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Biotech Barbeque: A Regulatory Figuration and Policy Making

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Plant Biotechnology in Canada

What does it mean when a policy maker refers to the regulation of biotechnology as a matter of barbeques and 'dinner theatre'? How do actors interact in the 'biotech community'? Drawing on in-depth interviews at all stages in the development and farming of genetically modified (GM) crops, this article brings the process sociology of figurations to clarify the social and informational dynamics between insiders and outsiders (the public) which we argue has formed around the regulation of GM plants in Canada. Whether intentionally or unintentionally, most public discussions of 'biotech' give the impression of a homogeneous industry focused on cloning and the genetic modification of existing organisms ('GMOs') such as plants and animals. This belies the diversity of the sector. A fear of the unknown, of risk and threat to fundamental ontological categories is summarized by fears of monstrous life forms and the dangers of attempting to manage chance and necessity through new technologies (Caygill 1996). Closer investigation reveals a diversity of activities, mostly at a molecular rather than organism scale (Gottweis 1995; Kloppenburg 1998). This challenges regulatory-legal frameworks and the ability of the public and existing regulators to 'know' both the actuality of biotechnology methods and the products. Public fears may not be primarily directed at the products of biotechnology but their loss of collective grasp on the governance of science and of everyday products.

Agricultural biotechnology is the second largest sector of the biotech industry after human health, representing about 12.5% of dedicated biotech firms in Canada. In 2003, Canada's growing biotechnology industry included 417 dedicated biotechnology firms, mostly concentrated in large population centers (Niosi and Bas 2001), up 67% over five years despite a dip in the venture capital market in 2001.1

Most research on agricultural biotechnology emphasizes the 'rigorous scientific testing' that products must undergo prior to entering markets in the EU and the United States (OECD 1992). 'Science accounts' of the regulatory process, say little about the social arrangements that create regulations or are involved in regulatory assessments (Barrett and Abergel 2000; Dunlop 2000; Newell 2002). Most critical analyses have focused on questions of property, privacy and the surveillance of ever larger collectivities through databank technologies (Rabinow 1996; Rose 1996; Gerlach 2002). A social science approach to what participants refer to as the 'biotech community' extends this literature. It problematizes the tendency toward technical debate focused only on procedures such as labeling and includes the division between regulatory insiders and an excluded public (Kalaitzandonakes and Phillips 2000; see Mansour and Bennet 2000).

What are the social dynamics of what we will argue is a regulatory 'figuration' (cf. Elias 1991)? This network or social world is reducible to neither a scientific logic, nor a political economy of the interests of those involved and can be said to include relations between offices and objects as well as persons (the traditional 'process sociology' focus). There has been some attention to regulatory structures but this tends not to focus as much on day to day regulatory interactions and practices (Black 1998). The present research illustrates the fluid and close-knit social networks, the importance of insider-outsider divisions in the regulation of agricultural biotechnologies in Canada.

Insider Viewpoints on the Regulatory Process

Our interviews focused on plant biotechnology and the actors involved in the regulatory approvals process in Canada: Plants with Novel Traits (PNTs) and Novel Foods (such as genetically modified corn and soy beans (more colloquially known as GM corn and GM soy).[1]Similar to the United States and Japan, Canada's product-oriented regulatory approach is based on the principle that assessments of the risks of Genetically Modified Organisms (GMOs), such as PNTs, should be based on the characteristics of the organism or the product, rather than the method by which it was produced. This contrasts greatly with the European Union's process-oriented approach (Jasanoff 1995; Levidow et al. 1996; Levidow, Carr, and Wield 2000).

Interviews

Figure 1 lists 28 semi-structured interviews across the biotech community (Shields et al 2004) which were part of a larger project on information flows and the changing governance structures of the Federal Government of Canada. [2] One of the surprises of this research was that a relatively small number comprises both the key biotech actors and the agencies and functions involved in the regulatory process across the entire industry from scientist to farm labourer and bureaucrats. This limited number and the confidential nature of commercial processes as well as regulatory cases hampered the in-depth interview approach and the use of transcripts. The quotations presented are a guarded sample.

