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Making Markets for New Foods

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Abstract:

An array of output trait agri-food products are being developed within the global biotechnology and agri-food sectors, including nutraceuticals, functional foods, dietary supplements, natural health products, vitamins and various other novel foods. These proprietary products exhibit credence attributes that may, in many cases, necessitate more proactive market-making efforts than were required for first generation, input traits. There is significant effort underway around the world to develop the conditions for developing, regulating and commercializing these products. This paper examines the economic nature of these products, reviews the market-making challenge, and examines efforts in a variety of countries to develop the appropriate regulations, standards and supply chains to ensure effective and efficient market introduction.

Key words:

Third generation novel foods; credence goods; market-making; regulation; supply chains

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1. Introduction

There is an important link between agricultural research and the health of consumers. The incidence and severity of many major diseases such as diabetes, coronary heart disease and cancer are affected by diet and nutrition. Through modern biotechnology and conventional breeding, agricultural research can change the nutritional composition of diets by lowering the cost of producing food that is more nutritious and by improving the nutrient composition of the foods that are currently grown. Agricultural research has the potential to improve the health of consumers and reduce the costs associated with nutrition related disease.

Historically agricultural research has focused on increasing food production. During the nineteenth and twentieth century, improvements in crop genetics, agronomic, chemical and mechanical innovations contributed to dramatic increases in agricultural productivity (Diamond 1997, Omstead and Rhode 2002). During the 'Green Revolution' of the 1960s and 1970s the main focus was to increase yields and herbicide and pesticide resistance (Alston, *et al*., 1999). Presently researchers are focusing more on developing higher quality products to provide healthier nutritional content.

While the science promises to deliver new and varied products that may enhance human health, it is not clear we have the appropriate legislation, regulations, marketing structures and institutions to safely and economically deliver those products to consumers. From a researcher's point of view three main issues arise in the management of agricultural innovation: protecting innovations from competition through intellectual property rights; regulating the safety of new product in the public and private sectors; and finding mechanisms to signal health and other credence claims. The international variation of legislation also creates challenges and barriers for development, since the regulatory differences can become underlying trade barriers.

The objective of this paper is to provide a general overview of the novel/functional foods industry—market trends, research areas and their future possible applications—and to examine the existing private incentives, current patterns of private and public investments in agricultural research, emerging market forces, supply chains, public expenditures and regulatory framework that underpin the industry.

2. Defining the Problem

Traditionally, public regulations for health and safety provide some level of assurance for consumers that the products they consume meet minimum standards while private brands signal to consumers the commitment of certain producers to the quality of their products. Many of the emerging and new products being developed in the global agrifood system currently fall outside the scope of current regulations and brands.

The most pressing, immediate problem is that there are no generally accepted definitions of what we are talking about. The boundaries between medicine and food have been blurred with the scientific evidence that some foods produce health benefits. As the issue arose in the 1990s multiple definitions were adopted, which has created industry and regulatory confusion. Different regulators and different parts of the industry use an array of terms—including novel food, dietary supplements, functional food, medical food, natural health products, vitamins and nutraceuticals—to identify value added food products with health benefits (see Table 1 for the main distinctions). Confusion arises because different associations and groups use different terms to identify the same things.

Lately industry has converged on the term 'functional food' as the most acceptable term for food items with health benefits. But even this term refers to different things by different associations. For example, the Institute of Medicine of the National Academy of Sciences, as well as the American Dietetic Association use the term functional food to describe food items which were created by agricultural research to enhance health benefits (ADA Webpage, 2004). Others, including the International Life Sciences Institute of North America (ILSI) and the International Food Information Council (IFIC Webpage, 2004), use functional food to describe a much broader category, referring to items that have health benefits beyond nutrition benefits.

The European Union (EU), United States (US) and Japan presently have no official accepted definitions. Novel food is defined in the EU as any food items not commonly sold before 1997 (EC No 258, 1997). The terms functional food and nutraceutical, terms used in Canada, are not officially accepted in the EU. The US has no official term, despite the existing regulations regarding health claims. Japan originally used the functional food term, but has since dropped it and changed to FUSHO (Food Used for Specified Health Reasons) for regulatory reasons (Heasman and Mellentin, 1999). In short, neither the scientific community nor regulators has any common definitions, which creates confusion between industry players and makes the harmonization of international regulation harder.

