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Public Policy Timeliness to Disruptive Innovation in Biotechnology: Information Feedback and the Regulation of Balancing Loops [†]

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Abstract

The objective of this paper is to identify endogenous pressures, and their time delays, that are responsible for regulatory change in the plant agricultural biotechnology area. An influence diagram, the initial step of the system dynamics (SD) method, makes explicit the role of information flows as a limiting factor for use by the various parties, and as a means of controlling strategic transactions that influence efficiency and the distribution of wealth. A SD model is developed based on the influence diagram to simulate the interaction between investors', consumers', and regulatory feedback within the model. This method is employed to clarify informational requirements, define causal relationships, and identify the main feedback loops that influence the dynamic behavior and to inform the regulatory process.

Keywords: biotechnology, system dynamics, disruptive technology, regulation, information feedback

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This paper investigates the reinforcing and balancing regulatory pressures that are impinging on the performance of agricultural and food biotechnology-based activity in Canada. Regulatory agencies are in the process of adjusting their procedures to take into account disruptive innovations in biogenetics, proteomics, pharmacogenomics, and bioinformatics (Burrill & Company 2000; Christensen 1997; The Economist 2000)[1]. This adjustment has become necessary because governments need to balance emerging tensions between the informational needs of consumers and investors. Information requirements of the regulatory agencies are changing. Part of the outcome of the regulatory process is to satisfy the informational needs of consumers and investors concerning the technology. Regulators need information on health and safety of new biogenetics-based products (transgenic crops, feeds, and foods), consumers demand information about product characteristics, and investors are in need of information on intellectual property rights (IPR) and administrative process.[2]

The objective of this paper is to identify endogenous pressures, and their time delays, that are responsible for regulatory change in the plant agricultural biotechnology area. An influence diagram, the initial step of the system dynamics (SD) method, makes explicit the role of information flows as a limiting factor for use by the various parties, and as a means of controlling strategic transactions that influence efficiency and the distribution of wealth. This method is employed to clarify informational requirements, define causal relationships, and identify the main feedback loops that influence the dynamic behavior in the regulatory process.

The lack of a method to operationalize institutional economic theory often restricts its influence among economists due to its perceived limiting potential for theory building and generalization (Coase 1998). The preoccupation of institutional economics with "pattern identification" has led, in recent years, to the suggestion that simulation methods, and in particular the SD method, is a means of operationalizing institutional economic concepts (for details on the relationship between institutional economics and SD concepts see Radzicki (1988) and Radzicki (1990)). Central to SD are the notions of feedback and of time delay. Actions within a system can be modeled, and their associated flows (whether physical, economic, and/or information) influence the accumulation, with some time delay, of levels within systems[3] (Forrester 1994; Richardson 1991). These interactions of stock-and-flow microstructures are used to study the macrobehavior of the system modeled. SD is also suited to address issues such as biotechnology regulation because of the disruptive nature of these innovations and of the lack of regulatory experience (March et al. 1991). This simulation approach can generate the information needed because it can: (1) supplement human bounded rationality in decision making (Simon 1991), (2) consider the unintended consequences of alternative regulatory option (Merton 1936), and (3) provide evidence to interpret results with institutional economic concepts. The proposed application of SD methods in this paper contributes to the integration of institutional economic theory with a modeling framework.

Institutional Concepts, Information Requirements, and the Regulatory Decision-Making

Institutional Concepts

The regulatory institutions of the agriculture and food sector are under increasing pressure from consumers and investors to adjust (Industry Canada 2000). Institutional change can be viewed as a mechanism to balance the interests of consumers and investors. Commons (1931) suggested that the regulatory framework adjusts by taking into consideration the pragmatic criteria of workability in institutional design. He made a distinction between various types of transactions: rationing, managerial and bargaining. The concept of a strategic transaction incorporates the dynamic element of institutional change as a response to a disruptive innovation. A strategic transaction is one that controls the limiting factor (Commons 1931). Once the strategic transaction has been set, all other factors can be dealt with using routine transactions by redefining the underlying rationing, managerial and bargaining transactions (Rutherford 1983). It also influences the institutional design of the regulatory framework, and the choice of "working rules" (Commons 1931).