Figure 1. Interviews

Departments / Institutional Actors	Total	Offices / Representatives Interviewed
Environment Canada (EC)	4	2 Biosafety 1 Biodiversity 1 Cartagena Protocol
Agriculture and Agri-Foods Canada AFFC)	2	2 Research Scientists
Health Canada (HC)	1	1 Evaluations, Microbial Hazards
Canadian Food Inspection Agency (CFIA)	3	1 Plant Biosafety Office 1 Office of Biotechnology 1 Evaluator (biotech specialist)
Industry Canada (IC)	2	2 Biotechnology Regulatory Virtual Office (BRAVO)
Industry	7	3 Product Developer (public and private sector) 1 User (farmer and silo operator) 3 Distributors (incl. transportation and commodity broking)
Expert Advisory Committee	3	3 Canadian Biotechnology Advisory Committee (CBAC)
Independent Consultants[3]	2	1 Agricultural Biotechnology 1 Agriculture Forestry
Biotechnology Industry Associations	4	1 Agricultural Biotechnology 1 Agriculture Forestry

Key players were identified from government documents and a regulatory 'map' developed early on in the project (Shields et al. 2002; see also Figure 2). Once the first few participants had been contacted and interviewed they suggested other players in a semi-snowball sampling. Through asking the interviewees to help redraw our map and locate themselves within it, an initial, rigid image of a network and linear process (see Figure 2) was progressively displaced by a fluid model of a regulatory system which respondents repeatedly described as an 'insider community'.

Regulatory Process - 'Six Steps'?

All respondents avowed that the biotechnological regulatory system was 'extremely complex', yet the number

of players involved is not extensive. The process can be summarized in only half a dozen steps and 'there are a small number of evaluators, you get to know them…' (Biotechnology Industry Product Developer Informant). The process for Plants with Novel Traits is often described to the public as 'six steps to safety' (see Fig. 2 after Crop Protection Institute of Canada 2000). The simplicity of these six steps belies the recursive and multiple interactions in actual cases, but this is not unusual in regulatory environments. The 'six steps are a shorthand that is invariably backed by an extensive 'Appendix', even in pamphlets, detailing the different regulatory options for different PNTs such as foods, animal feeds and discussing the environmental safety of PNTs which are released into nature. The point to be made is not that 'six steps' is a public relations gloss, but that it is a map which is useless as a guide because it lacks qualification in the form of other information and understandings which supplement its steps with the knowledge that the process is not linear but more akin to an extended conversation between several parties - perhaps even like the talk at a dinner party which may return to earlier topics at any point and which subsumes many side discussions which happen at their pace.

Not only can a developer interact with different evaluators and regulatory jurisdictions throughout the development process, but so too do the evaluators. After conducting the first interviews it became immediately apparent that the regulatory field is composed of vague boundaries where objects and people are continually moving around between institutions or actors (Fig. 1 left column). These defy univocal categorization and undercut the pure science ideals of the regulatory process. While an approval may be required from Environment Canada (EC), they may in turn contact the Canadian Food Inspection Agency (CFIA), Agriculture and Agri-Foods Canada (AAFC) or Health Canada (HC) to define the set of evaluations that will be necessary. These points are illustrated in the stress on the interpersonal and the comment that,

> Many aspects of Environment Canada are based on interpersonal relationships both within the department as well as across departments and internationally. For example, when we are faced with petitions you receive a 'heads up' email from other departments and then you strike up a working group, first within the department and then sign-off to medium level interdepartmental group. You develop a common answer and move up the ladder (Environment Canada Informant).

This is not as ad hoc as its sounds. Product developers outside of the regulatory agencies might have to present their product to multiple joint-departmental evaluations but understood that there were possibilities to negotiate the identity and nature of their products, none of which existed beyond trial stage or which might exist only as a trait, a capability or a process. Developers working in labs 'front-line' understanding of the regulatory process is broader but more linear:

> ....The first stage is concept validation, in this stage we consider what would make a difference for example "if only the world had..."; the second stage is prototype validation, where the scientists work at constructing these objects that will change the world; and, the third stage is the field trial, where we set out to examine and assess the risks and success of the objects (Biotechnology Industry - Product Developer Informant).

This description focuses entirely on scientists as actors and decision makers - as prime movers, regardless of the 'other hats' scientists may wear or careers they may pursue and the intersecting roles of entrepreneurs, managers, farmers, lawyers and policy makers and a wide array of disciplines and professions drawn in as consultants to regulators.

Categories and Objects

Complexity arises in part because products do not fit easily into neat divisions between flora, livestock or human health (Figure 2 4abc respectively). Not surprisingly, the objects of regulation in the biotechnology sector are 'boundary objects' whose instability continually challenges established conventions and requires active reworking of categories and negotiations over the fit between concepts and material processes (Star1999).

The regulatory processes for Plants with Novel Traits (PNTs) and Novel Foods (NF) are presented in official documents as rigorous and standardized. One simple example is the Domestic Substance List (DSL). The DSL was created to provide a scientific classification of biotech products and how they are to be assessed, thereby removing value judgments and unnecessary examinations. However, when such standards are implemented they make invisible the negotiation and social labour required for their development (Bowker and Star 1999:44). The more people adopt and incorporate the regulatory process into their actions without questioning its origin, the more hidden the social—and politic—origins become. Because of the limited expertise in the field, biotech product developers participated

extensively in creating the regulatory process. The regulations summarize a set of working routines, expectations and an outlook. Policies are created post hoc after regulatory experiences considered exemplary. Lists and procedural documents testify also to a habitus or modus operandii which has responded over the last decade not to routine but to continual difference, to non-conforming objects, cases and applications.