Table 1 Terminology around the world

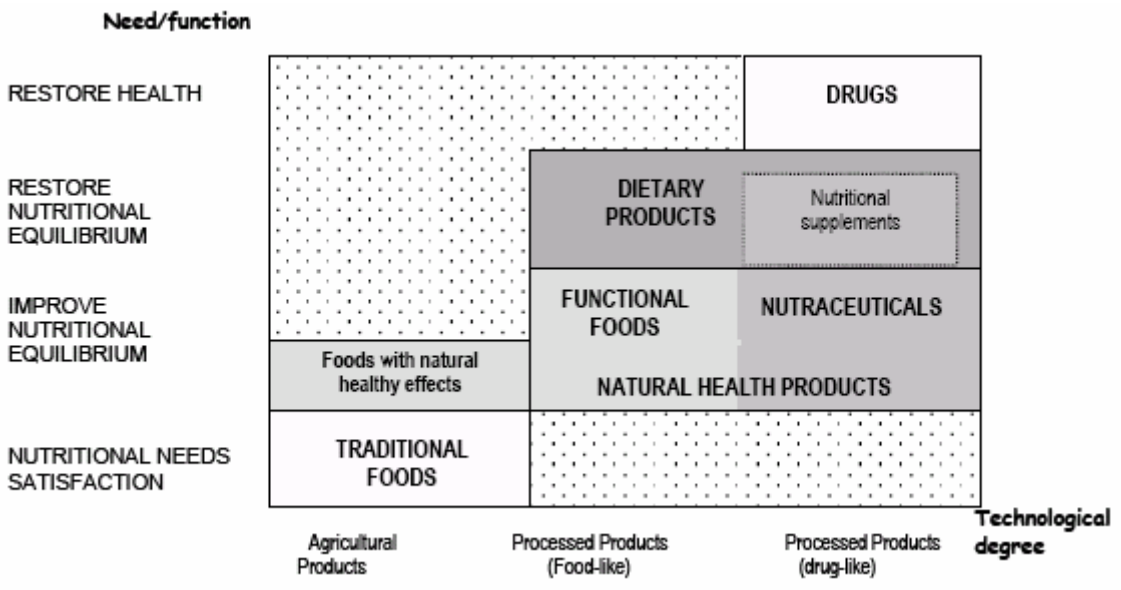
Location	Functional Food	Nutraceuticals	Medical Food/ Dietary Product	Novel Food
Canada	"*Functional food* is similar in appearance to, or may be, a conventional food, is consumed as part of a usual diet, and is demonstrated to have physiological benefits and/or reduce the risk of chronic disease beyond basic nutritional functions." Policy Paper, Nutraceuticals / Functional Foods and Health Claims on Food, 1998.	"A product isolated or purified from foods that is generally sold in medicinal forms not usually associated with food. A nutraceutical is demonstrated to have a physiological benefit or provide protection against chronic disease." Policy Paper, Nutraceuticals / Functional Foods and Health Claims on Food, 1998.	"Food for special medical purpose" term had been used in the Food and Drug act since 1954, revised in 1996.	Never used as a food before OR Modification which causes the food to undergo major change OR Genetically modified, Food and Drug Regulations - [Amendment (No. 948), as published in the "Canada Gazette Part II" - October 27, 1999].
United States	No official term by FDA, but ILSI, IFIC and The Institute of Medicine of the National Academy of Sciences use the term for food items, which have health, benefits beyond nutritional.	No official term by FDA, but the term widely used in the marketplace, "substances in or parts of a food that may be considered to provide medical or health benefits beyond basic nutrition, including disease prevention." IFIC.	"A medical food is prescribed by a physician when a patient has special nutrient needs in order to manage a disease or health condition." US Food and Drug Administration.	N/A
European Union	No official term by Food and Feed Safety. FLEP declared there is no need for official term, in the Discussion Paper on Nutrition Claims and Functional Claims. Although the scientific community use the term: "affect one or more targeted function of the body in a positive way." British Food Journal.	N/A	"Dietary foods for special medical purposes are intended to meet the particular nutritional requirements of persons affected by or malnourished because of a specific disease, disorder or medical condition" COMMISSION DIRECTIVE EC of on dietary foods for special medical purposes, 1999/21.	"Foods and food ingredients that have not been used for human consumption to a significant degree within the Community before 15 May 1997." EU Novel Food Regulation (NFR) EC No. 258/97 27 January 1997. Official Journal L 043, 14/02/1997 P. 0001 - 0006.
Japan	Functional Foods recognized as foods for specific health use in 1991. "FOSHU" this term replaced "functional food".	N/A	N/A	N/A

This paper uses the terms and definitions as defined by Health Canada to help provide a taxonomy for addressing these new products. Although Canada does not have regulations in place yet, they are the first and only country to develop a coherent official terminology for the range of products involved. In 1998 the Health Protection Branch of Health Canada put together the first Policy Paper that offered definitions for functional foods and nutraceuticals (Health Canada, 1998). According to Health Canada, functional food means any food products providing health benefits beyond nutrition. If the health beneficial ingredients are extracted from food products and sold in medical form (e.g. pill form) they are to be called nutraceuticals (Health Canada, Therepautic Products Programme and the Food Directorate, 1998). At the same time they strictly exclude products that treat, cure or prevent diseases. The novel food term was officially named in Canada in 1999, when the Food and Drug Administration Act introduced a new section (Division 28) regulating novel foods. In the definition of novel foods the Government of Canada includes substances that have no history for use as a safe food, food products manufactured with new processes and foods that have been genetically modified (Health Canada, 1999).