A disruptive innovation, such as the one of biotechnology, presents a case that illustrates how both consumers and investors want to control the strategic transaction in order to benefit from their use of routine transactions as a means to influence efficiency and welfare distribution. The limiting factor in the strategic transaction for agriculture and food biotechnology is the information flows between consumers, investors and regulators. Rationing transactions that could be important in this situation can include such things as the defining of IPR and trade agreements. These rules will have an impact on the size of quasi-rents that can be generated by investors. Other institutional rules related to the production of agriculture and food biotechnology products, such as standard legislation, can impact the managerial transactions. These rules could impact the cost of production at the firm level. Finally, bargaining transactions at the retail level can be effected by labeling requirements and product segregation. This could impact the availability of information for consumers and identifiable choices. All of these routine transactions have an impact on the efficiency of the agriculture and food biotechnology sector and the distribution of benefits and burdens between consumers and investors.

Information Requirements and Regulatory Decisions

The research framework fits within the context of the growing body of literature on the economics and social management of biotechnology (Eliason and Eliason, 1996; Grabowski and Vernon; 1994; Malherba and Orsenigo, 1996; Prevezer, 1997; Senker, 1996). Biotechnology-based products have found applications mostly in the pharmaceutical, agricultural and food sectors, as well as on the environment. While there have been research efforts devoted to the modeling of the biotechnology industry (Padmore, Schuetze, and Gibson, 1998a, 1998b), the literature reports no known efforts to model and to simulate over time the effect of policy changes. Also, no known representations of the biotechnology industry address the issue of time delays and the implication of feedback in policy decision-making.

Researchers have suggested that decision makers often are falling into decision traps (Hammon et al. 1998, 1999; Russo and Schumaker, 1989). The literature on decision behavior suggests these traps might be due to the misperception of information feedback in decision-making. Long time delays in the transmission of information flows change the perception of reality. These limit human rationality in the treatment of information for decision-making (Kampmann and Sterman, 1996; Simon, 1991). When decision processes are subject to long time delays, the scarcity of information creates uncertainty. This uncertainty limits the performance of decision-making processes and lowers the impact of expected results. This problem is applicable to the bio-industrial sector, where long time delays associated with the management of several processes.

SD is a well-established method for conducting research on the behavior of complex systems using mathematical systems of first-order difference equations (Forrester, 1961; Sterman, 2000). The SD approach is based on a causal and endogenous explanation of the functioning of structures (Coyle, 1998). The computer-based modeling of structures helps researchers simulate operational, tactical, and strategic questions to study the anticipated behavioral response of the system over time (Cloutier, 1999). This modeling approach also facilitates the interpretation of results using user-friendly visualization support that returns rapid feedback to researchers and decision-makers. The approach facilitates organizational learning and, if properly executed, provides a pathway towards the implementation of solutions.

The principles of SD are rooted in the modeling of feedback loops that take into account time delays within systems. The structure of feedback loops is modeled to track the impact of policy decision on dynamic behavior. The approach makes explicit and transparent the underlying assumptions of the model and makes for a convenient revision of these assumptions when new information becomes available (Sterman, 2000).

Information Scarcity and Regulatory Pressures

Prior to the emergence of biotechnology, agriculture and food products and processes, and their regulation, were well defined. An established set of institutional mechanisms (patents and plant breeders rights) had developed over time to secure expectations concerning IPR for investors, and a safe and reliable food supply for consumers (figure 1). For consumers, agriculture and food products were slight variations of the ones found in nature, and were considered safe from both health and environmental perspectives. Consumers, while not having a complete understanding of the process used in product development, had some understanding of the process or had confidence in the institutions that regulated agriculture and food products to understand and provide for safe product commercialization. From the industry perspective, the process of product commercialization was well known and the institutional mechanism to protect one's discoveries, and the benefit flows from those discoveries, were well-established. In addition, investors understood the regulatory process needed to bring a product to commercialization. The regulatory framework had well established informational flows, decision criteria, and regulatory processes that were accepted and known by consumers, investors, and regulators.

Recent biotechnology innovation in agriculture and food products and processes has generated uncertainty within the sector (figure 1). Consumers have health, safety, and environmental concerns of products being developed with these new technologies and are demanding more information from the regulatory institutions (Huff and Owen 1999; Veeman

1999; Hobbs and Plunkett 1999). They also are questioning the process by which products are developed (Kerr 1999). Their concerns include both ethical considerations and the potential environmental risks associated with biotechnology (Mooney and Klein 1999). Investors also have concerns from both product and process perspectives. Product development from a biotechnology platform has inherent risks and uncertainty. Investors do not know whether or not their R&D activities will provide a payoff in terms of a useful product. In addition, the regulatory body is attempting to establish an institutional mechanism to deal with biotechnology processes and products. As a result there is regulatory uncertainty. Finally, the extent of product acceptance by consumers is also unknown (Huff and Owen 1999; Owen and Gould 1999; Hobbs 1999). To complicate matters, there are long time delays between R&D activities and commercialization that magnify the uncertainty for investors.

