improved product approval by a factor of 1.15 for companies with poor approval records. Hypothesis 4 also predicted that a positive signal from a prominent reference
group would have a greater positive effect on the rate of regulatory approval for firms of non-U.S. origin. According to Model 5, an FDA consultation increases the USDA’s approval rate for GMO petitions by a factor of 5.60 for foreign companies. Model 6 supports Hypothesis 5, which predicted that an endorsement from a prominent reference group would have a greater effect on regulatory actor decision making when a biotechnology product is novel; the approval rate increases by 5.59 times for GMO products with novel technology (radical transgenic events). Finally, Hypothesis 6 predicted that a positive signal from a prominent reference group would have a greater effect if a GMO petition contains confidential business information. In Model 7, an FDA consultation’s positive impact on USDA approval increases by a factor of 4.03 for submitted petitions containing confidential business information.

**DISCUSSION AND CONCLUSION**

How could the USDA, with its strong reputation as a guarantor of the nation’s food safety, approve such a controversial product as Roundup Ready sugar beets without taking into account some of the obvious risks involved? Our results reveal an interesting yet ironic answer: A regulatory agent’s concern for its own reputation can lead to conditions under which its decisions are shaped by nonobjective information and social influence from external audiences. Because regulatory agencies seek to protect their reputations, they try to avoid behavior inconsistent with powerful stakeholders and prominent reference groups. Thus, disputed products may be approved if delaying or rejecting approval is expected to tarnish the agency’s reputation.

More interestingly, our findings also reveal that the value of regulatory reference groups (FDA consultations) increases with product and producer uncertainty, whereas the value of the stakeholder (agriculture trade association) requests is largely independent of such uncertainty. These contrasting results are worth further discussion here. We suggested that FDA consultations
had a significant moderating effect on organizational and product uncertainty because they could serve as social cues counteracting the negative influence of uncertainty about the products under review and the firms that produced them, thereby addressing the USDA’s altercentric reputation concerns. FDA consultations may also address the USDA’s egocentric reputational concerns because a positive signal (approval of a nutritional label) from a rival bureaucratic actor (FDA) could diffuse the blame and provide political cover were the USDA to approve a faulty product.

This interpretation is consistent with other studies that have analyzed how policymakers often “find themselves in a situation where they have a common interest in diffusing the inevitable blame” (Weaver, 1986: 389) and will therefore seek to make policy judgments similar to others, including rivals, in order to distribute culpability (Balla, Lawrence, Maltzman, & Sigelman, 2002). Collectively, regulatory reference groups—especially if they are prominent rival bureaucratic agencies—may have both social and political sources of influence on focal regulatory agencies, producing consequences which are more complex than prior theory and research have revealed. It would certainly be fruitful for future research to explore the role of inter-government-agency relationships in regulatory decision making.

In contrast, USDA stakeholders did not have any significant moderating effects except in the case of firms with a record of past failures. Our theory did not predict any increased moderating effects for stakeholder pressure, so the finding about past failures is worth further discussion. A history of failed petitions for approval essentially captures a firm’s poor reputation with the USDA and, as shown in Table 2, has a negative effect on product approval. However, the results suggest that stakeholder pressure may cause the USDA to overlook the firm’s poor record (see Model 8).

This paper makes an important contribution to the literature on business-government
relations. As noted earlier, prior management research in this area has generally drawn upon two different—and often competing—conjectures that discount either the agency of regulated firms or the interest of regulators. This paper acknowledges that the regulatory decision-making process cannot be well understood as a simple dyadic exchange between a regulator and the firm it regulates. By building on the social actor conceptualization of organizations (King, Felin, & Whetten, 2010), this study suggests that regulatory decision making can be viewed as a triadic negotiated process among firms, regulators, and third-party audiences such as reputation stakeholders and regulatory reference groups. Hence, this research extends the renewed interest in agency in institutional theory (Dacin, Goodrich, & Scott, 2002; Hiatt, Sine, & Tolbert, 2009) and emphasizes the interactive nature of regulatory processes in which firms are not only affected by but also affect regulatory agencies (Dobbin & Sutton, 1998; Edelman & Suchman, 1997; Weick, 1995).