Tactically, developers may choose (although not without debate) which category or definition their innovations fall under. Based on this, similar products by more—or less—knowledgeable, or more—or less—strategic developers may be subject to different regulations even though their development process is the same. Thus insider knowledge is technical (biological) and procedural but is also social in a micro-political sense:

> While web-sites, such as BRAVO [Biotechnology Regulatory Virtual Office], can give developers and consumers a framework, it's knowledge and people that count. Personal experience becomes a valuable commodity. For example, independent consultants who are ex-bureaucrats or industry practitioners have access to the 'market-niche' and they know who to call and know where to spend the time and where not to (Regional Biotechnology Association Informant).

A formal system of formidable regulatory hurdles, professional jargon and shared laboratory skills and experience differentiates these insiders from outsiders including less experienced biotechnology entrepreneurs, foreign competitors, nonexperts including consumers and the public at large who have an important stake in environmental safety and the quality of food systems. [4] Private sector managers who described themselves as long term 'insiders' conceded that, 'The DSL and regulatory process are clear but if you are new it could be difficult. Environment Canada knows us, we're NOT brand spanking new!' (Environment Canada Informant).

Figure 2. 'Six steps to safety': Biotechnology regulation in Canada.

1. Canadian Institute for Health Research and other codes of practice for laboratories and staff working with genetically-altered organisms.

2. Canadian Food Inspection Agency (CFIA) field trial confinement guidelines

3. PNT transportation and import controls

4. Either
   a. CFIA or Environment Canada assess environmental safety and impact of PNT crops on nontarget organisms, biodiversity, potential as a pest and for weed infestations,
   b. Or CFIA assesses livestock feed toxicity, stability, environmental impacts, potential to reach the human food chain,
   c. Or Health Canada assesses safety of Novel Foods: nutritional data, animal studies of toxicity, allergenicity, dietary impact

5. Registration

6. Market Release

The Community of Established Insiders

In our interviews, reputations appeared as a form of capital, of the ability to act and persuade others to act in desired ways.

> When you are going through the regulatory process you are assigned an evaluator and because there are a small number of evaluators you get to know them. These relationships are a value within the regulatory process because knowing the process and the evaluators places us above our competitors (Biotechnology Industry- Product Developer Informant).

Without its own labs and field trials, regulators had to rely on the ways a particular innovation was actualized or brought forth amongst plants by the product developer in their labs and trials. Trust is central (see below). The intangibility of 'novel traits' means that a consensus has to be formed around each product and regulatory process. According to one informant, 'this boils down to good working relations within this group and even with international relations; people get to know you and how you work to develop trust and distrust' (Environment Canada Informant).

Regulatory examiners described how they attempted to take into account both the tangible (things that are material and can be directly experienced or measured) and the intangible (such as probable risks, capacities and qualities and the objects created as novel traits are actualized in the lifecycle of a plant, in ecological relations or in the food supply chain). [5] PNTs are not only boundary objects. They are less actual, material organisms and more a type of virtual object - one that involves activities and objects that are present but not necessarily tangible nor necessarily represented - this is the source of the equivocation which is possible in categorizing these objects. Much of the conception and development of biotechnology is undertaken in this virtual mode. Before products can be developed research scientists must first question 'what is needed', and this is accomplished through risk assessments. As virtual products at the forefront of research are progressively actualized (for example, as they move from inspiring stories and computer analyses of r-DNA code to investments that demand actual lab space and field trials) the regulatory net becomes more concrete and more constricting. In some cases they only become visible or represented after considerable working up in laboratories or in application filings. "Making visible…is the crucial investment in forms that enable rule and management" (Luque 2001:192).

The challenges to the regulator and to those outside of the research and development process stem in part from the virtuality of PNTs and the difficulties of adequately representing them. The appeal to 'rules', and other attempts to standardize and affix norms, is indicative of the challenge posed by the virtual objects being regulated and the nonstandardized character forced on the regulatory process. This affects attempts to collectively manage conflict and resolve ambiguity of overlapping mandates amongst agencies.

> There is a rule in the biotech regulatory community that you should never carry out individual responses but formulate a joint response when officially addressing an issue of stakeholder concern. A joint response is intended to give stakeholders an impression of "consistency and transparency", that they are dealing with a unified regulatory network (Canadian Food Inspection Agency Informant).