The uncertainty associated with the introduction of biotechnology innovations in the agriculture and food sector is the driving force for institutional change. Consumers are demanding more and better information from regulators as a means of reducing their uncertainty. This has resulted in regulators demanding more information from investors. In addition, investors are demanding information from regulators on regulatory process in order to decrease the uncertainty. This demand for information is resulting in institutional change from regulatory agencies both in terms of enhancing the informational flow (between consumers and investors) and in the development of decision criteria to evaluate products (Hobbs and Plunkett 1999; Owen and Gould 1999; Industry Canada 2000).

Institutional change of the agriculture and food regulatory framework will evolve as a result of the new informational requirements of consumers and investors. The choice of institutional change will impact the efficiency of the agriculture and food sector and the distribution of benefits and burdens. Investors would prefer a regulatory framework that decreases their uncertainty. This could be done in a number of ways: (1) identification of acceptable biotechnology platforms, (2) establishment of a regulatory framework flexible enough to accommodate innovation, (3) elimination of unnecessary delays to commercialization and timeliness of process, (4) protection of IPR so that investors can benefit from their innovations, and (5) enhancement of product acceptability by providing information to consumers. Consumers on the other hand, would support institutional change that lowers their uncertainty. This could include: (1) information on the health implications of biotechnology products, (2) information on the environmental risks, (3) ethical considerations, and (4) opportunity costs associated with not consuming biotechnology-based products.

The Regulatory Process

In Canada, the regulatory framework for agriculture and food biotechnology authorizes the commercialization of products (Flint et al. 2000). This is similar to the US regulatory framework but differs from the Australian framework that authorizes the process (Flint et al. 2000). Canada's regulatory framework assesses biotechnology-based products in terms of their novel traits and their potential for impacts on health, environment, and production agriculture. The approach taken by government to deal with biotechnology was to amend existing legislation and regulation.

The commercialization of a plant product with a novel trait consists of a four step product authorization process. These steps include: (1) contained use (in a laboratory, growth chamber, or greenhouse), (2) contained field trials (small test plots under controlled condition that restrict plant interactions with the environment), (3) unconfined release (permitted to be grown in large quantities), and (4) commercialization (variety registration and commercial release) (Flint et al. 2000). Environmental assessments are undertaken after step 1 and before step 2 can be authorized, and again after step 2 and before step 3 can be started. This latter assessment determines the environmental safety of products with novel traits. After step 3 a food or feed safety assessment is undertaken. Pending authorization, commercialization can proceed.

The Government of Canada has recently announced a $CND 90 million initiative to address biotechnology-based regulatory issues as a means of responding to both consumers and investors demands for regulation (Industry Canada 2000). The government recognizes its role in balancing informational needs of consumers for health, safety, and the protection of the environment, with the informational needs of investors to secure their expectations for IPR and timeliness of regulatory procedures.

A Dynamic Hypothesis of the Regulatory "Balancing Act"

A dynamic hypothesis is developed using available information and knowledge of the existing agriculture and food biotechnology regulatory framework in Canada by means of an influence diagram[4]. Feedbacks represented in an influence diagram using reinforcing and balancing loops that cause the dynamic behavior of the system. The reinforcing feedback loop characterizes a behavior that feeds on itself to exhibit exponential and asymptotic growth or collapse. The balancing loop characterizes a behavior that tends toward equilibrium. It is the interplay of these feedback loops that, at a given point in time, create dynamic behavior[5].

The influence diagram illustrates the supply and demand for information by both consumers and investors. Information flows counterbalance the uncertainty resulting from the current void in agriculture and food biotechnology regulation.

The influence diagram, in figure 2, illustrates the reinforcing feedback loop (denoted R) of innovation as the basic economic dynamic of agriculture and food biotechnology. If consumers perceive biotechnology products in a positive light then the reinforcing loop is interpreted as follows. An increase in investors' ability to exploit agriculture and food biotechnology is supported by consumers' perception of potential benefits from their use. The consumers' perception of the value of biotechnology supports the investors' perception of potential economic quasi-rents. The perception of positive quasi-rents supports investments to further the capability to exploit biotechnology innovations. This reinforcing feedback would continue to experience economic growth. If consumers perceive biotechnology products in a negative light, then investors' perception of quasi-rents will decrease, thus the reinforcing loop will be dampened.