Cloutier and Saives (2002) offer a complementary taxonomy to categorize the functional eating product field to clarify the boundaries between food, functional food, nutraceuticals and drugs (see Figure 1). They addressed two dimensions of the characteristics: technological degree and need/function. The technological degree defines how the product looks (i.e. is it a raw agricultural product, a food-like processed product or a drug-like product) while the need/function dimension defines the product's effect on ones health (e.g. does it fulfill nutritional expectations by improving and/or restoring nutritional equilibrium and/or curing disease).

The functional eating product field diagram is useful to demonstrate the difference between nutraceuticals, functional foods and drugs, but it does not explicitly address where novel foods fit. Functional foods are not necessarily novel foods and vice versa, however the two categories can and do overlap. According to Agriculture Canada, functional food items can be grouped into four categories: basic food items (e.g. carrot); processed foods (e.g. oatmeal cereal) processed foods with added ingredients (e.g. calcium-enriched fruit juice); and enhanced foods with more of a functional component (via traditional breeding, special livestock feeding or genetic engineering) (Food Value Chain Bureau Website, 2004). Based on the definitions offered above, only the last category belongs to the novel food category.

Figure 1: Functional production fields

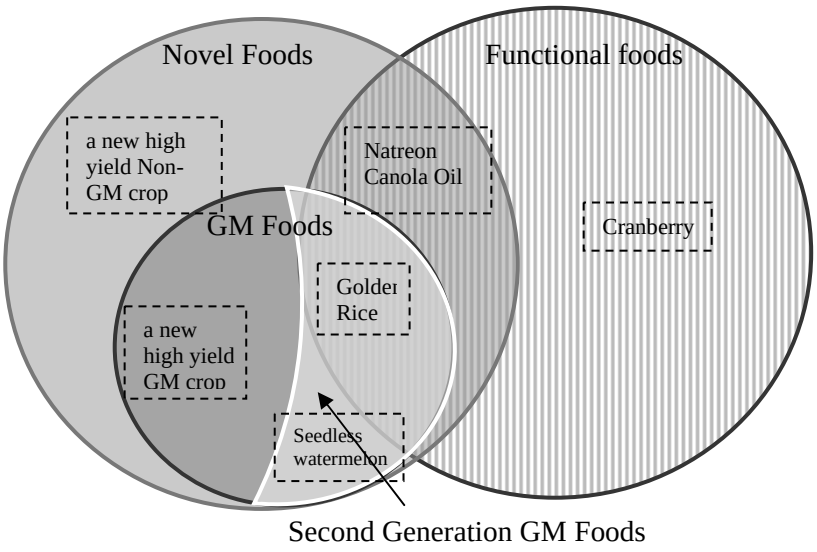


Source: Cloutier and Saives, 2002: 676

Similarly, there are some functional foods that have been part of our diet for a long time and hence are not novel, but they have recently been proven to have health benefits beyond nutritional (e.g. cranberries). GM foods warrant a special mention. While all GM crops are novel, only a few will be functional foods. There are an array of novel GM foods (e.g. herbicide tolerant GM crops) that have no functional food attributes while some second and third generation GM crops have extensive change (e.g. beta carotene Golden rice). Novel food products can also be developed through conventional breeding. One example is Natreon Canola Oil, which improves the stability of canola oil, eliminating the need for hydrogenization. As a result, the oil does not contain any trans fats.

Although all functional foods offer potential economic welfare improvement due to their health benefits, the main focus of our paper is the intersection between novel and functional food category (see Figure 2). The overlaps between novel and functional foods, especially those products developed by biotechnology, offer an interesting case, as they represent an area with an array of overlapping, different and at times conflicting regulations that may create insurmountable barriers for trade.

Figure 2: The relationship between functional, novel and GM foods



3. The Economics and Strategy of New Products

Consumer food and fibre markets are getting much more complex. Significant international migration, global mass media and rising disposable incomes have spurred a sharp rise in demand for differentiated consumer products and services in most national markets. Meanwhile, increased international trade and more rigorous application of science and technology have caused a sharp rise in the array of products and services available in those markets. The challenge facing both consumers and producers is how to search and select those products that meet their needs and wants from the wide array of products available.

The focus of this section is to identify those theoretical aspects that provide direction for the development of new regulations and standards for new quality based products.

3.1 Market failure

In a competitive marketplace made up of many informed buyers and sellers, market exchange is an institution that very effectively governs the production and consumption of goods and services. The prices generated in a market system create Adam Smith’s 'invisible hand' to match the marginal cost of providing a good to the marginal value of that good to society. In a great many instances in the market place, a simple exchange of goods and services at an agreed

upon price is a low-cost transaction that provides the correct incentives for the buyer and sellers. When the marketplace fails to operate in a manner such that the marginal social benefit is not equal to the marginal social cost of the action, then a market failure is said to exist. Market failures can be addressed through government, collective or private actions.