Not only are relationships a form of 'capital' they require constant maintenance, re-working - a continual labour of performance. [6] The working up of insider status and reliability or trustworthiness doubles the working up of the intangible objects which are being regulated. [7]

The collective nature of insidership was illustrated throughout our interviews. For example, there were many concerns about 'perceived' conflicts of interests arising from the working relations between AAFC and the CFIA. For example, many stakeholders have become concerned with the potentially contradictory goals pursued by a single organizational unit. Some firms perceive public regulators as competitors because they also operate national research laboratories (Newell 2003:58). For example, outside experts and the public have questioned the contradiction between the mandate of AAFC research branches to promote agricultural biotechnology in Canada, while the CFIA is responsible for regulating it under the Plant Protection Act, The Feeds Act, and Seeds Act. Both report to the same Minister. Yet, independent consultants rationalize the arrangement:

> There is a difference between a 'conflict of interest' and a 'perceived' conflict of interest. The only way to solve this 'perceived' conflict of interest is to increase levels of openness and transparency. We need to develop clear Departmental mandates in addition to integration. I don't believe that the problems with the CFIA can be solved by reporting to another Minister, but instead the need to change their internal structuring. Departments need to figure out their own roles (Biotech Experts Informant).

Insiders' loyalty to the regulatory system, community, or 'figuration' (see below) as a collective achievement meant that although definitions and understandings of products and issues might conflict at points throughout the system, elsewhere these objects could work together or even be dependent on each other (Mol and Law, 1994:659). The players, elements and objects within the system continually informed each other to maintain a sense of continuity and even to create a consistent 'surface' that conceals variation and tension from outsiders. When respondents offered that the regulatory system was 'extremely complex', they in effect demonstrated their power or importance as necessary guides, but presented an article of faith and a first step into the community - a first rule that initiates (such as the interviewers) should subscribe to.

Regardless of how this relationship is perceived, it is important that one recognizes the impact that social relationships have on the actions of others. Clearly, even amongst biotech community insiders, the regulatory process is not purely 'scientific'. Within the fluid, social world of biotechnology and the organizations found within it, a further network of networks can be discerned. Each actor such as a Department or firm maintains its own micro-world of ties to others within the macro-world of a surrounding network. As evidenced in the extensive use of non-

disclosure agreements, a stress on corporate secrecy and an emphasis on the complexity of the regulatory system and the scientific training required, firms seek micro-control over their products and information not only through agreements with farmers not to reuse seeds, through sterile seeds or 'terminator' genetic technologies, but also by limiting the divulgence of information and intellectual property in patents and very broad patent applications to exclude competitors from the field (Hayenga 1998:7). The dynamics of ties across microworlds allows us to observe how certain subjects occupying key nodes form and deform discrete groups. Subjects occupying key network positions may also be gatekeepers who mange flows of information crucial to the activity of others (see Lesser 1998:3).

But particularly amongst career bureaucrats who might be most expected to recognize these processual and political qualities of policy making, but who were new to the field, there was a sense that 'knowledge management' or other information technology or simple coordinating offices would resolve contradictions and bring clarity. This would take the form of a rather mechanical process which would have the advantage of being 'transparent' and easily audited. For example, BRAVO (Biotechnology Regulatory Virtual Office, Industry Canada) was established as an attempt to 'level the playing field' for developers by providing a single 'portal' for developers submitting PNTs into the regulatory process:

> ...to facilitate regulatory compliance, provide contact names and allow for quicker commercialization. It is a 'how to' guide and also an objective demystification of the regulatory landscape for the consumer, making the consumer aware that regulations do exist. We are here to explore biotechnology and build knowledge (BRAVO Informant).

Other informants were more sceptical about the agency which was the antithesis of long-nurtured insider 'savoir faire' and an attempt to negate social with informational networks. [8]Our sense was that it found its more ambitious goals frustrated by the need, in the final analysis, for applicants and regulators to interact over any meaningful development. And, not only was it an information office grafted on to the main regulatory interactions around biotech objects, but it fitted imperfectly with both insider process and outsider's demand for trustworthy information. Meanwhile, the agency's own respondents did not seem aware of the lack of consumer confidence in their focus on 'quicker commercialization' and 'making the consumer aware'.

The Regulatory Figuration

A regulatory figuration is a useful way of modeling the both the community of insiders and the outsiders revealed in our interviews. The attempts to fix norms and to demonstrate the value of insider knowledge and bio-science training to the exclusion of outsiders fit well with a process-sociological understanding of 'figurations' of established relationships. 'Figurations' are dynamic constellations of social relationships (Elias and Scotson 1994). The stress on the emergence and different paces of change is a further advantage of a figurational approach which,

> encourages us to consider innovation in terms of its temporal dimension: that is to say, particular innovations represent the product of generations of interwoven, interdependency ties and do not suddenly appear fully formed, as often is assumed in studies... (Dopson and Waddington 1996:1141).