A large number of factors influence the consumers and investors reinforcing loop because biotechnology innovations are disruptive and introduce additional detail and dynamic complexities not currently addressed within the existing regulatory framework. The literature suggests that the regulatory framework is a source of Knightian uncertainty for consumers and investors[6] (Hobbs and Plunkett 1999). Consumers are reluctant to embrace transgenic-based agricultural and food products given a lack of information about potential health risks, and also, unforeseen long-term consequences of their consumption and production (Huff and Owen 1999; Hobbs and Plunkett 1999). Similarly, investors want a regulatory framework that is clear, consistent, and predictable so that investments are protected and there is a level playing field with international competition (Huff and Owen 1999). The dynamic hypothesis includes the uncertainty for consumers and investors using balancing loops denoted B1 and B2 (figure 2).

Balancing loop B1 depicts an increase in investor uncertainty supports the demand for regulations that would clarify and define IPR and other regulatory aspects (Marks et al. 1999; Young 1999). This translates into added pressure for regulation in this area (Industry Canada 2000). In the interim, the uncertainty of existing government regulation decreases the opportunity for economic quasi-rents, by constraining this component of the reinforcing loop (R), and thus limits the exploitation of biotechnology innovation.

Consumers' concern over the introduction of agriculture and food biotechnology increases their uncertainty and decreases consumers' perceived benefits of biotechnology innovation (Hobbs and Plunkett 1999; Veeman 1999). Industry Canada (1998) reports that Canadian consumers have a limited understanding of the regulatory process and access to information regarding transgenic agricultural and food processes and products. These facts are captured by the balancing loop B2 where consumers' uncertainty arises due to a lack of information. This translates into a consumer demand for information and increases the pressure for regulation. Consumers' uncertainty decreases the perceived benefits from biotechnology. The structure of behavior depicted in the balancing loop B2 constrains the reinforcing loop (R) from the consumer side. Uncertainty surrounding the regulatory framework for agricultural and food biotechnology limits both consumers and investors. Balancing loops B1 and B2 stress how the existing regulatory framework needs to adjust to this new demand for information.

The Government recognizes that the regulatory framework must supply additional information to consumers and investors. This information is the limiting factor that has created uncertainty. For example, consumers' desire for food safety and health could translate into policies that supply labeling information to consumers. This is represented in figure 2 by the two balancing loops, B3 and B4. These loops emphasize the balancing act, between the demand and supply of information by consumers and investors, the Government would provide by introducing regulation. Balancing loop B3/4 shows that as information becomes available to consumers and investors, the pressure on government regulation would diminish. Balancing loop B3 depicts current investors uncertainty and provides a direct incentive for regulation in order to decrease this uncertainty. This will only occur after some time delay. Similarly, balancing loop B4 illustrates that current consumer uncertainty provides an incentive for government to supply information about products and processes to lower this uncertainty.

The introduction of regulation would supply information to both consumers and investors. This would support investors' perception for economic quasi-rents. As illustrated by the balancing loop B5, the regulation decreases the pressure for regulation. Similarly, regulation could provide consumers with the desired knowledge about health, safety, and environmental risks and thus lower the demand for further regulation (balancing loop B6).

Conclusions

Biotechnology into agriculture and food products is a disruptive innovation that is causing institutional change. The limiting factor in the strategic transaction is the informational requirements of consumers and investors. Consumers, investors, and regulators are in the process of redefining the strategic transaction. Once the strategic transaction is defined it will influence the working rules of the regulatory framework. These working rules will direct the rationing, managerial and bargaining transactions that will become part of the routine transactions. These routine transactions impact the efficiency of the agriculture and food sector, the distribution of wealth between consumers and investors, and streams of quasi-rents.

An influence diagram was used to model information flows required for biotechnology into agriculture and food products. This approach is a promising method of modeling institutional economic concepts and can be used to develop and generalized theory.