In standard economic theory, these market failures are usually associated with natural monopolies, public goods, common pool resources, other technical externalities and government failure. In the investment literature, a market failure known as 'the hold-up problem' can block investment-asset-specific investments. Despite overall benefits from their provision, the markets fail for public goods because no one can be excluded from their consumption. There are no feasible means for a firm to charge the users for the provision of the goods. As a result, public goods are underprovided by the marketplace. A lighthouse is an example of such a public good.

A market failure that has recently attracted attention in the investment literature is referred to as the hold-up problem. The hold-up problem, according to Milgrom and Roberts (1992), is "the general business problem in which each party to a contract worries about being forced to accept disadvantageous terms later, after it has sunk an investment or worries that its investment may be devalued by the actions of others." The hold-up problem may be induced by other forms of market failure but deals more specifically with the investment decision. Because the hold-up problem often prevents otherwise advantageous investment it can create market failures that are real obstacles to industry development.

There is a relationship between the presence of transaction-specific and asset-specific investments and the potential for ex post hold-up (Williamson 1983; Grossman and Hart 1986; Tirole 1988; Koss and Eaton forthcoming; Choate and Maser 1992). With asset-specific (specialized) investments, the value of the asset in its specific use is far greater than its value in the next-best use. In order for the initial specific investment to be undertaken the real rents to each party (returns in excess of *ex ante* investment) must not be negative. However, when one party's *ex post* opportunity cost is reduced to the initial investment, its bargaining power is also reduced, and it is less likely for this party to cover the initial investment. This party will recognize the potential for *ex post* hold-up and will therefore be unwilling to incur the *ex ante* investment cost. Hence, if the initial investment is high enough relative to the respective *ex post* opportunity cost, the initial investment will not be undertaken by that party and market failure will occur since the specific transaction is Pareto superior to all alternative transactions.

3.2 Addressing market failures through institutions

Institutions encompass a set of rules, both formal (e.g. statues) and informal (e.g. norms), that constrain the behavioral relationship among individuals or groups (North, 1991). Institutions are effective rules, not nominal rules, with an emphasis on enforcement (Eggertsson, 1994). They can be established, enforced and policed, either by an external authority or by voluntarily acceptance. They are predictable, stable, and applicable in situations that are repetitive. Institutions define the decision-makers' utility choice set and their structure of incentives.

The establishment and enforcement of property rights allows attributes to be traded within a market system. In many cases, if property rights can be effectively assigned, then a market for the attribute will develop and the market failure will be addressed. For example, plant breeders' rights give the owner a right to charge for the use of a variety. In some cases, the assignment of property rights is not sufficient to address a market failure. In these cases, other private, collective or public actions may be lower cost alternatives.

There are several forms of private action that can address market failures. In particular, Williamson (1983) suggested the common ownership (e.g. vertical integration) as a response to site specificity. Additionally, Klein and Crawford (1978) concluded, "the lower the appropriable specialized quasi-rent[1] the more likely that transaction will rely on a contractual relationship rather than common ownership. Conversely, integration by common or joint ownership is more likely the higher the appropriable specialized quasi rents of the assets involved."

Williamson (1983) argues that the potentially opportunistic party making an *ex ante* credible commitment to the exchange can support transactions that are (potentially) subject to hold-up. *Ex ante* credible commitment usually takes the form of partial redistribution of specific investment costs to the potentially opportunistic party.

Long term contracting can be another solution to some market failures. Specifically, Joskow (1987) states that, with many types of asset-specific investments, long-term explicit contracts can reduce the potential for *ex post* hold-up. However, with this solution it may be very costly to identify all the contingencies of the investment. Hence, appropriate institutional arrangements may be a solution to the threat of a hold-up.

[1] Klein and Crawford (1978) defined the quasi-rent as "value of the asset is the excess of its value over its salvage value, that is, its value in its next best use to another renter."

Coase (1960) argues that the governments can play the role of supra-firms, where their actions may reduce transactions costs. This is consistent with the notion that there is role for government in addressing some market failures. Many economists have argued that governments have a legitimate role in producing public goods, regulating natural monopolies, and addressing externalities through taxation, subsidization or regulation. Thus, in some circumstances, government institutions may be the most effective or lowest cost means of addressing market failures.

As Coase (1960) points out in much of his work, other forms of collective institutions, (sometimes referred to as non-government organizations, or the participation sector) may often be more effective than government. In his paper "The Lighthouse in Economics" he argues that Trinity House, an association of ship owners, was more effective than government in creating and operating the British lighthouse system. This is because the ship owners who were required to pay the tax and who created the system had both the knowledge and the incentives to build the appropriate number of lighthouses in the appropriate locations. This is similar to local governments being made responsible for providing local services.

3.3 Institutional responses

Particular institutions tend to be better suited than others to govern particular types of transactions. Picciotto (1995) classifies institutions into three general types and then describes what type of attributes these institutions best govern. One type of institution is represented by the hierarchy or government sector. This institutional structure's stakeholders are all citizens of the state. The incentive in this sector is the re-election of the politicians so as to maintain power. Hence, they pursue goals for the best interest of the whole society. A second set of institutions is represented by the participation sector. This sector has stakeholders who voluntarily join because they believe that benefits can be obtained by collective action. The members of the participating sector represent a group in society with a common interest. The last sector is the private sector. The individuals who own property rights are the stakeholders of this sector. The main incentive here is to maximize their return to asset investment (profit). Hence, each sector represents different individuals and has different incentives.