This is the starting point for a properly sociological approach grounded in game theory which emphasizes three aspects of networks. Dopson and Waddington points out that these go beyond the typical analysis of interactions found in the policy literature in four ways (Dopson and Waddington 1996) to which we will add a fifth:

- Webs of power which are simultaneously stable and in change;
- The interweaving of actions between multiple players who conflict as well as collaborate (Elias 1978b:95; Elias, 1983:141);.
- A stress on social relations between positions, rather than individuals;
- The inevitability of unanticipated effects of combined actions of many actors; and,
- Outsiders need to be included as a structural group produced by interactions.

Both the public and independent experts are present only in symbolic form within the regulatory process - and often in terms of symbols which marked their exclusion or lack of 'fitness' to participate. There is thus a strong sense of established insiders and outsiders (Elias and Scotson 1994). The advantage of Elias's approach is its inclusiveness

of these excluded actors[9]. These features allow a figurational analysis to operate both at a critical, analytical level while taking up individual occupational points of view and the self-image of committed actors who, in their view, are doing worthwhile jobs while facing others who do not understand the nature of their work, in this case life science research and biotechnological products. The absence of the public and expert outsiders from the internal discussion of the regulatory process to this point will have been noted by some readers (see below). Elias develops the concept of figuration as a way of uniting analyses of insiders and outsiders in social or institutional networks. These unhelpful dichotomies also include the division between the individual and society, stability versus instability, and forms of 'process reduction' which simplify the interdependence of actors or the conditions in which any plan is implemented. The characteristics of figurations can be summarized as:

Established insiders attribute superior characteristics to their own members, such as science training and experience, in the biotechnology regulatory case. Unspoken social conventions limit contact with or exclude others, such as the public or those not employed by developers and regulatory agencies, specifically. Praise gossip and blame gossip maintains a taboo on contact, lowering the status of agencies or actors who deal with the public, such as BRAVO.

- Established insiders attribute to themselves a charisma which is internalized to become part of personal identities while outsiders are stigmatized; and
- Outsiders internalize this inferiority, accept their ranking or are forced to act in terms of the status attributed to them by insiders.

In the biotech figuration, established insiders are marked by their tendency to describe the network as the biotech 'community'—a powerful but also a naïve metaphor which begs to be 'unpacked'. A further major characteristic of the 'established' is shared professional experience, objects and places (labs, companies—see Gieryn 1999; Gieryn 2006). Their vocational habitus includes a faith in 'science' and an insistence on justification of goals and of decision-making purely on 'scientific' principles and tests (Boltanski and Thevenot 2000). A corollary of this is an unwillingness to explain these techniques to lay participants and a frustration with both criticism and negative public perceptions regarding the wider implications of genetic biotechnology. 'Science' becomes a shared symbol amongst established insiders. Elias goes so far as to argue that these aspects of figurations establish a 'personality structure' derived from the demands of interdependent action with others within a given figuration (Elias 2000:213-14).

> This make-up, the social habitus of individuals forms, as it were, the soil from which grow the personal characteristics through which an individual differs from other members of his society. In this way something grows out of the common language which the individual shares with others and which is certainly a component of his social habitus—a more or less individual style, what might be called an unmistakable individual handwriting that grows out of the social script (Elias 1991:182).

In the world of biotechnology, 'citizenship' is defined by membership within the collective forms and adherence to the differentiation between insider and outsider. These are key to defining and policing attitudes and understandings of biotechnology in the face of a disordered public sphere 'outside'3—not simply a network of practices, ideologies or merely emergent norms.

The intangibility of objects and nature of knowledge and information in biotech regulation emerged as significant topics in interviews with both insiders and outsiders. Elias focused mainly on inter-personal relationships or dynamic constellations at the community level as a way of understanding the creation of group identity and the exercise of power through it (Elias & Scotson 1994). However, figurational sociology can be usefully extended beyond interpersonal relationships to objects which mediate those relationships, including forces and processes (after Elias 2000:261). In this, we draw on insights from actor network theory (Law & Hassard 1999) and the sociology of scientific classification (Bowker and Star 1999).

Dinner Theatre: Knowledge and Information in Regulatory Figurations

The figuration lies not only in social interactions but in stocks of information and in understandings. Keeping up with ever-evolving developments in biotechnology, the regulators usually develop interdepartmental working-groups that include representatives from industry and industry associations. These groups anticipate future sciences,

respond to industry breakthroughs, consult with interested stakeholders, and shape policy guidelines that may become legislation. Established insiders share a history of direct, face-to-face and informal interaction, a vector that appears to be essential in communicating understandings of the nature (i.e. ontology), value, risks and regulatory approaches to specific intangibles which are articulated indirectly using both conceptual and affectual modes of communication. Respondents latched on to the metaphor of one informant that their meetings are like a dinner theater (Environment Canada Informant). Thus, in some cases, suburban summer barbeques might be the actual site of meetings or the key moments in regulatory consensus.