A SD quantitative model based on the influence diagram presented in figure 2 is being developed using standard SD software. When completed, this model will include the key stock and flow variables comprised within the consumer/investor/regulatory interaction system. The focus of the interactions encompasses the information flow requirements and adjustment time delays of the balancing loops identified in the influence diagram. Many of the variables in the system cannot be calibrated using "hard" data and indicators. Instead, the model's design aims to characterize the interaction amongst key delays and stock-flow graphical relationships. These relationships and indicators are supported by SD graph table methods, the literature, and expert involved in the biotechnology sector. Such a quantitative model is key for scenario design and prototyping activity that address consumers and investors uncertainty mapped out in the influence diagram. The objective of the SD model is to learn from the proposed scenarios that will demonstrate the pressures that underlie the intricate dynamic and nonlinear interactions amongst the variables that interact within the model. The objective is not make prediction as to the market and regulatory outcomes but to learn about the role of information and of its management in the regulatory process (DeGeus, 1988).

Notes

[1] Christensen (1997) distinguishes between 'sustaining' and 'disruptive' technologies. The introduction of a disruptive technology has far ranging implications for consumers, firms, and markets. Sustaining technologies are more incremental in nature. Bioengineering technologies are an example of disruptive or discrete technologies.

[2] The industry typically distinguishes four 'waves' of transgenic agriculture and food products. The 'first wave' consists of agricultural input based traits (for example, Bacillus thuringiensis (Bt)/herbicide resistant Cotton, Bt/herbicide resistant corn, herbicide resistant soybeans, and canola). The 'second wave' of products are output traits that procure a value to consumers (for example, provitamin A (â-Carotene) in rice). The 'third wave' consists nutraceutical products that may be better for human health than commodities (for example, plant-based manufacturing of antibodies). The 'fourth wave' includes industrial product applications (for example, plastics and nylons made of oilseed crops). The products available on the market are based on input trait characteristics of plants. The adoption trends of these products in production agriculture have been phenomenal over the past five years. For the crop season 2000, the percentage of transgenic seed planted acres was 61% for cotton, 24% for corn, and 54% of soybeans planted acres in the United States. In Canada, 62% of canola planted acres used transgenic seeds (Clive 1999). Their economic benefits to producers, however, remain mixed depending upon the crop, location, growing conditions, etc. (Fulton and Keyowski 1999; Hyde et al.1998; Klotz-Ingram et al. 1999; Traxler and Falck-Zepeda 1999).

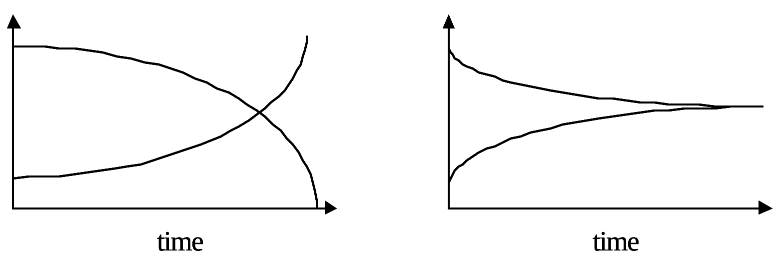
[3] SD includes a suite of flexible simulation methods that makes possible the development of dynamic hypotheses and the design of computer models to generate an associated set of empirical results (Forrester 1994; Morecroft and Sterman 1994; Sterman 1988, 2000). Most SD inquiries include three components: (1) expert knowledge, understanding of a problem, access

to information (provided from data, experts, literature, etc.), (2) an influence diagram to map out a dynamic hypothesis, (3) a computer model (Coyle 1998).

[4] Following established syntax in SD research (Roberts et al. 1983), an influence diagram represents the direction of influence between a set of components using ‘+’ and ‘-‘ symbols. A reinforcing feedback loop, denoted (R) and is followed and by an identification number, has an even number of ‘+’ to indicate the direction of the influence between the elements of a feedback loop. A balancing, or equilibrating loop, denoted (B) and is followed by an identification number. It possesses an odd number of opposing relationships among the influences within the feedback loop.

[5] The following graphs illustrate the dynamic behavior over time of reinforcing and balancing feedback loops, respectively.

Reinforcing feedback behavior **Balancing feedback behavior**



[6] Knight (1921) is credited for the distinction between economic risk and uncertainty. Economic uncertainty as defined by Knight rejects the possibility that the future be predicted using present or past measures of probability (Boudreaux and Holcombe 1988). This notion assumes indeterminacy, that is, the impossibility of predicting the future in all its richness to provide enough intelligence for decision-making. It also assumes that human judgment is a key ingredient that forms the basis for decision-making and does not rely on the notion of general equilibrium (Cloutier 1999).