Each institutional structure tends more effective than others at producing particular types of goods. The government sector is best at producing public goods (e.g. justice) that are

consumed by all citizens, and where the voice of interest groups is not important. Public goods are characterized by low excludability and low subtractability (rivalry). In this case, the low excludability makes privatization infeasible and the broad common interest in provisions is best represented at the government level where free riding can be eliminated.

The participation sector is best at governing common pool goods (e.g. marketing services) or public goods where voice is important. These goods have the problem of excludability, which prevents them from becoming private goods. In addition, the benefits of common pool goods are often restricted to a group of individuals or firms who are in the position to use the goods. In this case, it is in the common interest of the group to manage the good to their mutual benefit. It is also often the case that some group has greater interest in providing the good than the public at large and has more of the information required to manage the resource, making voice important.

The private sector tends to dominate whenever property rights can be assigned to make the goods excludable and the goods produced are subtractable. The property of exclusion allows private firms to charge for the use of the good. This allows the producers of the good to sell at the marginal cost of production. Where hold-up problems exist, transactions take place within larger private institutions or between institutions with long term contractual arrangements. Excludability is not a sufficient condition for a good belonging in the private sector. If a good has low subtractability then there are economies of size in its provision, resulting in the failure of a natural monopoly and creating the potential need for government intervention.

3.4 Applications to credence goods

Introducing new products is difficult in almost any circumstance, but especially so when the product offers new or different quality traits. There has been an increasing volume of research on the theoretical and practical challenge of introducing new credence style products.

Tirole (1988) laid out much of the foundation for the debate about credence goods. He posits that there are three types of goods: search goods, where consumers can visually identify attributes before consumption; experience goods, which require consumption to determine the attributes; and credence goods, where the unaided consumer cannot know the full attributes of consuming a good, at least for some period after consumption. Trust usually is a key element in markets involving experience and credence goods. In practice, a single product could embody

attributes that fit all three types of goods. For example, if one is looking for a tomato, one could 'search' through the bins and find one that looks good, smells ripe and is apparently free of insects or disease. Once a consumer takes it home and eats it, they experience the quality of the fruit, judging it based on a variety of subjective factors, such as flavor and texture. Ultimately, the utility derived from that tomato includes any longer-term benefits or costs of consuming the product, which become known some time after consumption. These could include some benefits such as anti-oxidants, or some costs, such as food borne pathogens (e.g. e-coli or salmonella) which would become known within a few days, or toxic elements (e.g. carcinogenic elements) that may have only a long-term cumulative effect on a person's health. More recently, a number of researchers have looked at extending this theory. Oliver (2003) offers cumulative prospect theory, Gollier and Treich (2003) looks at positive or negative knowledge stock effects, Nir (2004) applies cognitive dissonance to the problem and Ford (1990) applies consumer skepticism to the problem of credence goods. While these experimental approaches offer some selected insights, the bits and pieces of theory offer no unifying framework.

Nevertheless, there has been an increasing amount of relevant experimental effort to test various hypotheses. Vercammen (2005) suggests that most foods have multiple types of credence characteristics (e.g. health and nutrition, possibilities for adulteration and embodied production practices) which make the usual market mechanisms (e.g. reputation) fail. He argues that with a credence characteristic, voluntary labeling, liability and signals may fail to solve asymmetric information problems and that minimum safety standards and mandatory labels may be needed to nurture the market. Veeman (2005) argues that many credence attributes or product qualities are inextricably tied to issues of verification, traceability, certification and auditing. Larson (2003) examines eco-labels while Grolleau (2002) suggests mandatory labeling can switch nutrition information from a credence to a search characteristic but that scientific disagreement can invert the benefits. Federson (2001) examines the role of third party actors in the product system, concluding that consumers may prefer goods endorsed by informed activists while Hu, Veeman and Adamowicz (2004) conclude that mandatory labeling is valued considerably higher than is the case for the information revealed through voluntary labeling. In contrast, Noussair, *et al*., (2002) conclude that many people don't read labels.

We think it is important to think broadly and utilize techniques developed in other disciplines. The search, experiential and credence attributes of most foods are assured through a

combination of public and private regulatory systems (Table 2). In the production system, the public sector has tended to establish the general environment for private actors to effect transactions. Laws and regulations usually set the base rules for health and safety (e.g. in Canada The Food and Drugs Act set rules for human consumption, the Feeds Act sets rules for animal usage, the Canada Seeds Act specifies the performance standards for new germplasm and the Canadian Grain Commissions sets and monitors the standards for the seeds trade). At the retail level consumer labelling laws establish consistency of standards around labels. Meanwhile, the private sector frequently establishes common-property or private mechanisms to manage the transactional elements to the attributes. Companies employ trademarks, brands and warranties to assure customers of the value of their product. Experience has shown, however, that the costs of developing private standards are high; for many agri-food products there are efficiencies that can be gained through collective action (e.g. Canola Council of Canada story described in Gray, Malla and Phillips, 1999).