Sense-making

Established insiders exploit the need for non-codified knowledge as well as background process knowledge and high levels of trust (Polanyi 1962; Collins 2001; Patriotta 2003) (see below). What is not articulated includes experience of the practical context the overall goals and the degree of risk associated with different biotechnological procedures (at laboratory and at industry scales). Knowledge-based theories of organizations conventionally see this as embodied, idiosyncratic and uncodified (Nelson and Winter 1982; Nonaka and Takeuchi 1995). However, as part of a figuration, information and knowledge are not just a cognitive frame, shared practical skills nor a collective outlook. They are also institutionalized in social and material terms as a formative context which is the background condition for knowledge. Knowledge can be understood in more nuanced terms as 'sense-making' (Unger, 1987; Ciborra and Lanzara 1994).6

Over the last decade, regulators faced new challenges including lack of experience with genetic technologies, relatively new protocols for assessing the behavior and impact of genetically modified organisms and both possible ecological risks and public fears. This has meant that there has been relatively little established and routinized knowledge and a great deal of information to manage.

> An examiner is first trained through documents but picks up most of their knowledge through one-on-one training and discussions with managers and other co-workers (Environment Canada Informant).

In the informational economy of this and other regulatory figurations, the power and process dynamics of virtual objects are all important aspects of the regulatory figuration which should not be collapsed into a single register, whether sociological, informational or biological. Biotech objects come to be understood abstractly within the regulatory system in terms of their intersection with the DSL, not in their actuality. Substantial-seeming representations of rather virtual objects are an important ontological and economic output of the regulatory figuration (Jessop 2000; Luque 2001:191; OECD 2001).

The difficulty of visualizing a modified enzyme, for example, compared with a genetically modified tomato or other organism poses a constant challenge to public attempts to engage with biotechnological innovations. For biotechnology, the primary representation is the genomic map that is often taken as literal representation of the reality of the gene, despite the shift in ontological register from the concrete to the abstraction of a representation in a symbolic language. The notion of mapping assists in the slide from abstract representation to concrete reality by presenting a virtuality, the genome, and by permitting the conceit of this virtual territory to be imagined in terms of private property.

Trust and Agricultural Practice

Trust and mutual obligation is embedded within relationships that have become institutionalized as a figuration. Trust undergirds the collective construction and definition of objects. This must eventually be communicated to farmers and others in the agricultural sector such as silo operators and transporters, whom we also interviewed. Dramatic moral tales and apocryphal stories abound in establish the how, what and why of PNTs and other GMOs in the farmyard -the church-going habits of (therefore trusted) local growers, the multipurpose nature of dump trucks used to carry agricultural commodities, the Port of Montreal, Japanese inspectors with microscopes, and so on.

Trust is an assumption grounded in a feeling that may or may not be shared by a group of people. Examples of the establishment of trust in biotechnology include certification; familiarity (for example, trust increases the more times someone delivers on a promise); and mutual obligation (for example, all players involved have something to

lose if they do not deliver). All regulators depend on trust. Above all, at the operational level of farms, grain elevators and grain transporters,

> It really depends on the grain as to the extent that we clean the bins and separate the seeds. Corn hasn't become an issue yet, so there isn't a need for separate storage bins like there is with soy beans. With soy beans we would lose business if we didn't segregate. We trust our growers and transporters to have separated them and cleaned out their trucks. If we transport our load and the seeds are found mixed then we lose our premium, which is a lot of money to lose (Storage).

There are many practical and financial constraints placed on the grain transportation industry which make segregation and cleaning difficult, if not impossible. Some examples of the difficulties placed at the operational level are: cost of additional grain trailers for segregating GMO from non-GMO; the time required for thoroughly cleaning after each load; and, the extra staff required for handling the extra loads. Furthermore, there is little recognition and financial aid provided by the Canadian government at the operational level. In effect, the entire system of 'purity' depends on the professionalism of agricultural workers and operators.

> Each company we truck to has a different sheet to fill out stating that we have cleaned the truck and each sheet may require a different method. We trust our drivers to sweep the trailer out before going to load. We can't afford to have separate trucks or to specially clean each truck after each load. We know that trucking is becoming an issue with GMO and non-GMO but we don't want it to because we can't afford to change our procedures (Grain Transporter).

While the regulatory network is to be 'science-based', it becomes evidently clear that the regulations at the operational level are 'trust-based' and depend on the professionalism of individuals working in the agricultural sector[10]. The degree of cleanliness of silos was described as being determined in practice by the filtration standard of a 'ShopVac' (the most widely available and inexpensive contractor's vacuum available in Canada). 'Organic' ends as a probability - 90% pure, 98%, 99%...? The reality is that biotechnology products enter into an existing agricultural figuration of seeding practice, farmyard equipment and grain elevator technologies. In order to analyze the risks and politics associated with biotechnology development, attention needs to be paid to the messy objects, social networks and informal working relations of the agricultural sector in Canada.