This paper also contributes to the strategic management literature by highlighting how firms in highly regulated environments can engage in political or nonmarket strategies to influence regulatory decision making (Shaffer & Hillman, 2000; King & Shaver, 2001). Acknowledging the importance of studying firm behavior and performance in regulated environments, this line of research has provided conceptual understanding of how important government policy is to firm performance and when firms are likely to engage in political strategies (Dobbin & Dowd, 1997; Hillman & Hitt, 1999). While studies have explored how firms react to variation in their political environments (e.g., Henisz & Delios, 2001; King & Shaver, 2001), very few have explored how firms can influence regulatory actor decision making (Hillman & Keim, 1995). This study suggests the value of constituency- and coalition-building among third-party regulatory reference groups and critical stakeholders as a nonmarket strategy.
This study also contributes to the reputation research in two ways. First, we introduce the notion of egocentric and altercentric reputation concerns to analytically describe how distinct reputation concerns can affect regulatory decision making in distinct ways. The two types of reputation concern suggest that reputation is important not only in uncertain situations but also when a regulator is accountable to external audiences for its decisions. Egocentric reputation concerns focus on political sources of influence that trigger a focal actor’s efforts to remain accountable to target audiences, such as agriculture business associations. In contrast, altercentric reputation concerns focus on social sources of influence which increase the value of looking to reference groups such as the FDA to reduce the uncertainty with respect to regulated firms and their products. While past research has generally focused on firm reputation as a strategic asset for regulatory approval (Fombrun & Shanley, 1990; Zaheer & Mosakowski, 1997), our findings demonstrate that the regulatory actor’s reputation concerns can also affect its regulatory decision making and thus create strategic opportunities for companies seeking regulatory advantage.

Second, we show how symbolic signaling affects external audiences’ responses and subsequently influences market outcomes within regulated environments. While much of the reputation research has focused on information benefits (Fombrun & Shanley, 1990; Rao, 1994), scholars have begun to emphasize how non-informative social cues from prominent actors can affect firm reputation (King & Soule, 2007; King, 2008). We build on this momentum by analyzing how symbolic signals from important target audiences can affect the reputations of both regulatory actors and petitioning firms. Even though agriculture trade association endorsements and FDA consultations had a positive effect on regulatory approval, neither of them provided any substantial information or evidence that the GMOs had withstood a rigorous
risk evaluation. In fact, all the FDA had done was review the product’s proposed nutritional labeling based on company-generated reports.

This paper also offers practical implications to firms in highly regulated environments. Our findings suggest that regulated firms should seek to understand a regulatory actor’s reputation concerns in order to formulate influence strategies. For example, the agricultural biotechnology firms in our study that gained external support from agriculture trade associations received an approval decision about 162 days sooner than the average and those firms that held labeling consultations with the FDA shaved about 257 days off the average wait. This is consequential, since it can cost a biotechnology firm up to $2 million of forgone revenue for each day its product is under review rather than on the market (Monsanto, 2010). By considering a regulatory actor’s reputation, firms will have at their disposal not only conventional tools such as lobbying and expert testimony, but also nonconventional tools such as building constituencies and coalitions among critical stakeholders and other regulatory agencies and gaining their support. Consequently, a particularly important direction for future research and practice will be to investigate the relationship between these various tactics and to distinguish their relative importance.
REFERENCES


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Figure 1: Theoretical Model

Stakeholder product approval requests
(Agriculture trade associations requests)

H1 +

Regulatory Actor (USDA) Decision-making
(GMO approval)

H1 +

Product Uncertainty

Novel Product

H5 +

Confidential Business Information

H6 +

Company Uncertainty

Number of Past Failures

H3 +

Foreign Company

H4 +

Positive signals from regulatory reference actors
(FDA Consultations)
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<th>3</th>
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<th>6</th>
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<td>0.211</td>
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<td>0.094</td>
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<td>-0.260</td>
<td>0.256</td>
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<td>-0.146</td>
<td>0.230</td>
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<td>GMO testing time (years)</td>
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<td>1.463</td>
<td>0.181</td>
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<td>Number of positive public comments</td>
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<td>0.143</td>
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<td>Phenotype: Virus Resistance</td>
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<td>Phenotype: Other</td>
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**Correlation Matrix:**

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### Table 2: Cox Event-History Regression of GMO Approval Rate

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<th>Variables</th>
<th>Model 1</th>
<th>Model 2</th>
<th>Model 3</th>
<th>Model 4</th>
<th>Model 5</th>
<th>Model 6</th>
<th>Model 7</th>
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<td><strong>Independent variables</strong></td>
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<td>H1 Stakeholder (trade associations) approval requests</td>
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<td>0.674***</td>
<td>0.659***</td>
<td>0.659***</td>
<td>0.431*</td>
<td>0.582***</td>
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<tr>
<td></td>
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Robust standard errors in parentheses
* significant at 10%; ** significant at 5%; *** significant at 1%
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Robust standard errors in parentheses
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