Table 2: Product attributes and public and private responses

	Search attributes	Experiential attributes	Credence attributes
Public role in setting rules for the transaction	Consumer labeling laws to prevent fraud	Regulations ensuring consistent quality	Health, safety and environmental regulations Product liability and tort laws
Private mechanisms for managing the transaction	Voluntary labeling	Patents and trade marks backed up by identity preserving production and marketing systems	Patented products offering private/brand warranties backed up by identity preserving production and marketing systems

In essence, both public regulation and commercial product standards can only really be understood in the context of all mechanisms used to manage markets (Figure 3). At one extreme, governments or agents for governments set regulations to achieve public goals, such as health and safety or environmental objectives. At the other extreme, private companies develop brands and provide private warranties to assure consumers of the quality of their products. In the middle, an array of public, private and collective actors may be critical. The long-term

achievement of consistent quality in credence goods markets will require action on a part of all three types of actors (Smyth and Phillips, 2001, examine the canola industry to illustrate this point).

Figure 3: Relationships between regulations, standards and private brands

Regulations for public good purposes	Regulations based on standards	Commercial and Private Standards	Private brands become standards	Private brands And Warranties
Driver: Public good market failures without regulation	Driver: Common pool goods requiring voice; collective rather than firm based or regulatory based			Driver: Private, firm based profit maximization

4. Progress in Regulating New Foods

Resolving the holdup problem requires governments to support structures that effectively and efficiently delineate ownership and to provide a legal and regulatory underpinning to the claims of new products. While there has been movement in all three areas, progress is uneven and in places conflicting with the goal of greater commercialization.

4.1 Intellectual property rights

The extension of intellectual property rights (IPRs) to genes, genomics and living matter has changed the profile of the agricultural research industry. IPRs make it possible for the innovator to capture most of the benefits from the research, giving inventors an incentive to invest into research activities (Jackson, 2000). At the same time IPRs create barriers, protecting innovations, which can exclude some third world countries from benefiting.

Most developed countries have four main types of protection for agricultural research: utility patents; plant breeder's rights (plant variety right); copyrights; and trademarks and trade secrets. While plant breeder's rights exclude others from exploiting the given seed variety, patents allow owners to also prohibit the use of the patented item for research purposes. While

these rights were first extended in the US in the 1980s, this system of protecting new innovations in the food system has been internationalized through the World Trade Organization negotiations on Trade Related to Intellectual Property (TRIPs). Now almost every trading country is required to offer some sort of protection for new inventions.

The biggest problem is that some inventions can be protected so effectively by an overlapping set of mechanisms (patents, PBRs, trademarks and secrets) that other research organizations may be unable to negotiate to use these technologies (Lindner, 1999). This difficulty is compounded because utility patents, which are increasingly common, can severely restrict other organizations research possibilities, which is interfering with 'freedom to operate' (Binenbaum, *et al*., 2003).

One example of the patent problem is with Golden rice. After investing millions of dollars and 10 years of research the Swiss Federal Institute of Technology and University of Freiburg had to give up the research because the overwhelming problem of obtaining licenses for the many patents needed (RAFI Communique, 2000). The innovation used many different genes and protected new techniques which together accounted for 70 different patterns. The institution hired a private company to deal with the patent problem and marketing of the product. Although the research and full development of the product took place in the public sector the benefit was captured by a private company and the distribution of the product would be decided based on private interest, even though it was developed to provide benefit to poor countries.

4.2 Novel foods

To date the industry lacks effective regulation, which is holding up market development. Regulations are weak or ineffective in two broad areas: novel foods; and nutritional and health claims.

Diverging regulation of biotechnology in different countries creates a challenge for novel food manufacturers even before the health property issue arose for food items. The value added health benefits gave the problem a new perspective. Up until now, the strict GM regulations in some countries (e.g. EU) and the precautionary principle that was taken to protect the consumers is beginning to conflict with consumer interests. Consumers would overcome the precaution toward genetic modification if it offers direct health benefits. In Australia the resistance against GM is high, but recent studies showed that most of the consumers would buy the genetically modified product if it carries health benefits. Studies show they would be willing to pay a price

premium for the GM product (Burton and Pearse, 2002). In Canada a similar result was found based on a telephone survey (West, *et al*., 2002 and 2004). Interestingly the Canadian consumer is willing to pay a higher price premium in favor of GMOs. There is no known published study that investigates these questions in the EU where the conflict really persists due to lack of health claims and one of the strictest GMO policies.

a. Canada

The novel food term was officially named in Canada in 1999, when the Food and Drug Administration Act introduced a new section (Division 28) regulating novel foods. In the definition of novel foods the Government of Canada includes substances that have no history for use as a safe food, food products manufactured with new processes and foods that have been genetically modified (Health Canada, 1999). While this term provides a comprehensive trigger for regulating new foods, it is markedly different than the standards used in competing countries.

b. United States

United States has one of the most innovation-encouraging legislation systems. Although there is no official term for novel food, any new plant based food falls under the Foods Derived from New Plant Varieties Federal Register, May 29, 1992 legislation.