The Public

Strikingly absent in the regulatory system are members or representatives of the public. Any such voices, whether public interest organizations such as the Sierra Club or Council of Canadians (Canadian Institute for Environmental Law and Policy et al. 2000), or independent scientists such as the Royal Society of Canada are cast as outsiders to the process (Environment Canada 2001; The Royal Society of Canada 2001).

> The regulatory system may look rosier from the inside. Because of our science based focus we sometimes overlook problems the public may have in actually navigating the network and understanding its general goals (Canadian Food Inspection Agency Informant).

Problems of public exclusion were identified throughout the biotech community interviews with regard to 'consumer awareness'. For example, the biotechnology regulatory process is to be transparent and to consist of 'value-free scientific knowledge'. Furthermore, the product approvals of various departments are supposed to be open to public scrutiny and the evaluative process and criteria required to make approvals are to be explicitly formulated and easily accessible, so that a formal system of accountability exists across the network.

While the biotech community emphasized that the regulatory network was transparent and constructed by 'value-free science', they also emphasized the status of industry and stakeholder knowledge over that of the consumer and general public. In their words, there is little time and few resources allotted to educating the public—'John Q Public' lacks the requisite knowledge needed to understand biotechnology. Some independent consultants went further to state:

> Communicating to a public (and media) that is scientifically illiterate about a technically complex issue, where the devil is very often in the detail, is a struggle for any group. I'm not convinced that the public really cares about the regulatory system above wanting to be confident that it is protecting the consumer. However, the regulatory system could go farther to be more transparent and involve the public (Biotechnology Consultant Informant).

Many of the interviewees attempt to construct 'the public' as a homogenous object that lacks education and cannot assimilate information shared with them. Using 'scientific discourse' as a justification for the lack of knowledge transfer and lack of transparency illustrates the power inherent in these discourses, as well as the difference between 'informing' the public and making the public 'knowledgeable'. In our interviews, there is genuine incomprehension of public hostility from scientists and professionals working on biotechnology, which may lead to the conclusion that something is needed in their education to help science workers reflect ethically on their figurational status as insiders.

The biotech communities preferred field of debate is labeling, a marketing concern with managing consumer knowledge and the most vocal of critics via careful control over information without granting any opportunity for the formation of alternative and independent knowledges or sources of information. Tied into international trade treaties and food safety regimes it also binds state regulators (Kalaitzondonakes and Phillips 2000; United Nations Environment Programme 2002). Closely bound up with narratives of progress and the 'promise of biotechnology' itself, the marketing of specific products might be described as the fulfilling a legitimation and normalization function for the biotechnology community.

At the same time as fluid networks characterize the internal operations of the biotech regulatory system, this institutional structure is also a figurational formation which fixes meanings, builds a formative context for the situated knowledge of the 'experts' and reproduces a hard division between insiders and the public and other outsiders. Dissenting experts, who have included the Royal Society of Canada (2001), often find themselves excluded from insider status and attacked by both industry and regulators.

Concluding Comments

The biotech case is one of many existing regulatory figurations—and of figurations still to come in economies dependent on specialized knowledge, elusive objects or virtual products. Our argument has emphasized the highly interactive and socially busy world of biotech regulation, as evidenced in the quotations in this article - 'the need to consult', to formulate a 'joint response', to 'smooth out complications', to maintain 'an impression of consistency…' or to 'make the consumer aware'. Throughout this paper we have argued that the appeal to 'rules', lists and maps such as 'six steps' and other attempts at presenting a standardized regulatory process is indicative of the challenge of novelty and the fluidity of the objects of biotech regulation. But rather than a complex regulatory system in Canada, we argue that the regulatory process is easily recognizable and intelligible as a regulatory figuration made obscure by established insider informants, summed up in the argument that biotechnology regulation was too complex to be understood by neophytes or the public.

By drawing on the sociology of science and science studies literature, we have extended Elias's figurational approach beyond the social register to objects relations and to the informational dynamics of these social constellations, especially in the case of virtual objects or objects whose status is equivocal. In addition, we have emphasized the constitutive importance of outsiders to regulatory figurations.

The present research has illuminated the virtualities and social relations that play within the biotech regulatory process. It has further uncovered the active relation of insiders and outsiders leading to the argument that a figurational approach provides a stronger analytical base for understanding the dynamics of inclusion and exclusion and ultimately for understanding the sense-making and regulatory outcomes and outputs of the regulatory system. Front and centre, a regulatory figuration involves the fluctuating play of power at a micro social level, the fluidity of knowledge and the way expertise is a status established and conferred by insider membership. These are summarized in our respondents notion of regulation as 'dinner theatre'.