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Figure 1. Regulatory uncertainty of biotechnology products and processes

Breeding Type	Product: <u>Consumers</u>	Product: <u>Investors</u>	Process: <u>Consumers</u>	Process: <u>Investors</u>
Natural (known)	Similar to natural products	Consumer acceptance	Understanding Confidence in technology Confidence in regulatory process	Plant breeding Regulatory process
Biotechnology (Uncertain)	Health Safety Environment	Consumer acceptance Timeliness Regulatory process	Health concerns Ethical concerns Environmental risks (biodiversity)	R&D platforms Fiscal policies IPR protection

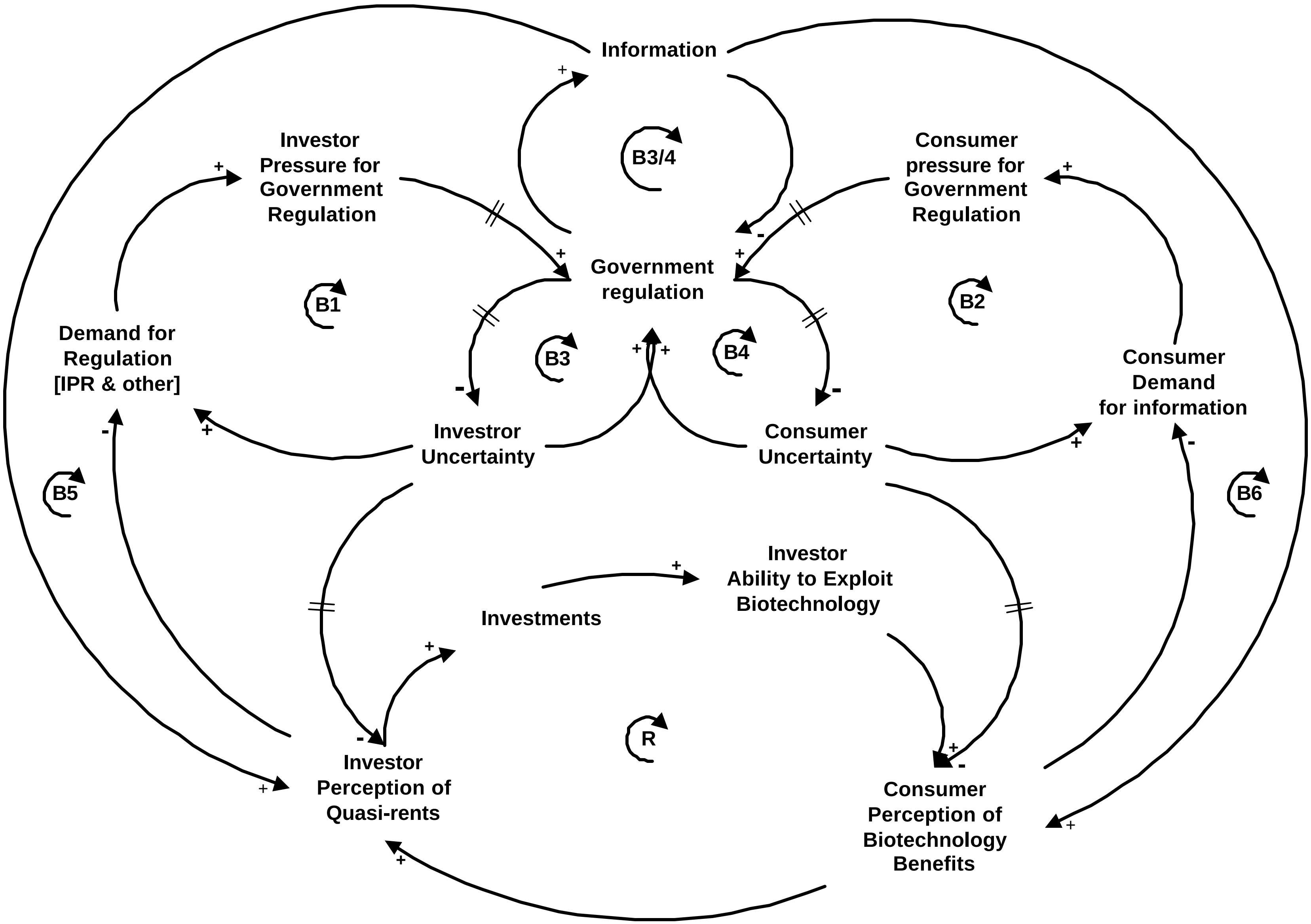

Figure 2. Influence diagram of the consumers and investors growth reinforcing loop, uncertainty and control of the limiting factor routine transaction feedback loops