There is no separate regulatory framework for genetically modified food in the US. They fall under the same new novel food regulations. Although the US is very open to transgenic plants, regulations to evaluate and approve genetically modified animals have yet to be developed. For example, transgenic salmon has been waiting for approval since 2000.

There is one recently proposed rule called the “Pre-market Notice Concerning Bioengineered Foods” that will introduce a 120 day market notice before approving a new GM product, to allow every party in the market to express concerns. (FDA, 2001)

c. European Union

The EU’s novel food definition is closely related to its legislation. Novel foods are regulated under Regulation (EC) No. 258/97, which requires that any new item that has not been used for human consumption before the regulation, falls under the legislation, except GMOs and food additives/coloring that have separate legislation (EC 258, 1997). GM food products are

regulated in the Regulation (EC) No 1829/2003 on genetically modified food and feed, Sept 22, 2003. The main points of the legislation are: the product must be approved by Scientific Committees to ensure that it is not harmful to consumers and does not impose possible risk to the environment; mandatory labeling requires tracing through all stages of the food processing system, from raw material growing, at all processing steps and in retail stores; and the approval is only valid for 10 years. The EU follows the 'Precautionary Principle', which states that no food item shall be released into the market, which lacks of scientific evidence that they are not carrying neither short nor long term danger to human health or the environment. (EC 1829, 2003) The problem is long-term consequences of new innovation and technology, like genetic modification, is uncertain. The main result of this strict regulation is that few GM food items can be found in the market in the EU. It also creates underlying import barriers, since the traceable mandatory labeling system does not exist in North America.

4.3 Nutrition and Health Claims

Even if new products can pass the health and safety hurdles erected by governments, they still have a challenge positioning their credence claims. Many economic studies show that consumers are willing to pay price premiums for additional health benefits from food products (West, *et al*., 2002 and 2004; Burton and Pearse, 2002). But, without a regulatory framework that allows firms to market their product's health characteristics, firms are unlikely to be able to capture the benefit of their innovations. Jarvis, *et al*., (2001) found evidence that suggests the delay of the Canadian regulatory framework has already caused innovation loss therefore decreased welfare for society. There are many different claims that can be accepted by legislation agencies. The main three forms of these claims are as follows:

- Nutrition Claims: generally permits highlighting certain reduction or increases of nutritional components such as micro and macro-nutrients, vitamins, and minerals.
- Health Claims: permits creating a relationship between certain food ingredients and some health condition or chronic disease.
- Function/Structure claims: permits to describe a general well-being resulting from a certain dietary ingredient.

a. Canada

Canada has officially stated definition for every term in this context. Novel foods are regulated by the Novel Foods Regulation (under the Food and Drugs Act Division 28), (Health Canada, 1999). Novel foods include every GM product and any other non-GM that was not used as food product before or was significantly modified from a traditional food product. Although genetically modified food products have to undergo the same registration/approval process as non-GM products a pre-market notification exists to permit safety assessment on any biotechnology-derived food product.

Currently it is not permitted to have any health claim on food items. Regulation was proposed on Jan 1, 2003 after a long investigation starting with a first policy decision in 1998. The current proposal (Health Canada, 2003) would allow two claims:

- Nutritional claim: 'free of trans fatty acids' or 'low sodium' regulated by nutrition component. The stated claims are narrower and stricter than in the US. For example, 'saturated fat free' label can be used in the US if the product contains less then 0.5 g saturated fat per serving while in Canada it can not contain any.
- Health claim: specified links between a chronic disease and a food product.

Foods cannot be labeled with a combination of the two nutrition labeling systems except in case of fat, trans fat and saturated fat.

b. United States

After Japan, the US took leadership in recognizing the importance of nutrition and health claims. The first regulation was established in 1990 with the Nutrition Labeling and Education Act of 1990 (NLEA). The act permits showing changes in dietary ingredient levels in food products. The following terms are accepted: *free*, *high*, *low*, or can compare the level of a nutrient in a food to that of another food, using terms such as *more*, *reduced*, and *lite*. The Act also allows the use of the word "*Healthy"* if the product contains the optimal amount of ingredients. These labels are individually regulated for vitamins/minerals and other ingredients. For example, a label contains 'saturated fat free' if the saturated fat content is below 0.5 mg per serving. The 'More' label can be used for vitamins if the food serving contains more than 20% of the daily value intake.

In 1994 an additional claim called Structure/Function claim was introduced by the Dietary Supplement Health and Education Act (DSHEA). The Structure/Function Claim describes the role of a nutrient or dietary ingredient intended to affect normal structure or functions in humans, for example, 'calcium builds strong bones'. Regulated in the Dietary Supplement Health and Education Act of 1994 (DSHEA), the label can appear on conventional foods and dietary supplements as well as drugs.