Clearly, even amongst biotech community 'insiders', the regulatory process is not purely 'scientific'. Denying the social leads outsiders to an objectified, static and impotent understanding of what takes place in the regulatory process. This regulatory figuration, which involves both conflict and collaboration and centers around the fluctuating play of power, creates fear for the public. In a sense, public fears may not be primarily directed at the products of biotechnology but the loss of collective grasp on the governance of science and of everyday products. Public participation, access to information regarding PNTs and other patented life science products, and the opportunity to form knowledge independently and outside of the narrowly defined set of legitimate criteria established by biotechnology 'players' is essential to the health of the public sphere.

Advanced liberal societies face the challenge of rendering visible 'knowledge economies' marked by intangibles

and the dominance of virtual forms of property and value. Justice within these 'knowledge societies; demands that these criteria of governance are met. This must be done to ensure the continued relevance of not only 'the public' but the political sphere to governance. This requires information flows across the current frontiers of the biotech figuration. Without access, independence and participation, publics remain merely consumers, lockedout of a regulatory and political relationship to production. However, the biotechnology regulatory figuration makes governing, explaining and identifying the regulatory process difficult, if not impossible. In sum, the biotechnology regulatory figuration must become a regulatory aid, not a regulatory problem for Canadians.

Endnotes

1. The sector is dominated by multinational research firms which have also forged transnational alliances to vertically integrate the biotechnology production with industrial supply chains. And in the case of commercial food markets, 'food clusters' have boasted that they 'will control the passage of food from soil to supper' (Holliday 1999:4; Economist 2000:6). 'Offshoring' of heavily regulated or prohibited biotechnologies, research practices or stages in the supply chain make it difficult to make meaningful regulation (see also Newell 2002; Scoones 2002).

2. Funded by the Social Science and Humanities Research Council of Canada.

3. Independent in the sense of not being employed either by a developer (such as a biotech firm) or a regulatory body (the Federal Government of Canada)

4. The skills required to regulate PNTs and insight into the commercial opportunities of plant genetics is best gained in industry labs. The lack of public sector employees with such skills has meant that 'the regulators' are largely drawn from the industry. The government departments involved have relied on industry working-groups to develop regulatory procedures - a process that the industry has seen as also a means to competitive advantage within the jurisdiction. Miller also found that participation in creating regulatory procedures which match a firm's existing laboratory protocols and equipment can be a way of imposing costs of compliance on lesser competitors (Miller 1999).

5. This distinction is important because it marks the growing importance of a set of non-actual but nevertheless real objects such as genetic sequences or other intellectual property that are now the focus of regulation and are the form of property which is at stake in biotechnology. The regulatory understanding of PNTs is not a matter of 'seeds' or of 'crops' per se but is described in terms of their traits - or virtues, to borrow a term from the lexicon of more ancient virtualities—functionalities, and their genetic code. These are virtualities, equally as real as the seeds and plants which are their corresponding actualization (see Shields 2003:Ch. 1-2). However, they are intangible objects. Rather than 'genes', effort focuses on genomes which are informational entitites consisting of code and worked on primarily as information sets not as chemicals or any physical elements.

6. At times the regulators may work collaboratively and be dependent on each other, but at other times they may work independently. Lab and field-trial evaluation procedures are fixed and highly codified but linked together by more fluid lines of interpretation, justification and shared beliefs in the appropriateness of statistical extrapolations from the small-scale of controlled tests to the larger scale and complexity of populations and environments.

7. Many appeals to recent discussions of 'social capital' as a way of understanding the social interactions described so far. However, the implications of the fluidity discussed about are that 'social capital' may not be a normative social context within which individuals are 'embedded' (Bourdieu 1982; Brown and Lauder 2000:227). It can be an unstable and intangible or 'virtual' entity itself: social capital can quickly lose its value as social currency. We are thus critical of theories of social capital in the sense of structural, cognitive (intellectual capital) and relational networks. These are also 'black boxes' that gloss over and rationalize the fluidity of such social worlds. Appeals to social capital beg the question by masking sociological aspects such as power, inequality, status, charisma and authority at the same time as it is often summoned to support theories of organization and innovation (eg. Brown and Lauder 2000:237; see also Mutch 2003).

8. Denying the social leads to an objectified but static and impotent understanding of the informational dynamics of the regulatory process (Taborsky 2001). This also emerges in the way in which knowledge as a social attribute of individuals (Rasmus 1999:2) and information as an object are elided within the regulatory space (Shields and Taborsky 2001).

9. This isotopy of the field is a specific quality of the figurational theory that is not well captured by either the 'Actor Network' literature nor recent attempts to go beyond it by introducing more fluid metaphors in the analysis of networks (Law and Hassard 1999).

10. For a statistical model to analyze the risks and trust involved in transported GM and non GM grains, see: "Costs and Risks of Testing and Segregating GM Wheat": 2002.

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