In 1997 the Food and Drug Administration Modernization Act (FDAMA) extended the meaning of health claim and allowed claims to specify relationships between food/dietary ingredients and chronic diseases. For example, 'diets high in calcium may reduce the risk of osteoporosis', before this the claim could not be associated with a dietary supplement. The health claims were revised again in 2003 by the FDA and pre-qualified claims were created for specific known heart connections, like dietary fat and coronary heart disease. (FDA, 2003)

c. European Union

Currently no legislative framework exists allowing health or nutrition claims to be present in food items. The tolerance towards labeling varies in the member EU countries (Jarvis, *et al*., 2001). To harmonize legislation the Commission of the European Communities proposed a regulatory framework for nutrition and health claims in 2003. The draft still has to be approved by the European Parliament and the Council of Ministers, and is proposed to come gradually into force by 2005 (COM, 2003). The approval of health claims belongs to the European Food Safety Authority (EFSA) and contains two kinds of claims:

- Nutrition claims: allow claims to state enhanced, reduced ingredients like 'low calorie' or 'high fiber'.
- Health claims: allow establishing specific link to a certain disease: like 'reduce risk of… disease'.

The proposed framework states that scientific evidence for health claims must be tested by an independent body within the EU. This means that no scientific tests made outside the EU will be accepted as evidence. This can lead to disadvantages for foreign firms that have to redo their tests in the EU in order to get a health claim and may cause delays for foreign firms and/or additional cost.

d. Other countries

Japan was the first country to recognize the importance of functional food and its potential economic impact. Functional foods or as they are called in Japan 'FUSHOs' have a separate regulation which allows the producers to display different health claims on the products (Scott Wolfe Management Inc., 2002). According to them other countries like Australia and New-Zealand are following the EU's precautionary approach taking it very slow when dealing with functional foods with possible health claims and genetic modifications.

Table 4: Regulation of novel, functional and GM food around the world

	Registering New Food Item / Novel Food[2]		**Health Claims/Functional Food Regulation**[3]
	Non GM	***GM***	
Canada	Novel food is defined and has separate legislation Act	No separate legislation	Currently, claims are not permitted Proposed regulation may contain: • Nutritional claims and • Health claims (narrower than US or EU health claims) but the two may not be combined
United States	No official term, but has separate legislation	Currently, no separate legislation, pre-market notice rule is proposed, voluntary labeling being discussed	Currently, 3 type of claims are permitted: • Nutrition claim • Structure/Function Claims (effective since 2000) • Health claim
European Union	Every new food is novel food since the new regulation in 1997	GMO food and feed products have separate registration and a mandatory labeling system	Currently no legislative framework; proposed regulation may take place by 2005 and allow: • Nutrition claims and • Health claims
Japan	Called FUSHO and separately regulated		

While there appears to be significant effort expended at the national level in search of new rules, the reality is that few of these systems provide the necessary base of credible information that industry and consumers can use to transact their business.

[2] Obtain registration for newly created food item, which are called novel food by definition in Canada
[3] Obtaining permit to advertise and label the added health benefit in the food item.

4. Conclusions and Implications

New foods with credence factors promise to offer significant private and public benefits but the introduction of those goods appears to have largely stalled due to incomplete institutions. The theoretical and empirical analysis of new product introduction, and especially credence goods, strongly supports the view that an array of institutions is needed to make introduction possible. This study leads us to four concluding comments.

In the first instance, we believe that the first gap in the system is a lack of terminology or definitions. In absence of a common set of terms, concepts and definitions, it is impossible to sort out who is doing what. We believe some universal terminology will need to evolve. This could come through industry-government interface within markets, with international synthesis being driven by industry, NGOs or the existing set of international rules and standards setting institutions (e.g. CODEX Alimentarius). It probably doesn't matter who leads, as all actors have a significant stake in the process and none has the majority of the capacity.

Second, the theory and emerging evidence suggests that relying totally on voluntary, proprietary industrial activity is unlikely to be adequate. Recent economic analyses of eco-labeling and other unverifiable product claims further supports the view that credence claims need to be backstopped by some higher order of authority than simply the market. While in some cases third-party audits may be adequate, in others government may need to become engaged.

Third, our preliminary analysis suggests that while there has been some effort at the national level to fill some of the gaps in the regulatory system, the results to date are both too limited and too diffuse to provide a strong footing for sustained international development.

Fourth, if different authorities do not engage and resolve this institutional failure, there is a real possibility that both domestic and international markets will be disrupted. Domestic markets are probably most at risk of a product failure that undermines consumer confidence in all credence goods, and by extension causes greater confusion and uncertainty about our food system. While there is ample reason to think we can improve our systems generally, problems arising in the credence food area will not be the best way to manage improvements. Finally, in absence of any common rules or procedures between international markets, novel foods are likely to face significant trade friction that could lead to sub-optimal investment and development.

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